

**Law No. 05/L -023**

**ON THE PROTECTION OF BREASTFEEDING**

**The Assembly of the Republic of Kosovo,**

Based on Article 65 (1) of the Constitution of the Republic of Kosovo,

Approves:

**LAW ON THE PROTECTION OF BREASTFEEDING**

**Article 1**

**Purpose**

1. This Law protects breastfeeding through its encouragement and promotion, as well as through restrictions on the marketing of designated products, as defined by this Law, for feeding infants and young children.

2. This Law has been aligned with EC Directive 2006/141/EC of the date 22 December 2006 on Infant Formulae and Follow-on Formulae and amending Directive 1999/21/EC and with the Regulation (EU) No. 609/2013 of the European Parliament and Council of the date 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

**Article 2**

**Scope of Application**

The provisions of this Law shall apply to health workers, health institutions, professional health associations, institutions for infant and small children care, manufacturers, distributors, marketing personnel of designated products for infant and young children and other subjects of Law defined by this Law.

**Article 3**

**Definitions**

1. The terms used in this Law shall have the following meanings:

1.1. **Feeding Bottle** - a device with an artificial teat which is used to feed an infant or a young child.

1.2. **Codex Alimentarius** - a set of standards, practices, guidelines or other internationally accepted recommendations about food, food production and its security.

1.3. **Codex Alimentarius Commission** - the United Nations body, which aims to protect

consumer health and fair practices respecting the international marketing of food.

1.4. **Pacifier** - an artificial teat for babies to suck.

1.5. **Distributor** - a natural or legal person in the public or private sector undertaking distribution, directly or indirectly, wholesales or retails of designated products.

1.6. **Label** - a tag, mark, drawing, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise appearing on a container of a designated product.

1.7. **Young children** - children aged between one (1) and three (3) years;

1.8. **Follow-on formula** - milk or milk product similar to, of animal or plant origin, prepared industrially, in accordance with the relevant Codex Alimentarius Standard, and marketed or otherwise represented as suitable for feeding infants and young children older than six (6) months of age.

1.9. **Infant Formula** - foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding;

1.10. **Infant** - child from birth under the age of twelve (12) months.

1.11. **Marketing** - promotion, distribution, sale, advertising, public presentation of the product, directly or through wide information services.

1.12. **Sample** - selected small amount of product that is given for free.

1.13. **Packing** - any form of packaging of a product, as a dedicated unit for sale, including any kind of material used for wrapping of the packaging.

1.14. **Marketing personnel** - natural or legal person, whose function includes the marketing of designated products from the scope of this Law.

1.15. **Designated product:**

1.15.1. infant formula;

1.15.2. any other product marketed or otherwise represented as suitable for feeding infants up to the age of six (6) months;

1.15.3. follow-on formula;

1.15.4. any other milk or milk like product marketed or otherwise represented as suitable for feeding infants and young children;

1.15.5. complementary food;

1.15.6. feeding bottles and pacifiers; and

1.15.7. any other product that the Ministry of Health may, by notice in the Official Gazette, declare to be a “designated product” for the purposes of this Law.

1.16. **Promoting** - every tool and method used to promote sale or purchase of any product, to present an idea or cause, or to result in desired affects.

1.17. **Health worker** - health professionals, non-professionals, and others working in health facilities, including voluntary workers.

1.18. **Breast milk** - milk produced by mammary glands of women.

1.19. **Subject of Law** - includes any natural and legal person, within the scope of this Law.

1.20. **Complementary food** - food prepared industrially or at home conditions as nutrition supplement to breast milk or a follow-up formula, when after the sixth (6) month of life, the baby’s nutritional requirements are not met only with milk.

1.21. **Employed woman who has recently given birth** - an employee who has recently given birth within the meaning of this law and who informs her employer of her condition, in accordance with this law.

1.22. **Employed woman who is breastfeeding** - an employee who is breastfeeding within the meaning of this Law and who informs her employer of her condition, in accordance with this Law.

#### Article 4

##### Protection of breastfeeding

1. Ministry of Health shall develop health policies and shall coordinate activities to protect the exclusive feeding with breast milk for the first six (6) months of life and continued feeding until the age of two (2) years or more, through promoting its advantages, and encouraging and supporting mothers to feed their babies with breast milk.

