



وزارة الصحة

Ministry of Health

State of Kuwait

Kuwaiti Code of **Regulating Marketing Breastmilk substitutes**

(foods and **related** products for infants and young children)

2014

The State of Kuwait Ministry of Health, in its desire to implement the decisions and recommendations of the World Health Assembly (WHA) concerning infants and young children and pertaining to:

- a) Measures ensuring infants are exclusively breastfed in the first six months of life.
- b) Measures ensuring that complementary foods given to children in the period following the first six months of life are suitable and safe [and] with the continuation of breastfeeding.
- c) Measures ensuring the protection and promotion of breastfeeding and ensuring the proper use of breastmilk substitutes (BMS) if needed.
- d) The terms and conditions regulating BMS sales, marketing and advertising that would ensure promoting breastfeeding.

This Code has accordingly been issued to produce and regulate the mechanism and the aforementioned measures in accordance with the following items and articles:

Article One: Definitions

Throughout this Code, the following terms and phrases shall bear the meanings each assigned to them, unless otherwise indicated by context:

- ❖ **Breastmilk substitutes:** any breastmilk substitute industrially produced in accordance with **applicable** Codex Alimentarius standards, and **according to** Gulf standard specification, to meet infants and young children's nutritional requirements, **such** substitutes are prepared to suite children's normal needs, and include each food or product within the scope of this Code, including home-prepared foods.

- ❖ **Special foods or **product** within the scope of this Code** include:
 - a) Infant formula (including manufactured foods with special medical uses for infants).
 - b) Follow-up formula.
 - c) Any product marketed or presented as appropriate for feeding infants and young children up to three years of age including bottled water for infants, herbal teas and juices produced for infants.
 - d) Complementary foods.
 - e) Feeding bottles, **teats**, and pacifiers.
 - f) Any other product **other than what was mentioned before** endorsed by the Higher Commission for the Promotion of Breastfeeding published in the Official Gazette as a product within the scope of this Code.

- ❖ **Infant Formula** means a food formula extracted from cows' milk or a similar product of animal or plant origin and is industrially produced and **marketed** as appropriate for feeding infants from birth up to six months or one year of age, and includes foods manufactured for special medical uses for infants, such as **Breastmilk Substitutes** manufactured for metabolic **diseases**, foods of thick consistency for infants with reflux conditions, manufactured from modified protein, or lactose-free for lactose-allergy or lactose-intolerance conditions, **and** others.

- ❖ **Follow-up Formula** means a food formula extracted from cows' milk or a similar product from animal or plant origin industrially produced and marketed as appropriate for feeding infants and young children **from** six months and up to 3 years, and include, for example, PediaSure, meant for children aged 1-10 years, or **Nutrini** for children over one year of age, in addition to all the products within the scope of this Code, which contain calories higher than the needs of normal children.
- ❖ **Complementary food** means the foods suitable for feeding infants and young children during the weaning period to complement breastmilk or BMSs. This includes foods prepared at home and processed foods, provided that such foods meet infants and young children's nutritional requirements at this stage, and they are introduced to infants only after six months of age.
- ❖ **Infant** means from birth up to 12 months of age.
- ❖ **Young Child** means a child from 12 months to 3 years of age.
- ❖ **Trade Mark** means the commercial name under which the product is sold.
- ❖ **Container** means any form of packing and packaging of products within the scope of this Code for retail sale as an ordinary unit or packed group.
- ❖ **Container Label** means the content of the label affixed or printed on product container and contains the trade mark, ingredients, marks and other explanatory images, whether in writing, printing, copying, engraving, or paste..
- ❖ **Sample** means a small amount of the special products within the scope of this Code and which are offered free of charge.
- ❖ **Supplier** means any person, institution or any other entity, engaged in the manufacturing or **supply** of a product within the scope of this Code, either directly or through a contract or an agent or supervision based on an agreement **between** the two **parties**.
- ❖ **Distributor** means any person, institution, or any other entity, involved in commercial business activities, whether on wholesale or retail sales basis, or in marketing any product within the scope of this Code.
- ❖ **Promotion or Marketing** means promoting, marketing, distribution, and advertising products through public relations and information services and any other means, by, for example, offering samples, promotions, free gifts, or **low cost supplies** to hospitals, physicians, mothers, and other persons **involved in** maternal and child health, and promotions include the so-called medical, nutritional or preventive claims, among others.

