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REGIONAL MODEL LAW FOR WEST AND CENTRAL AFRICA

regulating the marketing of
breastmilk substitutes, foods
for infants and young children
and related feeding utensils



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defending breastfeeding

Acknowledgment

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COMMENT

This model law incorporates the provisions of the International Code of Marketing of Breastmilk Substitutes (the Code) and the subsequent relevant resolutions of the World Health Assembly (WHA) including the Guidance on ending the inappropriate promotion of foods for infants and young children (hereinafter referred to as WHO 2016 Guidance) and elements of relevant Codex Alimentarius standards and guidelines.¹

1 This regional model law is based on the Model Law developed by the IBFAN International Code Documentation Centre (ICDC) which is annexed to Code Essentials 2 : *Guidelines for policy makers on implementing the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions* (2nd Edition)

PART I

PRELIMINARY

The purpose of this Model law is 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.

1. This law applies to the marketing of “*designated products*” as defined in section 2 of this law. It also applies to their quality and to information related to infant and young child feeding.

COMMENT

Use of the term “*designated product*” with a distinct definition provides clarity and avoids having to repeat lengthy explanations throughout the legislation.

2. In this law, unless the context otherwise requires—
 - “*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, video, telephone;
 - (b) on any digital platform including websites, internet, email, social media platforms, mobile application or any other electronic media;
 - (c) display of signs, billboards, or notices; or
 - (d) exhibition of pictures or models.

“*Advisory Committee*” means the body established in accordance with section 24 for implementation of this law.

“*Artificial feeding*” means feeding with any manufactured food product that replaces breastmilk either partially or totally.

“*Brand name*” means a name by which a product is marketed.

“*Breastmilk substitute*” means any milk (or product that could be used to replace milk, such as fortified soy milk) that is specifically marketed for feeding infants or young children and including, but not limited to, infant formula, follow-up formula for older infants, and young child formula.

COMMENT

This definition is based on the definition for “*breastmilk substitute*” of Recommendation 2 of the WHO 2016 Guidance. The terms “*infant formula*”, “*follow-up formula for older infants*” and “*young child formula*” are defined in this section of the Model Law.

“*Container*” means any form of packaging of a designated product for sale as a retail unit.

“Designated product” means

- (a) a breastmilk substitute including infant formula, follow-up formula for older infants and young child formula;
- (b) any product marketed or otherwise represented as suitable for feeding infants up to the age of 6 months;
- (c) a food product for older infants and young children;
- (d) a feeding bottle, teat, pacifier; and
- (e) such other product as the Minister may declare “designated product” for the purposes of this law.

COMMENT

The scope of the Code has been difficult to apply in national laws due to its ambiguity. Use of the term “designated product”, which lists the range of products covered by the law, clarifies the scope of the law. The definition for “breastmilk substitute” is based on Recommendation 2 of the WHO 2016 Guidance and the three mentioned products are each defined in this section. Part (b) of this definition includes other products that can replace breastmilk and should thus never be promoted as suitable for feeding infants under 6 months of age. This would include products such as packaged water or biscuits when they are promoted for all infants. The products included in part (c) are also defined in the section.

“Distributor” means a person, corporation or other entity engaged in the business of marketing any designated product, whether wholesale or retail.

“Follow-up formula for older infants” means a milk (or product that could be used to replace milk, such as fortified soy milk) formulated industrially to constitute a liquid part of the diet of infants from the age of 6 months.

COMMENT

The definition for “follow-up formula for older infants” is primarily based on the definition for “breastmilk substitute” in Recommendation 2 of the WHO 2016 Guidance. It is also based on the definition for “follow-up formula for older infants” that will be included in the revised Codex Alimentarius Standard for follow-up formula (CXS-156). The most recent draft of revised Standard 156 is included as Annexes III and IV of Report 22 (2021) of the Codex Alimentarius committee on nutrition and foods for special dietary uses.

“Food product for older infants and young children” means a manufactured food or drink other than a breastmilk substitute, that is specifically marketed or otherwise represented as suitable for feeding older infants or young children.

COMMENT

This definitions is based mainly on the definition of the WHO 2016 Guidance. Refer also to the definition for “young child” and note that “food product for older infants and young children” defines a category of designated products.

