

## **El Salvador – Law on the Promotion, Protection and Support of Breastfeeding, adopted on 26 June 2013**

The National Assembly of El Salvador finally adopted a Law on Breastfeeding, on 26 June 2013. This is the result of a 20-year long struggle by breastfeeding supporters and health workers. Only two articles were slightly modified from the draft submitted by the Committee on Health and Environment, which was based on the proposal put forward by CALMA (Centre for Breastfeeding Support, an IBFAN member in El Salvador). The picture shows members of the National Assembly and the public applauding the historic vote.

(Note: In some parts I have deliberately translated literally what the original text says, in order to highlight inconsistencies, incorrect terminology and the use of several expressions to refer to the same substance, namely breastmilk substitutes. I have highlighted in blue the various ways in which breastmilk substitutes have been named throughout the law. J-P. Allain, 5 July 2013)

### **Decree No. 404**

#### **The National Assembly of the Republic of El Salvador**

#### **CONSIDERING**

- I. That pursuant to the Constitution, the human person is the origin and the purpose of all State activity which is organized for the attainment of justice, legal security and the common good.
- II. That children have the right to live in family and environmental conditions that allow them to achieve their complete development, and for which they will have State protection of their physical, mental and moral health, guaranteeing the right to education and assistance.
- III. That El Salvador is a signatory to the Convention on the Rights of the Child and is committed to ensuring that all sectors of society, in particular parents and children, have the basic knowledge of health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation, as well as guaranteed access to the necessary education, among others.
- IV. That in order to give concrete reality to above statements it is necessary to pass a law to promote, protect and support breastfeeding, a practice that ensures the best nutrition, growth and optimal development of infants, reducing morbidity and mortality.

**THEREFORE**, exercising its constitutional faculties and upon the initiative of the President of the Republic, hereby

**DECREES** the following

## **LAW ON THE PROMOTION, PROTECTION AND SUPPORT OF BREASTFEEDING**

### **TITLE I - GENERAL PROVISIONS**

#### **SINGLE CHAPTER: AIM, SCOPE AND COMPETENT AUTHORITY**

##### **Aim**

Art. 1 - This law shall establish the necessary measures to promote, protect and maintain exclusive breastfeeding up to six months and continued breastfeeding up to two years of age, ensuring its benefits and indispensable contribution to the nutrition, growth and complete development of infants. It also shall regulate the marketing of **breastmilk substitutes**.

##### **Rights**

2. - All boys and girls shall have the right to be breastfed so as to guarantee their lives, health, growth and complete development. Mothers have the right to breastfeed their children, with the support of the father, family, community, employers and private organizations. The State shall guarantee these rights.

##### **Scope**

Art. 3 – This law shall apply to all physical and juridical persons, private or public, who care for pregnant women, breastfeeding women and infants, as well as to public or private employers, including the Salvadoran Social Security Institute, the Rio Lempa Hydroelectric Executive Commission CEL, and those who manufacture, market, distribute or import breastmilk substitutes or carry out any other activity related to breastmilk substitutes.

##### **Competent Authority**

Art. 4 – The Ministry of Health, referred to in this law as “the Ministry”, shall be the competent authority for the implementation of this law.

The Ministry shall coordinate with other duly certified bodies to develop activities for the promotion, protection and support of breastfeeding.

##### **Competences**

Art. 5 – The Ministry’s competences shall be the following:

- a) To implement this law and to ensure its implementation.
- b) To issue the sanitary registration of breastmilk substitutes and to deny such registration when they do not comply with established standards.
- c) To inspect and monitor the quality and safety of formulas.
- d) To prepare national promotion, protection and support plans with a sectoral reach and social participation for breastfeeding.

- e) To verify that health providers are adequately trained to promote breastfeeding and optimal infant feeding practices among mothers and the public.
- f) To ensure that health providers inform, guide and assist families and the community to achieve adequate breastfeeding practices.
- g) To establish violations and impose sanctions, according to procedures established under this law.
- h) Any other competence established by the Health Code and other related provisions.