❖ **Advertisement means:**

- a) Offering any commercial product within the scope of this Code in any **means** with the purpose of promoting the sales or use of such a product, including but not limited to:
- b) Advertising in print, radio or televised media outlets, including social media and any other means of advertisement.
- c) Advertisement by **Billboards**, buses, container labels, etc.
- d) Photo or three-dimensional configuration exhibitions.
- e) The sponsorship **of events or activities (for example medical conferences) by the supplier, distributor, or any person acting on their behalf**, without obtaining official approval in accordance with ministerial decision #57 for 2010.
- f) Displaying or posting the mark or logo of products within the scope of this Code in any promotion or advertisement for a product not within the scope of this Code, such as promotions for contraception methods or other medications.
- g) Commodities **sold** at hospital gift shops for child birth occasions and others which bear, on or inside them, pictures or three-dimensional configurations of products within the scope of this Code.
- h) Any other practice deemed by the Higher Committee as "an advertisement" within the scope of this Code.

❖ **Health Care System** means governmental and private sector health care institutions, including private health care clinics, and organizations directly or indirectly involved in maternal, infant and **pregnant**, kindergartens, and child care institutions, among others. And for the purposes of achieving the objectives of this Code, this **definition** also includes pharmacies and other points of sale.

❖ **Health Care Workers** means any person who is part of the health care system, whether on professional or voluntary basis.

❖ **Higher Committee** means the Higher Committee for **Promotion and Support of Breastfeeding** and the implementation of the baby-friendly hospital initiative designated by an administrative decision from the Ministry of Health.

Article Two: Scope of Kuwaiti Code

The Kuwaiti Code applies to the sales and marketing practices relevant to BMSs, including complementary foods from milk products and other foods and drinks marketed as suitable for use as a partial or complete breastmilk substitute, in addition to feeding bottles and **teats**. It also applies to their quality, availability and the information on their use.

Article 2-1 The sales of BMSs, complementary foods and related products mentioned in Article 2, up to 3 years of age shall be prohibited , and advertisements for said products shall be prohibited in the various points of sale, and their sales shall be limited to authorized pharmacies, cooperatives and shopping centers only.

Article 2-2 Local producers and importers of BMSs and complementary foods shall commit to said products' meeting relevant **international (Codex) and Gulf standards and specifications**.

Article 2-3 Ensure the proper use of BMSs when needed for premature babies, babies with special needs, **foundlings**, and orphans, **through a decision of the specialized physician, on the infant's need** for such substitutes in which case said products are provided through official channels.

Article Three: Information and Education

Article 3-1 The approval to publish informational and educational material on **infant and young child feeding** is the responsibility of the Ministry of Health, which may authorize the Higher Committee for the Promotion and Support of Breastfeeding or any other party, which does not have any direct or indirect commercial interest in the field of **infant and young child feeding**, in order to ensure strict compliance and enforcement of the provisions of this Code, by referring to the Law **organizing advertising materials related to health** # 38 for 2002 and its regulations

Article 3-2 The informational or educational material related to **infant and young child feeding, whether written, audio, or visual**, shall:

3-2-1) Include only correct and factual information, and pictures or text that may encourage the use of a specific product, formula- feeding, or discourage breastfeeding may not be used.

3-2-2) Shall be written in Arabic or English or both languages.

3-2-3) Does not **imply or create a belief** that bottle-feeding is equivalent to **breastfeeding or artificial milk is** superior to breastmilk.