“Health care facility” means a public or private facility engaged in the provision of health care or in health care education. It also includes day-care centers, nurseries or other infant and young child-care facilities.

“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 the following:

- (a) a claim that describes the physiological role of a nutrient in growth, development and normal functions of the body;
- (b) a claim concerning specific beneficial effects of the consumption of foods or their constituents on health or normal functions or biological activities of the body; or
- (c) a claim relating to the reduced risk of developing a disease or health-related condition as a result of consumption of a food or its constituents.

COMMENT

The definition for “*health claim*” is taken from the Codex Alimentarius Guidelines for use of nutrition and health claims (CAC/GL 23).

“*Health professional*” means a health worker with a professional degree, diploma or license, such as a medical practitioner, a registered nurse or midwife.

COMMENT

Section 22 provides an exception to the prohibition on manufacturers and distributors to provide educational and informational materials that refer to a designated product. Such materials may only be provided to health professionals and not to the larger category of “*health workers*”. Each country must define “*health professional*” according to national laws and regulations.

“*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.

“*Infant*” means a child from birth up to the age of 12 months.

“*Infant formula*” means a milk (or product that could be used to replace milk, such as fortified soy milk) formulated industrially and intended to satisfy, by itself, the nutritional requirements of infants from birth and during the first 6 months of life and includes any formula for special medical purposes for infants.

COMMENT

The definition is primarily based on the definition for “*breastmilk substitute*” in Recommendation 2 of the WHO 2016 Guidance and the definition for “*infant formula*” of Codex Alimentarius Standard for Infant formula and formula for special medical purposes intended for infants (CSX-72).

“*Label*” means a tag, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, attached or otherwise appearing on a container of a designated product.

“*Labelling*” includes any written, printed or graphic matter that is present on the label, accompanies the product or is displayed near the product, including that for the purpose of promoting its sale or disposal.

“*Logo*” means an emblem, design or symbol by means of which a manufacturer or distributor or a product is identified.

“*Manufacturer*” means a person, corporation or other entity engaged in the business of manufacturing a designated product whether directly, through an agent, or through an entity controlled by or under contract with it.

“*Marketing*” means any act or operation relating to the sale of a designated product including but not limited to display, storage, distribution, import, export, promotion and advertising and includes product public relations and information services.

“*Minister*” means the minister for health.

“*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 legislation or regulations in force.

“*Nutrient content claim*” means a nutrition claim that describes the level of a nutrient contained in a food.

COMMENT

The definition for “*nutrition claim*” and “*nutrient content claim*” are taken from the Codex Alimentarius Guidelines for use of nutrition and health claims (CAC/GL 23).

“Older infant” means an infant from the age of 6 months up to the age of 12 months.

COMMENT

It is necessary to define older infant because the term is used in the definitions for certain designated product in this Model Law. The definition is taken from the definition that will be included in the revised Codex Alimentarius standard for follow-up formula (CSX-156). The most recent draft of revised Standard 156 is included as Annexes III and IV of Report 22 (2021) of the Codex Alimentarius committee on nutrition and foods for special dietary uses.

“Pacifier” means an artificial teat for babies to suck.

“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.

“Sample” means a single or small quantity of a designated product provided without cost.

“Young child” means a child from the age of 12 months up to the age of three years (36 months).

“Young child formula” means a milk (or product that could be used to replace milk, such as fortified soy milk) that is formulated industrially to constitute a liquid part of the diversified diet of young children.

COMMENT

There is not yet a Codex Alimentarius standard for the product commonly known as “growing-up milk” or “toddler milk” and intended for young children. The revised Codex Alimentarius standard for follow-up formula, however will have a “section B” for this product. Several names will be given to this product in the revised standard, including “Drink for young children with added nutrients”, “Product for young children with added nutrients”, “Drink for young children”, “Product for young children,” or “any appropriate designation indicating the true nature of the product, in accordance with national or regional usage.” In this Model Law, the product is referred to as “young child formula”. The definition for “young child formula” is based on the definition for “breastmilk substitute” in Recommendation 2 of the WHO 2016 Guidance and the definition that will be included in the revised Codex Alimentarius standard for follow-up formula (CSX-156). The most recent draft of revised Standard 156 is included as Annexes III and IV of Report 22 (2021) of the Codex Alimentarius committee on nutrition and foods for special dietary uses. Refer also to the definition for “young child” in this section.

