Republic of Lebanon Parliament

Law No. 47 of 11/12/2008 Official Gazette No. 55 of 13/12/2008

Law Organizing the Marketing of Infant and Young Child Feeding Products and Tools

Chapter I : Common Provisions

Chapter II : Information and Education

Chapter III : Prohibitions related to Promotion

Chapter IV : Prohibitions related to the Container and the Label

Chapter V : Health Care Facility and Health Worker Responsibilities

Chapter VI : Administration

Chapter VII : Registration and Sale of Designated Products

Chapter VIII: Pharmaceutical Inspectors

Chapter IX : Penalties

Chapter X : Final provisions

Chapter I: Common Provisions

Article 1: Scope

This Law entitled "Law Organizing the Marketing of Infant and Young Child Feeding Products and Tools" applies to designated products as defined in Article 3.

Article 2: Aim

This Law aims at providing safe and healthy food to infants and young children by protecting, promoting and supporting breastfeeding and ensuring safe use of infants and children food and complementary food products (when needed) according to adequate information, and providing the right information and educating parents and health workers about infant and young child health and nutrition through regulating the methods and practices of marketing and distribution to achieve this aim.

This Law encourages exclusive breastfeeding during the first six months of age, and adopting the adequate complementary food practices as of the age of six months; making sure breastfeeding is continued for not less than two years, as a way of endorsing infant and young child nutrition.

Article 3: Definitions

The definitions of the terms stated below are the definitions used throughout this Law.

1. <u>Advertise:</u> means to make any representation by any means whatsoever for the purpose of promoting the sale or use of a designated product including but not limited to:

a. audio, visual, or written publication including the books, television, radio, films, pictures, tapes (all sorts of videotapes, cassettes, disks, and compact disks), lectures, seminars, postal mail, e-mails, websites, telephones, mobile phones, SMS messaging, and faxes;

b. slogans, billboards, signs, pamphlets, brochures, booklets, posters, or any insinuation to or display of any product;

c. exhibition of pictures or models;

d. sponsoring an event or occasion through the product;

e. display or insert in any publication as a logo or sign of pregnancy or child birth in any publicity even if it is not in the scope of infants or young children feeding products like in the contraceptive means or gifts offered by traders including pictures or small models of designated products or on boxes or chocolate or flower arrangements or with and inside balloons designed for child birth occasions or even include these designated products in the gifts like feeding bottles or pacifiers in flower arrangements or balloons;

f. any other practice or means as the Minister of Health may, after consultation of the National Committee and by notice in the Official Gazette, declare to be a means of "Advertising" for purposes of this Law.

2. <u>Promote:</u> means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product. This includes distributing samples of the products, free gifts, discounted gifts, or special offers for hospitals or physicians or others. Promotion includes what is called health assumptions.

3. <u>Market:</u> means to promote, distribute, merchandize, sell, or advertise a designated product, and includes product public relations and information services.

4. <u>Manufacturer</u>: means a natural or legal person, corporation, or other entity engaged in the business of manufacturing a designated product whether directly, through an agent, or through a person, or entity controlled by or under an agreement with it.

5. <u>Distributor</u>: means a natural or legal person, corporation, or other entity engaged in the business, whether wholesale or retail, of marketing any designated product.

6. Minister: means the Lebanese Minister of Health.

7. Ministry: means the Lebanese Ministry of Health.

8. <u>National Committee</u>: means the National Committee for the promotion and protection of breastfeeding, which monitors the implementation of this Law, and which is appointed in accordance with Article 18.

9. Infant: means a child from birth up to the age of one year (12 months).

10. Young Child: means a child from the age of one year up to the age of three years (36 months).

11. Designated Product: means

a. infant formula

b. follow-up formula

c. any other product marketed or otherwise represented as suitable for feeding infants and young children up to the age of three years

d. feeding bottles, teats, and pacifiers

e. such other product as the Minister of Health may, after consultation of the National Committee and by notice in the Official Gazette, declare to be a "designated product" for purposes of this Law.

12. <u>Infant Formula</u>: means a milk or milk-like product of animal or vegetable origin formulated industrially, and marketed or represented as intended to satisfy the nutritional requirements of infants from birth up to the age of one year.

13. <u>Follow-up formula</u>: means a milk or milk-like product of animal or vegetable origin formulated industrially, and marketed or represented as suitable for feeding infants and young children older than six months of age.

14. <u>Complementary food</u>: means any food suitable or represented as suitable as a substitute for or an addition to breastmilk, infant formula, or follow-up formula.