3-2-4) Shall not contain the name, logo, drawings, **trademark** or any other description of any product within the scope of the Code nor to any of said products suppliers or distributors. The exception to this condition is the information **regarding** special products presented to health care workers, whereby said information shall be restricted to **scientific and factual matters** associated to ingredients and methods of **use** such special products.

3-2-5) Contain a clear explanation for each of the following:

- a) The benefits and superiority of breastfeeding.
- b) The high value of exclusive breastfeeding for six months **then continuing with breastfeeding up to 2 years of age or beyond**.
- c) **The initiation and maintenance** of exclusive breastfeeding and **continue** breastfeeding after that.
- d) **The difficulty of reversing the decision not to breast-feed**.
- e) The importance of **introducing** complementary foods after six months of age.
- f) Why the early introduction of formula or complementary foods negatively affect breastfeeding.
- g) **Complementary** foods can be easily prepared at home using local ingredients.

Article 3-3 **When** the educational materials referred to in (Article 2-3) contain information about infants and young child feeding with any food or drink offered to the child by a feeding bottle or cup, they should include also include the following points:

- a) Instructions on the proper product preparation and use, including instructions on cleaning and sterilizing utensils.
- b) **How to Cup Feed an infant.**
- c) **The health hazards of bottle feeding and improper use of infant formula.**
- a) An estimate **of the financial implications of** feeding infants with such products according to recommended amounts.

Article 3-4 The supplier or distributor, when presenting any educational material **on infant and young child feeding** to mothers or healthcare workers, shall submit a request attached with copies of said material to the Higher Committee for approval, following the procedures decided by the Committee.

Article Four: Prohibitions

Article 4-1

- a. Any person, institution, or any other entity, or anyone acting on their behalf, involved in the manufacture, supply or distribution of products within the scope of this Code, or in commercial or marketing **or promotion** businesses, shall be prohibited from promoting any product or special food within the scope of this code at points of sale, health care facilities, schools, markets, cooperatives, commercial markets or any other place, and the prohibited promotional practices include, for example, but not limited to, the following:
- b. Advertisement using the various promotional means such as posters, display boards and screens, among others.
- c. Using promotional methods during the sale of products, such as discount coupons, discounts or special offers, or giving gifts, presents or free products, or any other method.
- d. Giving one or more samples of products within the scope of this Code to any person, health facility or any other facility.
- e. **Perform any awareness-raising or educational functions to mothers or pregnant women on infant and young child feeding, should not seek direct or indirect contact of any kind .**
- f. Distributing advertisement or educational material related to **infant and young child feeding.**
- g. Suppliers, distributors and persons acting on their behalf shall be prohibited from giving lectures to health workers at health care facilities, with the exception **of** providing information on special products, provided such **information scientific and factual** and related to technical aspects and methods of using products within the scope of this Code, and in line with **Article Three** of this Code. And after obtaining the written approval of the Council of Heads of Pediatric Departments, and organizing the event in a group meeting arrangement under the supervision of the head of the department or the person acting on their behalf.

Article 4-2 The supplier, distributor, or any person acting on their behalf shall be prohibited from:

- a) Donating or presenting an amount of a product within the scope of this code at a price lower than the declared price, if any, and in the event that such a price does

- not exist, health care workers and any health care facility may not be offered a price under 80% of the retail price.
- b) Donating or distributing any **equipments or services** bearing the name, emblem , logo, trade mark, or any other mark for any product within the scope of this Code to health care workers or **any health care facility**.
 - c) Donating or distributing **materials**, including (but not limited to): pens, calendars, posters, note books, growth curves, height meters, promotional prescription papers, children's toys, which bear the name, logo, emblem, trade mark, or any other description of any product within the scope of this Code, at any health care facility or point-of sale.
 - d) Giving presents, free offers, token or financial contributions to health care workers or public interest associations associated with maternal and child health, including (but not limited to): scholarships, research grants, or funding meetings, seminars, continuous education courses, conferences or others.
 - e) Sponsoring events or competitions, providing consultation telephone lines, or organizing awareness-raising campaigns targeting pregnant or nursing mothers, parents of infants and young children or their family members. It shall also be prohibited to sponsor or organize **campaigns related to** fertility, pregnancy or child birth, or **infant and young child feeding** or any other relevant topic.
 - f) Having any direct or indirect communication with pregnant women and nursing mothers.