2. Protection of breastfeeding in healthcare institutions is regulated by sub-legal act, in accordance with the “Innocenti Declaration” of years 1990 and 2005, “Ten steps to successful breastfeeding” the “International Code of Marketing of Breast-milk Substitutes” and subsequent relevant World Health Assembly Resolutions, and the “Global Strategy on Infant and Young Child Feeding”.

3. Health workers shall protect breastfeeding through promotion and encouragement based on the procedures defined by the sub-legal act in accordance with paragraph 2 of this Article.

4. All forms of promotion and encouragement of breastfeeding should provide accurate and evidence based information about: the advantages of breastfeeding, proper nutrition for mothers, preparation of mother and baby for breastfeeding as well as disadvantages of breast milk replacement feeding.

5. Pregnant woman, parent, custodian and the immediate family of an infant in a medical institution should have guaranteed access to information and materials that encourage and promote breastfeeding, which are based on scientific evidence and are approved by the Ministry of Health or entities authorized by it, as defined by the sub-legal act based on paragraph 2 of this Article.

6. Health professionals are obliged to conduct health education about breastfeeding through communication of information and provision of materials from paragraph 5 of this Article.

7. Ministry of Health shall preserve the right to issue sub-legal acts in the field of infant and young child feeding, to ensure implementation of guidelines, and practice codes of the international food standards known as the Codex Alimentarius.

#### **Article 5**

##### **The rights of employed women to breastfeed**

1. Every employed breastfeeding woman is entitled to the rights guaranteed by the relevant legislation in force in Kosovo.

2. Every employed breastfeeding woman, if not utilizing the maternity leave after the sixth (6) month of the leave and according to relevant legal provisions into force, from the sixth (6) month up to one (1) year, has the right of using two (2) hours of paid break daily during the working hours, additional to the regular break, for breastfeeding, as defined by this Law.

3. Every employed breastfeeding woman after the first year up to two (2) years shall have the right of using one (1) hour of paid break daily during the working hours for breastfeeding, in addition to the regular daily break.

4. Every employed breastfeeding woman shall use a one (1) or two (2) hours paid break daily during the working hours at the beginning, in the middle or at the end of the working hours, in agreement with the employer and regarding this she shall notify in writing the employer along with the certificate issued by the doctor which certifies that the employed woman is breastfeeding.

#### **Article 6**

##### **Absolute prohibition of exposure**

The breastfeeding employee should under no circumstances be compelled to work in jobs where she is exposed to the risk for her and her infant health or safety, defined by the relevant legal provisions into force.

#### **Article 7**

##### **Packaging and Label of designated products**

1. Designated products that are imported, manufactured, marketed and circulate in Kosovo market, should comply with the provisions set forth in this Law.

2. Designated products whose packing and label does not comply with the provisions of this Law are forbidden to be imported, manufactured, offered, placed on sale or otherwise traded in the market.

3. The labelling of infant formulae and follow-on formulae should be designed to make clear distinction between such products to provide the necessary information about the appropriate use of the products so as not to discourage breast feeding. The requirements, prohibitions and restrictions in this paragraph, paragraph 5 and paragraph 7 of this Article shall also apply to the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed and advertising.

4. Packing or label of designated products, except feeding bottle and pacifier, that is imported, manufactured, offered, traded or otherwise presented in a market, must indicate in a visible place and in a clear, conspicuous and easily readable manner, in official languages, the following particulars:

4.1. overall and clear instructions for the manner of preparation and use of designated product in words and in easily understood graphics;

4.2. the age after which the designated product is recommended, in words and numeric figures and in the case of a complementary food, the recommended age shall not be less than six (6) months;

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

4.4. complete details on the composition, the ingredients and the nutritional analysis of the designated product;

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

4.6. the batch number, date of manufacture, term of use or/and expiry date;

4.7. the name and national address of the manufacturer or distributor.

5. Inclusion of photograph, drawing or other graphic representation, other than for illustrating the methods of preparation, in packing and label of designated products, except complementary food, is prohibited.