15. Pacifier: means an artificial teat for babies to suck. It is known by many names like "dummy".

16. <u>Container</u>: means any form of packaging of a designated product for sale as a normal retail unit, including wrappers and needles.

17. <u>Label</u>: means a tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, compacted, stuck or attached on a container of a designated product.

18. <u>Sample</u>: means a small or single quantity of a designated product even if of a large size, provided without cost.

19. <u>Health care facility</u>: means any establishment including public or private institutions, associations, organizations, public and private clinics, dispensaries, and medical centers engaged directly or indirectly in the provision of health care or in health care education such as medical faculties and universities. It also includes day-care centers, nurseries, infant and child care facilities, orphanages, shelters that house infants and children, clinics of private health workers, and any establishment for infant and child care.

20. <u>Health professional</u>: means a health worker with a professional degree, diploma or licence, such as medical practitioners, pharmacists, nurses, and midwives working in a health care facility, or such other person as may be specified by the Minister of Health after consultation of the National Committee and by a notice in the Official Journal, to be a "health professional or worker" for purposes of this Law.

21. <u>Health Worker:</u> 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.

22. Inspector: means the pharmaceutical inspector appointed under Article 26.

Chapter II: Information and Education

<u>Article 4:</u> The Ministry is responsible for broadcasting or distributing the information and educational materials related to infant and young child feeding. It may delegate the task to the National Committee or any other party which has no direct or indirect commercial interest in infant and young child feeding in order to guarantee the implementation and compliance with the provisions of this Law.

<u>Article 5:</u> Information and educational materials, whether written, audio, or visual, which refer to infant and young child feeding shall:

a. contain only correct and current information and shall not use any picture or text that encourage the use of a designated product, bottle-feeding, pacifiers, or discourage breastfeeding;

b. be written in Arabic;

c. not give an impression or create a belief that the designated product is equivalent to, comparable with, or superior to breastmilk or to breastfeeding;

d. not contain the name, logo, drawing, trademark, or any other description of any designated product, nor of any manufacturer, marketer, or distributor

provided that this clause (d) shall not be applicable to information about the designated product provided to health workers, as long as this information is restricted to scientific and factual matters regarding the nutritional content and methods of use of the designated product.

e. clearly and conspicuously explain each of the following points:

1. the benefits and superiority of breastfeeding;

2. the value of exclusive breastfeeding for six months, followed by sustained breastfeeding for two years or beyond;

3. how to initiate and maintain exclusive and sustained breastfeeding;

4. why it is difficult to reverse a decision not to breastfeed;

5. the importance of introducing complementary foods from the age of six months;

6. how and why any introduction of bottle feeding or early introduction of complementary foods negatively affects breastfeeding;

7. that complementary foods can easily be prepared at home using local ingredients.

<u>Article 6:</u> If the material referred to in article 5 includes feeding infants with infant formulas, follow-up formulas, or any other food or drink administered with feeding bottles or cups, it must include the following points:

a. instructions for the proper preparation and use of the product including cleaning and sterilization of feeding utensils;

b. how to feed infants and young children with a cup;

c. the health risks of bottle feeding and improper preparation and use of the product.

<u>Article 7:</u> Manufacturers and distributors of materials related to infant and young child feeding and nutrition must give the data to the National Committee in accordance with the published resolutions that serve the provisions of this Law.

Chapter III: Prohibitions related to Promotion

<u>Article 8:</u> A manufacturer, distributor, or marketer, shall not him or herself or by any other person on his or her behalf, promote any designated product in the points of sale, health care facilities, or any other place.

Prohibited promotional practices include but are not limited to:

a. advertising;

b. sale devices such as special displays, baby-talkers, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;

provided that this clause -b- does not restrict establishing pricing policies and practices that aim at providing the designated products for long-term reduced prices.

c. giving of one or more sample of a designated product to any legal or natural person, or any of the health care facilities, including hospitals and clinics;

d. donation or distribution of any information or educational material referring to infant and young child feeding or performance of educational functions related to infant and young child feeding.

The persons mentioned in the above article may provide the information about designated products to health care professionals as long as it is restricted to scientific and factual matters, and related to technical concepts and methods of use of these products, and compliant with the articles of chapter 2 of this Law related to information and education.