Article Five: Health Care System

Article 5-1 The Ministry of Health shall be responsible for protecting breastfeeding, the communication of the Kuwaiti Code , by-law, decisions, circulars etc, by all available means, and holding seminars or workshops, developing and printing Code awareness-raising publications, and the incorporation of the Code in public and private health workers training curricula.

Article 5-2 The Ministry of Health shall approach educational and health education institutions, such as (Ministry of Education, Faculty of Medicine, Nursing College, Health Sciences College, among others) for incorporating the topic of "Breastfeeding Promotion and Protection" in their curricula.

Article 5-3 Health workers involved in maternal and child health shall promote and encourage breastfeeding by applying the practices that directly or indirectly lead to **initiation and maintenance** of exclusive breastfeeding, and continued breastfeeding with the introduction of appropriate complementary foods **with continued breastfeeding up to 2 years of age or beyond.**, and shall be knowledgeable of the principles of this Code and comply with its articles.

Article 5-4 Health workers in maternal and child care departments, and regulatory parties conducting registration, examination, authorization and release of products within the scope of this code shall be prohibited from the following:

5-4 a) Accepting any presents, contributions, **or material inducements or others** regardless of their value, from suppliers, distributors, or any person acting on their behalf.

5-4 b) Accepting or giving samples of the products within the scope of this code to any person.

5-4 c) Explaining the methods of using products within the scope of this Code, if needed by mothers or family members, unless in an individual setting away from other mothers. And in such cases, a clear explanation shall be provided on the risks associated with **unnecessary** or improper use of infant formula, in addition to other information provided in (Article Three) of this Code.

5-4 d) Conducting professional research or evaluation or any other activity under any description at the health care facility level that is related to products within the scope of this Code, without the prior written **approval** of the Higher Committee for the Promotion of Breastfeeding.

Article Six: Container Labels

Article 6-1 Prohibitions related to labels of foods and products within the scope of the Kuwaiti Code

6-1-1) Supplier or distributor shall not display or sell foods, drinks or products whose labels contain pictures or drawings other than what is needed to provide instructions for the preparation of the product.

6-1-2) Supplier or distributor shall not display or sell foods or products within the scope of this Code, unless their container labels **has on it** the following Arabic, clear, **and easily readable** message (excluding feeding bottles, **teats**, and pacifiers):

- a) Written instructions for appropriate preparation of the products, with easily understood explanatory images.
- b) The recommended child age for starting product consumption in numbers or words in a clear font next to the name of the product.
- c) **A list** of ingredients with clarification of the source of milk or milk-like used in the product.
- d) The nutritional analysis of product ingredients.
- e) Product storage conditions, before and after the container is opened, in accordance with the instructions in effect in Kuwait.
- f) Batch number, dates of production and expiry, in accordance with storage conditions and instructions in effect in Kuwait.
- g) Name and Address of supplier or local distributor.
- h) Any new controls.

Article 6-2 Infant formula and follow-up product labels

6-2-1) Suppliers and distributors shall not display or sell infant formula and follow-up products unless their labels include (in addition to items listed in Article 6-1), the following items:

- a) **The words "Important Notice" or their equivalent; referring to the phrase that underneath it, prominently appears on the label.**
- b) That the phrase "Breastmilk is the best food for your baby" or a similar phrase explaining the superiority of breastfeeding or breastmilk showing in large fonts not less than one-third the font size of product name and not less than 2 millimeters in height.