PART II

CONDITIONS FOR MARKETING

COMMENT

Each country will draft the sections of this part according to relevant national law and situation. These sections are presented as examples.

3. It is prohibited to market a designated product unless the product is in conformity with applicable national standards *[or in the absence of a national standard, insert the relevant regional standard or Codex Alimentarius standard for manufacture, composition, safety, labelling and quality]*.

COMMENT

Countries can refer to applicable national or regional standards or if appropriate, the Codex Alimentarius standards that regulate the manufacture, composition, safety, labelling and quality of designated products. Drafters should consult with national experts on control of imports, production and marketing of foods and feeding utensils to learn about existing regulations and procedures.

- 4A. *[Insert section 4A or section 4B as appropriate]*
It is prohibited to market a food product (other than a breastmilk substitute) as suitable for feeding older infants or young children unless its nutrient

levels are in accordance with *[insert the relevant national or regional dietary guidelines or nutrient profile model]*.

COMMENT

Section A is based on Recommendation 3 of the WHO 2016 Guidelines. Foods for older infants and young children, other than breastmilk substitutes, should not be marketed as suitable for this age range unless the nutrient levels are in accordance with relevant national or regional dietary guidelines or nutrient profile models where they exist. In the absence of guidelines or models, a country should include section 4B instead of section 4A in the national law.

- 4B. *[Insert section 4A or section 4B as appropriate]*
The *[insert appropriate national authority]* must develop nutrient composition standards for food products for older infants and young children within *[insert time delay]*, that cover at least the following elements:
- (a) minimum required energy density;
 - (b) limits for added sugar and total sugar;
 - (c) limits for total fats;
 - (d) limits for sodium; and
 - (e) definition of categories of food or drink products that should never be marketed as suitable for older infants or young children

5. *[Insert the following provision in countries with a system of product registration or certification]:*

It is prohibited to import, distribute for sale, sell, or expose for sale a designated product that is not registered in accordance with the provisions of *[insert reference]* or does not comply with the conditions of its certification/registration.

PART III

COMMERCIAL PROMOTION OF DESIGNATED PRODUCTS

Prohibitions related to promotion of designated products

6. Except as provided in sections 7, 8 and 9, 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:
- (a) advertising;
 - (b) sales devices at the retail level such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;
 - (c) giving a sample to any person;
 - (d) provision or distribution of information or educational material related to infant or young child feeding or performance of educational functions related to infant or young child feeding for parents or other guardian of infants or young children;
 - (e) include the volume of sales of designated products (1) (2) (4) and (5) in the calculation of its employee remuneration or bonuses, nor set quotas for sales of such designated products.

COMMENT

Section 6 applies to designated products other than “*food products for older infants and young children*”. Those products are the subject of sections 7, 8, 9 and 10. Promotion for breast-milk substitutes and for feeding bottles or teats is prohibited in the model law in accordance with the International Code. Food products for older infants and young children do not fall under the scope of the Code unless they are marketed or otherwise presented as substitutes for breastmilk. It has been recognized, however, that inappropriate promotion of those products also compromises optimal feeding of infants and young children. The World Health Assembly addressed this issue by adopting the WHO 2016 Guidance. Consistent with the Guidance, this model law restricts but does not entirely prohibit promotion for those products.²

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Section 6(d) is based on Recommendation 6 of the WHO 2016 Guidance. It should be noted that the prohibition of providing education to parents and other caregivers on infant and young child feeding in Recommendation 6 of the WHO 2016 Guidance applies to health care facilities. In order to end the negative impact of educational activities or materials provided by manufacturers or distributors it is recommended that the practice be prohibited in all places.

Prohibitions related to food products for older infants and young children

7. 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 older infants and young children unless such promotion includes a visible and easily understood statement indicating
- the recommended age for introduction of the product, which is not less than 6 months; and
 - the importance of exclusive breastfeeding for the first 6 months of life followed by the introduction of safe and adequate complementary foods along with continued breastfeeding for up to two years or more.

Each message must be displayed in a conspicuous manner. *[or insert particulars relating to character size, placement, appearance, etc. For example, "in characters no less than one-third the size of the characters in the product name, and in no case less than 2 mm in height"]*

COMMENT

Section 7 is based on Recommendation 4 of the WHO 2016 Guidance.