<u>Article 9:</u> A manufacturer, distributor, marketer, any legal or natural person, shall not him or herself or by any other person on his or her behalf:

a. donate or provide any quantity of the designated product to a health worker or a health care facility at lower than the published wholesale price where one exists, and in its absence, lower than 80% of the retail price;

b. donate to or distribute within a health care facility equipment or services that carry, promote, or indicate the name, logo, drawing, trademark, or any other characteristic of a designated product, manufacturer, or distributor;

c. donate to or distribute within a health care facility materials that include, among others, pens, calendars, posters, notepads, binders, growth charts, and toys which refer to or may promote, or indicate the name, logo, drawing, trademark, or any other characteristic of a designated product, manufacturer, or distributor;

d. offer or give any gift, donation, or financial contribution to a health worker even if he is a trainee, or to associations of health workers engaged in mother and child health, to mother and child health care facilities, universities, medical faculties involved in pediatrics, obstetrics, gynecology, and nutrition, including but not limited to scholarships, research grants, or funding for meetings, seminars, continuing education courses or conferences;

e. sponsor events, contests, telephone counseling lines, or campaigns addressed to pregnant women, nursing mothers, parents of infants or young children, family members and caretakers, nor sponsor campaigns related to reproductive health, pregnancy, childbirth, infant or young child feeding or related topics;

f. include the volume of sales of designated products when calculating employee or worker remuneration or bonuses, nor set quotas for sales of designated products;

g. perform educational functions related to pregnant women or mothers of infants and young children;

h. contact pregnant women or mothers of infants and young children whether directly or indirectly in the framework of their work.

Chapter IV: Prohibitions related to the Container and the Label

<u>Article 10</u>: A manufacturer, distributor, or marketer shall not offer for sale or sell a designated product if its container or label affixed thereto includes pictures, drawings, or graphics other than those used to clarify the methods of preparation.

A manufacturer or distributor shall not offer for sale or sell a designated product unless the container or label affixed thereto indicates the following, in a clear, conspicuous and easily readable manner, in Arabic:

a. the words "IMPORTANT NOTICE" in capital letters using a 14-sized font referring to the statement under it: "Breastmilk is the ideal food for infants and young children up to the age of two years. It promotes immunity and protects against diarrhea and other illnesses", in visible, darker, and larger characters than the other characters written on the container. The characters should be no less than one-third the size of the characters in the product name. The words "IMPORTANT NOTICE" and the statement following it must be visible in the center of the container, even when held, and not be covered by anything including the container's lid and its extremities.

b. the word "Warning" and indicated thereunder, the statement:

1. For designated products other than the feeding bottles, teats, and pacifiers: "Seek the advice of a physician before using an infant formula. If you use a feeding bottle, your baby may refuse to feed from the breast. It is better to feed from a cup".

2. The warning word and the statement indicated thereunder should be written clearly, in darker, and larger characters using font (14). These characters should also be larger than those used for the product's name.

The warning word and the statement indicated thereunder should be clearly visible in the center of the container even when held, and not be covered by anything including the container's lid and its extremities.

c. the name and local address of the manufacturer or distributor printed on the container provided that the container is adequate and preserves the quality and safety of the product.

d. any other detail possibly required.

<u>Article 11:</u> A manufacturer, distributor, or marketer shall not offer for sale or sell a designated product other than feeding bottles, teats, and pacifiers unless the container or label affixed thereto indicates in a clear, conspicuous and easily readable manner, in Arabic, the following particulars:

a. instructions for appropriate preparation and use in words and in easily understood graphics;

b. the age after which the product is recommended in numeric figures;

c. a warning about the health risks of improper preparation and of introducing the product prior to the recommended age;

d. the ingredients used, and the source and kind of the milk or any comparable product;

e. the composition and nutritional analysis;

f. the required storage conditions both before and after opening the container, taking into account climatic conditions;

g. the batch number, date of manufacture, and date before which the product is to be consumed, and expiry date by day/month/year in a unencoded way, taking into account climatic and storage conditions;

h. the feeding chart with instructions of preparation stating the necessity of disposing the leftovers;

i. does not use the terms "maternalised", " humanized" or terms similar thereto or any comparison with breastmilk;

j. does not use texts that may tend to discourage breastfeeding;

k. in the case of follow-up formula, states that the product shall not be used in infants less than six months old.

<u>Article 12:</u> A manufacturer, distributor, or marketer shall not offer for sale or sell any feeding bottle or teat unless the container or label affixed thereto indicates in a clear, conspicuous and easily readable manner, in Arabic, the following particulars:

a. instructions for cleaning and sterilization in words and graphics;

b. a statement explaining that feeding with a cup is better and more hygienic than bottle feeding;

c. 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 tooth decay.