- c) A phrase explaining that the product should be used when needed and after consulting with a specialized physician, and the proper method of use. Provided this information is indicated in fonts not less than one-third the font size of product name and not less than 1.5 millimeters in height.
- d) Indicating the feeding schedule, preparation method and a note on **discarding any formula remaining in the bottle after a feeding** .
- e) Does not use phrases such as "humanized" or "maternalized" or similar phrases implying that the product is **equivalent to** breastmilk.
- f) Does not use phrases that would lead to discouraging breastfeeding.
- g) Regarding infant follow-up formula, there needs to be a notification that follow-up preparations **are to be used** after 6 months of age.

Article 6-3 Labels of Feeding bottles and teats. Suppliers and distributors shall not display or sell feeding bottles or **teats** unless their container label includes the items indicated in Article (6-1), in addition to the following information in Arabic:

- a) Displaying the phrase "important notice" and under which the following appears:
- b) "Breastfeeding is the best and breastmilk is the ideal food for infants and young children's healthy growth and development, and it protects from diarrheas and other diseases" in large fonts not less than one-third the font size of product name and a font height not less than 2 millimeters.
- c) **Cleaning** and sterilization instructions accompanied by illustration graphs.
- d) A phrase indicating that feeding with a cup is healthier than bottle-feeding.
- e) A warning not to leave the feeding bottle in the mouth of the child for long periods of time because sugar in infant feeding liquids may cause dental caries.
- f) Name and local address of producer or distributor.
- g) This is with the exception of **Ready to feed** milk bottles used in hospitals considering the small size of their containers.

Article 6-4 Pacifier container label. Suppliers and distributors shall not display or sell infant pacifiers unless their container labels include the items provided in Article (6-1) in addition to the following phrase:

"Warning: using pacifiers may conflict with breastfeeding" in a font size not less than one-third the product name font size and not less than 1.5 millimeters in height.

Article Seven: Management and Implementation

Article 7-1 The Ministry of Health is the main party responsible for implementing the Kuwaiti Code.

Article 7-2 The Ministry shall coordinate with other relevant ministries for ensuring the implementation of this Code.

Article 7-3 For the purposes of implementing this Code, the following measures may be taken:

- a) Issue decisions needed for the implementation of this Code, and realizing its goals and objectives.
- b) Request consultation with public, private, and other relevant parties for ensuring the implementation and the strict adherence to the Code.

- c) Exercise the powers and functions needed for realizing the goals and objectives of this Code.

Article 7-4 In order to ensure implementation and follow-up, there shall be formed upon a ministerial decision, a higher committee for the promotion and support of breastfeeding in the State of Kuwait and subsidiary committees for the promotion and support of breastfeeding in governorates and health areas, and the decision shall give the committees the powers to implement this Kuwaiti Code, executive and relevant decisions and measures needed for the promotion and protection of breastfeeding.

Article 7-5 The Higher Committee shall hold periodic meetings for following-up on implementation.

Article 7-6 The Higher Committee shall be assigned the following functions in implementing the Code:

- a) Propose and implement a national policy for supporting, protecting, and promoting breastfeeding.
- b) Forming subsidiary committees and working groups for implementing the functions of the committee as needed at the local levels.
- c) Follow up the implementation of the Ministry's plan for applying international standards on promoting, supporting and protecting breastfeeding.
- d) Review available educational information on feeding infants and young children and supplying health institutions with guidelines, standards, and work policies.
- e) Developing and implementing continuous training programs for health care workers on dealing with breastfeeding and Code requirements.
- f) Follow -up the work of committees and working groups formed in hospitals and health areas for applying standards and implementing policies and plans.
- g) Conducting field-visits to follow-up on the implementation, and conducting assessments for following-up progress in implementation.
- h) Ensuring wide-scale publicizing and circulation of this Code through available means.
- i) Issuing instructions for inspectors on measures taken against any person or entity deemed in violation of the provisions of this Code.
- j) Subcommittees shall review reports and complaints on violations and other issues relevant to the Code and submit them to the Higher Committee for taking the appropriate measures.
- k) Coordinate with the WHO and other local and international organizations relevant to the protection, promotion and support of breastfeeding to keep abreast with new developments and ensure the implementation of the program at the highest possible levels.
- l) Conduct research and field studies needed for following-up and development of breastfeeding promotion programs in coordination with relevant parties and in accordance with legal methods.
- m) Other functions that may be assigned to the Higher Committee.