8. 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 older infants and young children if such promotion includes:
- any text, image or other element that suggests the suitability of the product for infants under 6 months including but not limited to references

to development milestones clearly reached before 6 months, or the use of pictures of infants appearing to be younger than 6 months;

- any text, image or other element that is likely to undermine or discourage breastfeeding, that compares a designated product with breastfeeding or breastmilk or create a belief that a designated product is equivalent or superior to breastfeeding or breastmilk;
- 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 foods;
- any recommendation to feed the product in a feeding bottle or otherwise promote the use of bottle feeding;
- any text, image or other element that may be conveyed or construed as an endorsement by a health professional, an association of health professionals or other body unless approved by *[insert the appropriate regulatory body]*; or
- a health claim or a nutrition claim other than a nutrient content claim related to a food product for older infants and young children that is permitted under national law.

COMMENT

Sections 8 (a) to (f) are based on Recommendation 4 of the WHO 2016 Guidance. The text of section 8 (c) is not included in Recommendation 4 as one of the elements of prohibited messages but it is included in the IBFAN ICDC Model Law. Section 8 (f) is based on WHA Resolutions 58.32 (2005) and 63.23 (2010); the Codex Alimentarius Guidelines for use of nutrition and health claims (CAC/GL 23) and the Guidelines on formulated complementary foods for older infants and young children (CAC/GL-8). "Health claim," "Nutrition claim" and "nutrition content claim" are defined in Section 2 of this Model Law.

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- 2 Some countries in the region and elsewhere have opted to ban any form of promotion of foods for infants and young children as well as breastmilk substitutes. If there is sufficient evidence of harmful effects, countries may choose to have more stringent provisions regarding this category of product.

The World Health Assembly and Codex Alimentarius have called for a prohibition of health and nutrition claims for foods for infants and young children unless specifically authorized by national legislation. Section 8 (f) prohibits all health and nutrition claims with one exception. A country may choose to permit, for example, a nutrient content claim for certain foods for older infants and young children pertaining to nutrients of public health importance.

9. 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 older infants and young children using any element similar to the labeling used for any of that manufacturer or distributor's breastmilk substitute products including similar brand names, package designs, text, color schemes, symbols, mascots or slogans.

COMMENT

Section 9 is based on Recommendation 5 of the WHO 2016 Guidance. Instead of using the phrase "*cross promotion*," the section describes and prohibits this marketing technique.

Other prohibitions related to manufacturers and distributors of designated products.

10. A manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf
- (a) provide to or distribute within a health care facility equipment, services or materials that refer to or may promote a designated product;
 - (b) give or distribute free of charge or subsidize any quantity including samples of a designated product to a health worker, a health care facility or any other part of the health care system;
 - (c) provide to or distribute in a health facility gifts for parents or other caregivers of infants and young children;
 - (d) 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; or

- (e) solicit or establish relationships with parents and other caregivers of infants or young children through baby clubs, social media groups, child-care classes, contests, events, campaigns or by any other means.

COMMENT

Section 10 applies to manufacturers and distributors of all designated products. The prohibitions are those covered by article 6 and 7 of the Code and those included in Recommendation 6 of the WHO 2016 Guidance.

The second part of Recommendation 6 of the WHO 2016 Guidance states that health workers, health care institutions and systems as well as associations of health professionals and non-governmental organizations should not be on the receiving end of any of these prohibited activities. Government leaders, policy makers, health care administrators, professional associations and funders, among others, should invest in educating and informing health workers and non-governmental organizations, especially those in the field of maternal and child health about the provisions of this law and their importance in protecting breastfeeding and the health of mothers, infants and young children. Professional codes of ethics can be used to sanction activities that rise to the level of professional misconduct.

PART IV

LABELLING

COMMENT

Each country will likely have existing requirements for labels of food and related products. Generally, such laws require that labels should be clear, conspicuous and easily readable in designated language(s). Food labelling laws may also require a statement of ingredients, composition, preparation instructions, storage conditions, expiration dates, batch number and the date of manufacture. Existing provisions could be incorporated by reference and harmonized with those suggested in this Model law.