Article 13: A manufacturer, distributor, or marketer shall not offer for sale or sell the following:

a. 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".

b. 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 ".

The statements in paragraphs -a- and -b- shall be written in characters darker, larger, font 14sized and bigger than the other characters written on the container. The characters should be no less than one-third the size of the characters in the product name.

They must be written in Arabic, in the center, clearly visible even when held, and not be covered by anything including the container's lid and its extremities.

The products mentioned in the previous paragraphs -a- and -b- are not subject to the stipulations of this Law unless they are marketed or represented as being suitable for infant and young children.

Chapter V: Health Care Facility and Health Worker Responsibilities

<u>Article 14:</u> The Ministry, Minister, and heads of Health Care facilities shall take the adequate measures needed to protect breastfeeding and to promote this Law. They shall give information and advice to health workers regarding their responsibilities and particularly ensure that health workers are familiar with all the information specified in this Law.

Health care educational institutions shall incorporate "breastfeeding management" in their curricula.

Article 15: Health workers:

1. shall encourage, support, and protect breastfeeding by encouraging pregnant women and mothers to breastfeed their children up to the age of two years or beyond;

2. are expected to know the provisions of this Law, particularly chapter II related to information and education;

3. shall work to promote practices that directly or indirectly lead to the initiation and continuation of breastfeeding.

<u>Article 16:</u> Health workers, health care facilities, and educational health and medical institutions related to mother and child health shall not:

a. accept or receive any gift, contribution, benefit, money, or the like, no matter what the value may be, from the manufacturer or distributor of a designated product, or from their representative, or any other person;

b. accept, receive, or give any sample of a designated product to anyone;

c. clarify or explain the instructions of use of a designated product to anyone except individually to the mother or family members who need them. In this case, they shall give a clear and full explanation of the risks of improper or unnecessary use of the designated product with the information stipulated in chapter II of this Law related to information and education;

d. conduct any kind of professional assessment, research, or activity related to a designated product in health care facilities without a pre-issued written approval from the National Committee.

Chapter VI: Administration

<u>Article 17</u>: Implementation

1. The Ministry is principally responsible for the implementation of this Law.

2. The Minister shall, when necessary, call upon other ministries to ensure the implementation of this Law.

3. For the purpose of implementing this Law, the Minister has the following powers and functions:

a. to promulgate such rules as are necessary or proper for the implementation of this Law 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 the Act and the rules promulgated hereunder;

c. to cause the enforcement of this Law;

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 Law.

Article 18: The National Committee for the promotion and Protection of Breastfeeding

The Minister forms a National Committee for the promotion and protection of breastfeeding to implement this Law and the rules promulgated in accordance with its provisions.

The National Committee is composed of the following members:

a. the Director General of the Ministry of Public Health, president

b. the Director General of the Ministry of Economy and Trade, member

c. the Director of Preventive Medicine at the Ministry of Public Health, member

d. the President of the Order of Pharmacists of Lebanon or a representative appointed by the president, member

e. the President of the Order of Physicians of Lebanon or a representative appointed by the president, member

f. the President of the Order of Physicians of North Lebanon or a representative appointed by the president, member

g. the President of the Order of Nurses of Lebanon or a representative appointed by the president, member

h. a representative of the Midwives Association of Lebanon, member

- i. a representative of the Higher Council of Childhood in Lebanon, member
- j. a representative of the National Committee of Women Affairs in Lebanon, member
- k. a representative of consumer protection organizations, member
- 1. a representative of organizations supporting and promoting breastfeeding, member
- m. a legal consultant appointed by the Order of Lawyers, member
- n. a representative of UNICEF, controller.
- o. a representative of WHO, controller.

provided that no person who has any direct or indirect financial interest in any designated product shall be appointed to the Committee.

Article 19: A Member of the National Committee assumes his/her tasks as long as he/she holds his/her administrative or governmental position. In case a member is not a government official, he assumes his/her tasks in the National Committee for three non renewable years, unless he/she no longer has his/her representative title.

Article 20: Powers and Functions of the National Committee

The National Committee has the following powers and functions:

- a. to advise the Minister on national policy for the promotion and protection of breastfeeding;
 - b. to supervise the local committee in each Mohafaza;

c. to advise on designing a national strategy for developing communication and public education programmes for the promotion and protection of breastfeeding; information and educational materials on the topics of infant and young child feeding; continuing education for health workers and health care professionals on lactation management and the requirements of this Law;

d. to review reports and complaints of violations and other matters concerning this Law;

e. such other powers and functions that the Minister entrusts the National Committee with.