Article Eight: Registration of Products within the Scope of this Code

Article 8-1 All products within the scope of this Code shall be registered at the Kuwaiti Ministry of Health in accordance with their relevant procedures and regulations.

Article 8-2 Applicants for registration of any product within the scope of this Code shall meet the terms and conditions of Ministerial Decision # 532/2002.

Article 8-3 A registration certificate shall be issued upon approving the registration of a product within the scope of this Code.

Article 8-4 A registration certificate may not be awarded unless the product meets applicable quality standards recommended by the Codex Alimentarius Commission and Gulf specifications, and product container labels meet the conditions provided in this Code.

Article Nine: Inspectors

Article 9-1 The Higher Committee shall nominate inspectors for monitoring the implementation of this Code from health care workers, ministry of commerce and municipality, and shall issue the decisions needed for that purpose, provided that no person with a direct or indirect financial interest with any supplier or distributor of products within the scope of this Code is nominated.

Article 9-2 Inspectors shall, within the scope of their functional powers:

- a) Inspect any location where any product within the scope of this Code is imported, manufactured, sold, stored, displayed for sale, or advertised, or any other relevant activity is carried out.
- b) Give citations for violations of this Code.
- c) Exercise powers at their disposal as needed.

Article 9-3 Following each inspection, inspectors shall report citations given to their relevant subcommittee for taking appropriate measures.

Article 9-4 Individuals and organizations shall be entitled to lodge complaints with the subcommittee or directly with the Higher Committee, or by using the **complaints line** at the Ministry of Health regarding any violations of this Code.

Article 9-5 Following receiving citations and complaints reports on any violations of this Code, the Higher Committee shall submit reports and recommendations to the Ministry of Health for taking the required legal measures.

Article Ten: Penalties and Penalty Provisions

Article 10-1: Penalties

10-1-1 When violations of this Code provisions are proven, and without prejudice to any harsher penalty provided in other regulations, the violator (including any individual, company, or institution manufacturing, importing, distributing, or promoting BMSs) shall be subject to the penalty provided in Article Two of Law # 38 for 2002 on regulating advertising health related items.

10-1-2 Public and private health care workers violating the provisions of this Code shall be referred to investigation and to the subsequent implementation of administrative measures and penalties decided against them.

10-1-3 [cases involving]Workers in other fields, such as the Ministry of Education and others, violating the provisions of this Code, [shall be dealt with] by requesting their employing party to implement administrative measures and penalties against them.

Article 10-2: The Power to Issue Decisions

10-2-1 Relevant officials at the ministries of health, commerce, municipality, and education who are charged with the implementation of this Code, and following a notification published in the Official Gazette, may develop subsequent executive decisions for activating the purpose of this Code.

10-2-2 In particular, and without prejudice to the integrity of previous decisions, said decisions shall describe:

- a) The functions of the Higher Committee and its subsidiary committees.
- b) The terms and procedures for registering products within the scope of the Kuwaiti Code.
- c) Determining the qualifications and powers of assigned inspectors for the purposes of implementing this Code.
- d) Procedures for presenting educational or informational material to the Higher Committee.
- e) Procedures for presenting complaints and violations reports to the Higher Committee and relevant legal parties.

Article Eleven: Enforcement The articles of this Code shall enter force upon publication in the Official Gazette.