Prohibitions applicable to labelling of designated products

11. It is prohibited to offer for sale or sell a designated product, other than a food product for older infants and young children, if the labelling thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation.
12. It is prohibited to 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, storage and use in words and in easily understood graphics;
 - (b) the age in numeric figures after which the product is recommended;
 - (c) a warning about the health risks of improper use, preparation or storage and of introducing the product prior to the recommended age;

COMMENT

Section 11 prohibits all images for labels of breastmilk substitutes and feeding bottles and teats. This differs from Article 9.2(d) of the Code, which prohibits “*pictures or text, which may idealize the use of infant formula*”. Article 9.2(d) is difficult to apply in practice. For example, many companies replaced baby images with those of baby animals or flowers. The prohibition of all images for infant formula and other breastmilk substitutes as well as for feeding bottles and teats solves this problem. Note that photographs, drawings or other graphic representations are not prohibited on labels for food products for older infants and young children.

- (d) the list of ingredients;
- (e) a declaration of nutritional content, including energy value and the amounts of protein, available carbohydrate, fat, salt, sugar and amounts of any other nutrients as required by national legislation or dietary guidelines;
- (f) the required storage conditions both before and after opening, taking into account climatic conditions in the country where the product will be used;
- (g) the batch number, date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions in the country where the product will be used; and
- (h) the name and national address of the manufacturer or distributor.

COMMENT

Section 12 is based mainly on Article 9 of the Code. Section 12(e) is included in accordance with Recommendation 3 of the WHO 2016 Guidance. It is important that manufacturers and distributors be required to declare nutrient content on labels of foods for older infants and young children to facilitate development of nutrient profile models as recommended by WHO.

- 13.** It is prohibited to offer for sale or sell a designated product other than a feeding bottle, teat or pacifier if the label contains a health claim or a nutrition claim other than a nutrient content claim related to a food product for older infants and young children and that is permitted under national law.

COMMENT

“Health claim,” “Nutrition claim” and “nutrition content claim” are defined in Section 2 of this Model Law. Section 13 is based on WHA Resolutions 58.32 (2005) and 63.23 (2010); the Codex Alimentarius Guidelines for use of nutrition and health claims (CAC/GL 23) and the Guidelines on formulated complementary foods for older infants and young children (CAC/GL-8).

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The World Health Assembly and Codex Alimentarius have called for a prohibition of health and nutrition claims for foods for infants and young children unless specifically authorized by national legislation. Section 13 prohibits all health and nutrition claims with one exception. A country may choose to permit, for example, a nutrient content claim for labels of certain foods for older infants and young children pertaining to nutrients of public health importance.

Prohibitions related to labelling of infant formula, follow-up formula for older infants and young child formula

- 14.** It is prohibited to offer for sale or sell an infant formula, follow-up formula for older infants or young child formula unless the labelling thereto, in addition to the requirements of Sections 11, 12 and 13, conforms to the following:
- (a) contains the words, “IMPORTANT NOTICE” in capital letters and indicated thereunder, the following or similar statements 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 2 mm in height”]*:
 1. “Breastfeeding is the best way to feed infants and young children. Breastmilk is ideal for healthy growth and development of infants and young children” and “Giving breastmilk only is recommended during the first 6 months of life, followed by the introduction of safe and adequate complementary foods and continued breastfeeding for up to two years or more”;
 2. the product should be used only on the advice of a health professional as to the need and proper method for its use;
 3. that the baby’s health depends on carefully following all instructions for preparation, use and storage of the product;
 4. that it is more hygienic to use a cup than a feeding bottle; and
 5. that use of the product should not lead to the cessation of breastfeeding.

COMMENT

The Codex Alimentarius standard for infant formula and formulas for special medical purposes intended for infants (CSX-72) requires that the labels for infant formula include the statement “*Breastmilk is the best food for your baby*” or a similar statement as to the superiority of breastfeeding or breastmilk. The second part of the statement required by Subsection 14(a) (1) is in line with international infant feeding recommendations. Subsections 14 (a) (3) (4) and (5) are also suggested additions to the requirements of Article 9 of the Code and the requirements of the Codex standard.