6. Any representation on packing and label of designated product, except complementary food, that states or suggests that a relationship exists between the certain product or constituents thereof and health, including the physiological role of a nutrient in growth, development or normal functions of the human body, is prohibited.

7. In addition to the requirements of paragraph 4 of this Article, packing or label of designated products shall conform to the following:

7.1. For infant formula or follow-on formula:

7.1.1. contain the words, "IMPORTANT NOTICE" in capital letters and indicated there under, the statement "Breastfeeding is the best. Breast milk is the ideal food for the healthy growth and development of infants and young children; it protects

against diarrhoea and other illnesses” in characters no less than one-third the size of the characters in the product name, and in no case less than two millimetres (2 mm) in height;

7.1.2. the word, “Warning” and indicated there under, the statement, “Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional. It is important for your baby’s health that you follow all preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup” in characters no less than one-third the size of the characters in the product name, and in no case less than one and a half millimetre (1.5mm) in height.

7.2. in preparation instructions for infant or follow-up formula in powdered form that:

7.2.1. powdered formula may be contaminated with microorganisms during preparation;

7.2.2. it is necessary for formula to be prepared one feed at a time using water at or above seventy degrees Celsius (70°C); and

7.2.3. any prepared unused milk must be discarded immediately after every feed;

7.2.4. includes a feeding chart in the preparation instructions;

7.2.5. specifies the source of the protein;

7.2.6. it is prohibited to use the terms “materialized”, “humanized” or terms similar thereto or any comparison with breast milk;

7.2.7. it is prohibited any text that discourages breastfeeding; and

7.2.8. in the case of follow-on formula, states that the product shall not be used for infants less than six (6) months old.

8. The packing or label of the skimmed or condensed milk, in powder or liquid form, marketed or otherwise represented as suitable for infants, shall contain the words: “This product should not be used to feed infants” in characters no less than one-third the size of the characters in the product name, and in no case less than two millimetres (2 mm) in height.

9. The packing or label of the low-fat or standard milk, in powder or liquid form, marketed or otherwise represented as suitable for infants, unless the container or label affixed thereto contains the words, “This product should not be used as the sole source of nourishment of an infant” in characters no less than one-third the size of the characters in the product name, and in no case less than two millimetres (2 mm) in height.

10. Packing or label of a feeding bottle or teat, in addition to the requirements of paragraph 4.6 and 4.7 of this Article, shall contain in a clear, conspicuous and easily readable manner, in official languages, the following particulars:

10.1. the words, “IMPORTANT NOTICE” in capital letters and indicated there under, the

statement, "Breastfeeding is best. Breast milk is the ideal food for the healthy growth and development of infants and young children; it protects against diarrhoea and other illnesses" in characters no less than one-third the size of the characters in the product name, and in no case less than two millimetres (2 mm) in height;

10.2. the statement, "WARNING: It is important for your baby's health that you follow the cleaning and sterilization instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from the breast. Feeding with a cup is more hygienic than bottle feeding" in characters no less than one-third the size of the characters in the product name, and in no case less than two millimetres (2 mm) in height;

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

10.4. the name and national address of the manufacturer or the distributor.

11. Packing or label of a pacifier shall contain the words, "WARNING: Use of a pacifier can interfere with breastfeeding" in characters no less than one-third the size of the characters in the product name, and in no case less than two millimetres (2 mm) in height.

### **Neni 8**

#### **Contain, circulation and imports of designated products**

1. Designated products may be imported and can circulate within the Kosovo market only if they comply with this law and other enforced Laws.

2. Import and circulation of designated products within the Kosova market have to fulfill international criteria for such product and shall not contain any substance in such quantity as to endanger the health of infants and young children.

### **Article 9**

#### **Prohibition on promotion of designated products**

1. The promotion, in any form, directly or indirectly, to the public of designated products by manufacturers, distributors, marketing personnel or any other natural and legal person on their behalf, is prohibited.