Article 21: The Local Committee

A local committee is formed in each Mohafaza so as to assist the National Committee. The local Committee is composed of:

- the head of the Public Health Department in the Mohafaza from the Ministry of Public Health, president

- an obstetrician-gynecologist, member
- a pediatrician, member
- a representative of organizations supporting and promoting breastfeeding member
- a representative of consumer protection organizations, member
- a pharmaceutical inspector, member and rapporteur

provided that no person who has any direct or indirect financial interest in any designated product shall be appointed to the Committee.

The local committee is appointed by decision of the Minister of Public Health upon the suggestion of the Director General of the Ministry and consultation of the National Committee.

The members of the local committee shall hold office for a term of 3 years and shall be eligible for renomination as far as the nongovernmental members are concerned.

Article 22: Powers and Functions of the Local Committee

Local committees shall oversee the implementation of the National Committee recommendations. These committees have to submit a report to the National Committee pertaining to how the Mohafaza is implementing this Law and to problems encountered in monitoring and support.

<u>Article 23:</u> The National Committee holds a meeting, summoned by its chairperson, at least once a month, when necessary, or by the written demand of at least half its members.

The local committee holds a meeting, summoned by its chairperson, at least once a month, when necessary, or by the written demand of at least half its members, or when the National Committee requires so.

The National Committee or the local committees may invite national or foreign experts to take part in the meetings as observers.

Internal regulations specify the task of both the National Committee and the local committee by decision of the Minister of Public Heath upon the suggestion of the Director General of the Ministry.

Remunerations for attending the meetings of the National Committee and of local committees are decided by decree of the Council of Ministers upon the suggestion of the Minister of Public Health.

Chapter VII: Registration and Sale of Designated Products

Article 24: The following is applied for registry of designated products:

1. Designated products are registered at the Ministry of Public Health (Pharmacy Department) in accordance with the provisions of Pharmacy Practice Law. A special register is established for this purpose.

2. Upon adoption of this Law, a manufacturer, producer, vendor, or importer of a designated product shall straighten out his/her situation and register the product within six months of creating the register. After that period, he/she is prohibited from importing, manufacturing, selling, marketing, or displaying any unregistered or expired designated product.

3. No certificate of registration will be granted unless the designated product is in accordance with the quality standards recommended by the Codex Alimentarius Commission and in the Code of Practice of infant and child food products, and unless the container and the label affixed thereto are in accordance with the requirements stipulated in this Law.

Article 25: Designated products shall be sold only in pharmacies.

Chapter VIII: Pharmaceutical Inspectors

<u>Article 26:</u> Pharmaceutical inspectors at the Ministry of Public Health are responsible for monitoring the implementation of this Law.

<u>Article 27:</u> Any natural or legal person has the right to file a complaint to the Ministry or the National Committee related to violations of this Law and the rules made pursuant thereto. Upon receiving a report on violations of this Law and rules made pursuant thereto from an inspector or others, the National Committee submits its recommendations to the Minister in order to take proper legal actions.

Chapter IX: Penalties

Article 28:

1. Any natural or legal person violating this Law and the rules made pursuant thereto is subject to the provisions of Chapter X of the Pharmacy Practice Law.

2. Health workers are subject, in addition to the aforementioned, to administrative sanctions that include temporary suspension of his / her work permit for a maximum duration of 6 months.

In case of repeated violation, he /she will be forbidden from practicing his/her profession.

3. Health professionals are submitted to disciplinary sanctions according to the provisions and rules in use at the Order to which he/she belongs.

Chapter X: Final Provisions

<u>Article 29:</u> The resolutions required for the implementation of this Law shall be published in the Official Gazette especially:

a. internal regulations and functions of both the National and Local Committees;

b. the conditions and procedures of registering designated products and creation of a special register at the Ministry of Public Health in order to monitor them;

c. the qualifications, powers and procedures entrusted to the inspectors appointed in accordance with this Law;

d. the procedures for submitting information and educational material to the National Committee;

e. guidelines related to issuance of medical prescriptions for designated products.

<u>Article 30</u>: Details of the implementation of this Law shall be specified in decrees that will be taken at the council of ministers upon suggestion of the Minister of Public Health.

Article 31: The Legislative Decree No. 110 of 16 September 1983 related to Marketing of Breast Milk Substitutes is terminated with all the laws and regulations contradicting its provisions.

Article 32: This Law shall come into effect upon publication in the Official Gazette.