- (b) For products in powdered form, display a warning under or close to the preparation instructions in characters *[insert particulars relating to character size, placement, appearance, etc.]* stating that
1. formula in powdered form is not sterile and may be contaminated with pathogenic micro-organisms during the manufacturing process or may become contaminated during storage or preparation;
 2. 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, which can be achieved by leaving the water for no more than 30 minutes after boiling; and
 3. any unused formula must be discarded immediately after every feed.

COMMENT

WHA Resolution 61.20 (2008) urges Member States to ensure that labelling of powdered formula conforms with the standards, guidelines and recommendations of the Codex Alimentarius Commission including the WHO/FAO guidelines on safe preparation, storage and handling of powdered infant formula.

- (c) includes a feeding chart in the preparation instructions;
- (d) does not use the terms “*maternalised*”, “*humanized*” or any term that compares a designated product with breastfeeding or breastmilk or creates a belief that a designated product is equivalent or superior to breastfeeding or breastmilk;
- (e) does not use text or any other representation that may tend to discourage breastfeeding;
- (f) does not include text or any other representation that recommends or promotes bottle feeding;
- (g) does not include any text, image or other element that may be conveyed or construed as an endorsement by a health professional, an association of health professionals or other body unless approved by *[insert the appropriate regulatory body]*; or
- (h) specifies the source of the protein;
- (i) does not have any element that may create confusion with or promote another of the manufacturer or distributor’s designated products, in particular similar brand names, package designs, text, color schemes, symbols, mascots or slogans;
- (j) in the case of follow-up formula for older infants, states that the product shall not be used to feed infants less than 6 months old or used as the sole source of nutrition for older infants and that older infants should receive safe and adequate complementary foods in addition to the product, in characters *[insert particulars relating to character size, placement, appearance, etc.]*;
- (k) in the case of young child formula, states that the product shall not be used for infants younger than 12 months of age, and should not be used as the sole source of nutrition, in characters *[insert particulars relating to character size, placement, appearance, etc.]*.

COMMENT

Subsections 14 (c) through 14 (k) are based on Article 9 of the Code, recommendations 4 and 5 of the WHO 2016 Guidance and on provisions that will be included in the revised Codex Alimentarius Standard for follow-up formula (CXS-156). The most recent draft of revised Standard 156 is included as Annexes III and IV of Report 22 (2021) of the Codex Alimentarius committee on nutrition and foods for special dietary uses.

Prohibitions related to labelling of food products for older infants and young children

- 15.** It is prohibited to offer for sale or sell a food product for older infants and young children unless the labelling thereto in addition to the requirements of sections 12 and 13, indicates in characters *[insert particulars relating to character size, placement, appearance, etc.]* the following particulars:
- (a) the recommended age for introduction of the product, which is not less than 6 months; and
 - (b) the importance of exclusive breastfeeding for the first 6 months of life followed by the introduction of safe and adequate complementary foods along with continued breastfeeding for up to two years or more.
- 16.** The labelling of a food products for older infants and young children shall not include
- (a) any text, image or other element that suggests the suitability of the product for infants under 6 months including but not limited to references to development milestones clearly reached before 6 months, or the use of pictures of infants appearing to be younger than 6 months;
 - (b) any text, image or other element that is likely to undermine or discourage breastfeeding, that compares a designated product with breastfeeding or breastmilk or creates a belief that a designated product is equivalent or superior to breastfeeding or breastmilk;
 - (c) any text, image or other element that undermines or discourages appropriate complementary feeding or that may suggest that the product is inherently superior to home prepared foods;
 - (d) any recommendation to feed the product in a feeding bottle or otherwise promotes the use of bottle feeding;
 - (e) any image, text or other element that may be conveyed or construed as an endorsement by a health professional, an association of health professionals or other body unless approved by *[insert the appropriate regulatory body]*; or
 - (f) any element that may create confusion with or promote another of the manufacturer or distributor's breastmilk substitute products, in particular by use of similar brand names, package designs, text, color schemes, symbols, mascots or slogans.

COMMENT

Sections 15 and 16 are based on Recommendation 4 of the WHO 2016 Guidance. Recommendation 4 applies to messages used to promote products including messages used on product labels. Section 15(c) is not among the elements of promotional messages prohibited by Recommendation 4 of the WHO 2016 guidance, but is suggested as an addition for labelling of food products for older infants and young children.