2. Prohibited promotion of the products from paragraph 1 of this Article, includes:

2.1. advertising in written, audio or visual format, including advertising through internet or social media;

2.2. places for presentation, demonstration and testing of the products;

2.3. distribution and giving of one or more samples or packages of the designated product to any person;

2.4. sales devices such as special display, distribution/sale of discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;

- 2.5. donation or distribution of information or educational material referring to infant or young child feeding; and
  - 2.6. performance of educational functions related to infant or young child feeding; and
  - 2.7. provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers and any other form of promotion.
3. As an exception, manufacturer, distributor, marketing personnel or any other physical and judicial person acting on their behalf may promote complementary food provided that:
- 3.1. such promotional practice does not take place in a health care and infant and young child care facilities; and
  - 3.2. any material in any format promoting complementary food encourages exclusive breast-feeding for the first six (6) months of life and sustained breastfeeding for up to two (2) years and beyond.
4. Manufacturers, distributors and any natural or legal person, is prohibited from:
- 4.1. providing any quantity of a designated product to a health worker, health institutions, professional health associations, institutions that provide care for infants and young children, at lower price than the published wholesale price where one exists, and in its absence, lower than eighty percent (80%) of the retail price;
  - 4.2. offering and provision of designated products free of charge to health workers, health institutions and subjects of Law;
  - 4.3. donation or distribution to health workers, health institutions, professional health associations and institutions that provide care for infants and young children, equipment, services or materials such as pens, calendars, posters, notepads, growth charts and toys, or any other forms, which refer to or may promote the name or logo of the manufacturer or designated product;
  - 4.4. offering or provision of any awards, gifts, contribution or benefit to a health worker, health institutions, professional health associations, and institutions that provide care for infants and young children, including fellowships, research grants or funding for meetings, seminars, continuing professional education, courses, conferences or other similar forms;
  - 4.5. sponsoring in written, in audio-visual and electronic media various programmes, events, campaigns, contests, telephone counselling lines or other related activities dealing with mother and child health;
  - 4.6. including the volume of sales of designated products when calculating employee remuneration or bonuses, nor set quotas for sales of designated products.
  - 4.7. including the volume of sales of designated products when calculating commercial-

trade subjects' remuneration or bonuses, or setting quotas for sales of designated products.

#### **Article 10**

##### **Prohibitions for health workers, health institutions and health associations**

1. Health workers, health institutions and professional health associations are prohibited to:
  - 1.1. receive prizes, gifts, contributions or benefits, financial or otherwise, of whatever value by a manufacturer, distributor or subjects to law of designated products;
  - 1.2. accept or distribute samples of designated products;
  - 1.3. promote and encourage the use of designated products excluding special cases, excluding the case when documented medical indications for their use.
2. Health worker is prohibited from marketing of the designated products.
3. Health professional of health institution is obliged to prepare the substitute of breast milk when such feeding within the institution is necessary by medical indication and this is documented in a medical report.
4. Health professional of health institution is obliged to introduce to and educate the parent or custodian of the infant and young child of the options for feeding with designated products, only in cases when this is necessary by medical indication and this is documented in a medical report.
5. Designated products can be used for professional evaluation or research at institutional level, only with the prior written approval of the Ministry of Health.

#### **Neni 11**

##### **Approval of donation**

As an exception, donations of equipment, educational materials or designated products by manufacturers, importers or distributors shall be made only upon written approval of the Ministry of Health. Such equipment or materials may not bear the donating company's name or logo, and shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

#### **Article 12**

##### **Monitoring**

1. Monitoring of the implementation of the provisions of this Law in health institutions is performed by administrative bodies, as follows:
  - 1.1. Ministry of Health - Division of maternal health, child and reproductive health;
  - 1.2. Director of the health institution;

1.3. Quality Coordinator of the health institution.

1.4. Civil based organizations and other organizations that act in encouraging, protection and promotion of proper infant and child feeding based on the agreement with the Ministry of Health.

2. Coordinator of the quality of health care institution informs the institution's Director in writing the findings in health monitoring, which is obliged to take measures to avoid the irregularities found during monitoring and subsequently inform in writing the Division for mother, child and reproductive health in the Ministry of Health.

3. Division of maternal, child and reproductive health will inform, if needed in writing respective inspectorate about findings following monitoring.