Provisions related to labelling of feeding bottles and teats

- 17.** It is prohibited to offer for sale or sell a feeding bottle or teat unless the labelling thereto in addition to the requirements of section 11 meets the following conditions:
- (a) provides instructions for cleaning and sterilizing the product in words and in easily understood graphics accompanied by an explanation of the importance for the child's health of carefully following the instructions;
 - (b) contains the words, "IMPORTANT NOTICE" in capital letters and indicated thereunder, the following or similar statement in characters *[insert particulars relating to character size, placement, appearance, etc.]*:
 1. "Breastfeeding is the best way to feed infants and young children. Breastmilk is ideal for healthy growth and development of infants and young children" and "Giving breastmilk only is recommended during the first 6 months of life, followed by the introduction of safe and adequate complementary foods and continued breastfeeding for up to two years or more";
 2. if you use a feeding bottle, your baby may refuse the breast;
 3. that it is more hygienic to feed with a cup than with a feeding bottle;
 4. use only with adult supervision; and
 - (c) includes the name and national address of the manufacturer or distributor.

COMMENT

The only requirements of Article 9 of the Code that apply to labels of feeding bottles and teats include that they should be designed to provide the necessary information about appropriate use and so as not to discourage breastfeeding. This section provides a model for regulating labels of feeding bottles and teats. The warning in Section 17(b)(4) is based on the warning required for labels of feeding bottles by European Committee for Standardization, EN 14350:2020 Childcare articles – Drinking Equipment – Safety requirements and test methods.

Provisions related to labelling of pacifiers

- 18.** A manufacturer or distributor shall not offer for sale or sell a pacifier unless the labelling thereto, in addition to the requirements of section 11, contains the following particulars:
- (a) provides instructions for cleaning, sterilizing and care of the product in words and in easily understood graphics accompanied by an explanation of the importance for the child's health of carefully following the instructions; and
 - (b) the following or similar statement: *"Warning: Use of a pacifier can interfere with breastfeeding"* in characters [insert particulars relating to character size, placement, appearance, etc.].

COMMENT ON PART IV

Milks other than breastmilk substitutes are not designated products covered by this Model law. Drafters should examine existing food labelling laws to ensure that labels of powdered or condensed milks are required to include a statement to the effect that the product is not intended as a food for infants under 12 months of age.

PART V

INFORMATION, EDUCATION AND COMMUNICATION

Information and educational materials about infant and young child feeding

- 19.** Information and educational materials that refer to infant and/or young child feeding shall be accurate and current and explain clearly and conspicuously the following:
- (a) the benefits and superiority of breastfeeding;
 - (b) the value of exclusive breastfeeding for 6 months and the importance of introducing adequate and safe complementary foods at the age of 6 months while continuing to breastfeed until 2 years of age or more;
 - (c) how to prepare for, initiate and maintain exclusive and sustained breastfeeding;
 - (d) the difficulty of reversing a decision not to breastfeed;
 - (e) the negative effects on breastfeeding and child health of bottle feeding or early introduction of complementary feeding; and
 - (f) the advantages of preparing complementary foods at home using local ingredients.
- 20.** Information and educational materials which refer to infant and/or young child feeding shall not
- (a) use any pictures, text or other element that encourage artificial feeding, or the use of feeding bottles or that discourage breastfeeding;
 - (b) give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or to breastfeeding;
 - (c) contain the name or logo of any designated product or 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 authorized by section 21 of this chapter.

COMMENT

Article 4.3 of the Code allows reference to a company's name or logo on information and educational materials but prohibits reference to a proprietary product within the scope of the Code. This model law prohibits reference to company names and logos as well for such materials. See also section 6 (d) which prohibits a manufacturer or distributor or any person acting on its behalf to provide or distribute information or educational material or perform educational functions related to infant and young child feeding for parents or other guardians of infants or young children.