### **Article 13**

#### **Supervision and Inspection bodies**

1. Implementation of this Law shall be overseen by inspectorates and other bodies on the basis of competence defined as:

1.1. Health Inspectorate shall oversee the implementation of Article 4 paragraph 3, 5, 6; Article 9 paragraph 1, paragraph 2 sub-paragraph 2.3, 2.5, 2.6, 2.7; Article 9 paragraph 3 sub-paragraph 3.1; article 9 paragraph 4 sub-paragraph 4.1, 4.2, 4.3, 4.4 Article 10 and article 11.

1.2. Labour inspectorate shall oversee implementation of Article 5, article 6; Article 9 paragraph 1; Article 9 paragraph 4 sub-paragraph 4.1, 4.2, 4.3, 4.4 and 4.6.

1.3. Veterinary and Food Agency shall oversee the implementation of Article 7.

1.4. Education Inspectorate shall oversee implementation of Article 9 paragraph 1; Article 9 paragraph 2 sub-paragraph 2.5, 2.6; Article 9 paragraph 3 sub-paragraph 1; Article 9 paragraph 4 sub-paragraph 4.1, 4.2, 4.3 and 4.4.

1.5. Market Inspectorate shall oversee the implementation of Article 7, paragraph 1, Article 9 paragraph 1; Article 9 paragraph 2 sub-paragraph 2.2, 2.3, 2.4; Article 9 paragraph 4 sub-paragraphs 4.2 and 4.7.

1.6. Media Commission shall oversee the implementation of Article 9 paragraph 1; Article 9 paragraph 2 sub-paragraph 2.1, 2.5; Article 9 paragraph 4 sub-paragraph 4.5.

### **Article 14**

#### **Administrative sanctions**

1. Entities for the following violations shall be fined as follows:

1.1. for any violation of Article 4 of this Law, natural person is subject to a fine of five hundred Euro (500.00 €);

1.2. for any violation of Article 5 and 6 of this Law, the small enterprises are subject to a fine of one thousand Euro (1,000.00 €) the medium enterprises are subject to a fine of two thousand and five hundred Euro (2,500.00 €), the large enterprises are subject to a fine of five thousand Euro (5,000.00 €);

1.3. for any violation of Article 7 and 8 of this Law, the small enterprises are subject to a fine of one thousand Euro (1,000.00 €), the medium enterprises are subject to a fine of two thousand and five hundred Euro (2,500.00 €) the large enterprise is subject to a fine of five thousand Euro (5,000.00 €); producer, importer and distributor shall be subject to a fine of twenty thousand Euro (20,000.00 €);

1.4. for any violation of Article 9 of this Law, the small enterprises are subject to a fine of one thousand Euro (1,000.00 €), the medium enterprises are subject to a fine of two thousand and five hundred Euro (2,500.00 €), the large enterprises are subject to a fine of five thousand Euro (5,000.00 €); producer, importer and distributor shall be subject to a fine of twenty thousand Euro (20,000.00 €), the natural person shall be punished by a fine of one thousand Euro (1,000.00 €) and a legal person and other entities with a fine of five thousand Euro (5,000.00 €);

1.5. for any violation of Article 10 of this Law health worker is subject to a fine of five hundred Euro (500.00 €) and in case of repetition, a one (1) year suspension of revocation of the licence; while a health institution shall be subject to a fine of five thousand Euro (5,000.00 €).

1.6. for any violation of Article 11 of this Law, producer, importer and distributor shall be fined with twenty thousand Euro (20,000.00 €) while health institution shall be fined with five thousand euro (5,000.00 €) and measures will be taken that the donation be permanently taken from them.

#### **Article 15**

##### **Repealing provisions**

With the entry into force of this Law, the Law on the promotion and protection of breastfeeding No. 02/L-81 promulgated by Regulation No. 2007/7 for promotion and protection of breastfeeding for children, approved by the Assembly of Kosovo and all the provisions of sub-legal acts of the Ministry of Health that are contrary to this Law shall be repealed.

#### **Article 16**

##### **Entry into force**

This Law shall enter into force fifteen (15) days after publication in the Official Gazette of the Republic of Kosovo.

**Law No.05/L-023**

**24 October 2015**

**Promulgated by Decree No.DL-029-2015, dated 13.11.2015, President of the Republic of Kosovo Atifete Jahjaga.**