Information and educational materials about artificial feeding or use of a feeding bottle

- 21.** If the material referred to in sections 19 and 20 includes the topic feeding with a breastmilk substitute or the use of a feeding bottle, it must also
- (a) include instructions for the proper preparation, storage and use of the product including cleaning and sterilization of feeding utensils;
 - (b) explain how to feed infants with a cup and that it is more hygienic to use a cup than a feeding bottle;
 - (c) mention the health risks of feeding with a breastmilk substitute, the use of a feeding bottle or improper preparation of the product;
 - (d) mention that feeding bottles should be used only with adult supervision;
 - (e) explain that:
 1. formula in powdered form is not sterile and may be contaminated with pathogenic micro-organisms during the manufacturing process or may become contaminated during storage or preparation;
 2. 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, which can be achieved by leaving the water for no more than 30 minutes after boiling; and
 3. any unused formula must be discarded immediately after every feed.

- (f) mention the higher cost of feeding an infant or a young child with the recommended quantities of such a product compared with breastfeeding;
- (g) explain that the practice of feeding with follow-up formula or young child formula is not necessary.

Information for health professionals concerning designated products

- 22.** Manufacturers and distributors may give material about designated products to health professionals if such material:
- (a) is restricted to scientific and factual matters regarding the technical aspects and methods of use of the product;
 - (b) provides 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
 - (c) is otherwise in accordance with this chapter.

Submission of materials to the Advisory Committee

- 23.** Any person who produces or distributes any materials referred to in Part V shall submit copies to the Advisory Committee according to procedures as shall be prescribed.

COMMENT

This procedure could be beneficial for countries that create an Advisory Committee for this application of this Act.

PART VI

ADMINISTRATION

Advisory Committee for implementation

- 24.** There is hereby created an advisory committee to the Ministry of Health for the implementation of this law under the coordination of *[insert the appropriate department or section]*
- (a) The advisory committee shall be composed of the following members:
1. The minister of Health or his representative who shall be its ex officio Chairman;
 2. (...)
 3. (...)
 4. Such other persons as the Minister may, by official Notice, appoint as members of the Advisory Committee; provided that no person shall be appointed who has any direct or indirect financial interest in any designated product.
- (b) The Minister shall appoint the members of the Advisory Committee within 90 days of the promulgation of this law.

COMMENT

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 Commerce, and representatives of organizations of health professionals, consumers organizations, mother 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.

- 25.** The Advisory Committee is created to facilitate the implementation of this law. The powers and functions of the committee shall include the following:
- (a) create regional committees to carry out the functions of the Advisory Committee at the regional level, as may be prescribed;
- (b) ensure widespread distribution, publicity and information about this law to persons and entities that may be subject to or affected by its provisions including the following:
1. officials empowered to monitor and enforce this law;
 2. relevant health workers and their professional associations;
 3. manufacturers and distributors;
 4. owners and operators of media outlets

- including the newspapers, magazines, television and radio stations; internet websites and advertising agencies;
5. relevant civil society organizations and associations; and
 6. relevant government departments.
- (c) develop the materials and procedures necessary for monitoring compliance with this law;
 - (d) strengthen the capacity of officials empowered to monitor and enforce this law;
 - (e) establish a procedure for accepting and responding to complaints of violations or other matters related to this law;
 - (f) examine and evaluate reported violations;
 - (g) review materials submitted in accordance with Section 23 for compliance with the provisions of Chapter V and
 - (h) report periodically on relevant activities.

- 29.** Where an offence under this Act has been committed by a company, every person who, at the time the offence was committed, was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

Provided that nothing contained in this section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or his consent.

Offenses and Penalties

- 26.** Any person who contravenes any provisions of sections 3 through 10 of this law commits an offense and may be liable to a fine of *[insert range of fines]* and /or imprisonment of *[insert range of sentences]*.
- 27.** Any person who, in any other manner, contravenes the provisions of this law, commits an offense and may be liable to a fine of *[insert range of fines]* and / or imprisonment of *[insert range of sentences]*.
- 28.** In addition to any civil/and or criminal penalties imposed on a person in respect of any contravention of this law, further administrative penalties may be imposed including the following:
- (a) an order to cease an activity in violation of any provision of this law within a specified time period;
 - (b) suspension or revocation of any license to manufacture, import or otherwise market a designated product;
 - (c) the seizure of goods or objects used to commit the infraction.

COMMENT

Each country will insert the appropriate sanctions.

PART VII

FINAL PROVISIONS

30. Commencement

COMMENT

Each country will determine the commencement date for the law in accordance with legislative procedures.

- 31.** This law repeals all previous provisions to the contrary [*in particular...*] and will be executed as law of the State.

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