All private, public or autonomous institutions, even those not mentioned in this law, shall provide the Ministry with the information it may request for the fulfillment of its competences under this law.

## **DEFINITIONS**

Art. 6 – For the purposes of this law, the following definitions shall apply:

**Human milk banks:** Specialized units responsible for collecting, promotion, protection and support of breastfeeding and activities of processing, quality control, for its distribution under medical prescription.

**Manufacturer:** means a corporation in the private sector engaged in the business or function, whether directly or through an agent or through an entity controlled by or under contract with it, of manufacturing a product within the scope of this law.

**Authorized information:** Updated, true and objective information based on data that can be applied to a population and on scientific evidence.

**Infant:** A boy or girl up to the age of twenty four months.

**Exclusive breastfeeding:** Infant feeding with breastmilk, without any other food or liquid. Exclusive breastfeeding must be initiated at birth and continue until the child reaches six months.

**Prolonged, continued or extended breastfeeding:** means continuation of breastfeeding after six months and up to two years or more.

**Breastmilk:** Living and changing liquid tissue secreted by the mammary glands of women and which, for infants from zero to six months, fulfils all the nutritional, enzymatic, immunological and emotional needs and ensures optimum growth and development.

**Breastfeeding mother:** means a woman who breastfeeds her infant with the milk of her own breasts.

**Sample:** means single or small quantities of a product provided without cost.

**Special situations:** means health conditions defined in existing rules established by the competent authority and in legally declared situations of catastrophe or public disaster.

**Breastmilk substitute:** means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.

**Breastfeeding promotion:** means activities to communicate and inform about the advantages and virtues of breastfeeding.

## **TITLE II -THE NATIONAL BREASTFEEDING COMMISSION**

### **SINGLE CHAPTER: ESTABLISHMENT, COMPOSITION, IMPEDIMENTS AND REQUIREMENTS**

#### **Establishment**

Art. 7 – The National Breastfeeding Commission, henceforth called “the Commission” or by its acronym CONALAM, shall be established as a consultative body of the Ministry,

#### **Aims of CONALAM**

Art. 8 – The main purpose of CONALAM is to support and advise the Ministry in matters of protection, promotion and support of breastfeeding.

Art. 9 – The Commission shall be composed of one representative and one alternate representative of the following institutions:

- a) Ministry of Health or its delegate who shall preside;
- b) Ministry of Labor and Social Security;
- c) Ministry of Education;
- d) Salvadoran Social Security Institute;
- e) Women Development Institute;
- f) National Council for Childhood and Adolescence;
- g) School of Medicine of the University of El Salvador;
- h) Medical Association of El Salvador;
- i) The private sector (a representative of a company);
- j) Breastfeeding Support Centre.

#### **Impediments**

Art. 10 – Legal or physical persons who are involved in the manufacture, importation or marketing of products deemed to be breastmilk substitutes shall not be members of the Commission.

### **Requirements**

Art. 11 – Members of the Commission shall have a professional degree and possess experience in the subject matter; they shall act ad honorem for a once-renewable two-year term.

### **Functions and duties**

Art. 12 – The Commission shall have the following functions and duties:

- a) to advise and cooperate in the drafting of plans and programs related to breastfeeding;
- b) to advise and cooperate in strengthening the breastfeeding culture;
- c) to advise and cooperate in research and studies on the practice of breastfeeding that serve as a basis for public policies in this area;
- d) to advise and cooperate in the constant review and updating of breastfeeding indicators that serve to measure progress of this practice;
- e) to issue opinions and technical conclusions on the promotion, protection and support of breastfeeding, as requested by the competent authority;
- f) any other function requested by the governing body.

## **TITLE III - SUPPORT TO BREASTFEEDING**

### **CHAPTER I - ADVERTISING AND PROMOTION OF BREASTFEEDING**

#### **Advertising**

Art. 13 – The Ministry, public health professionals, including the Salvadoran Social Security Institute, the Rio Lempa Hydroelectric Executive Commission CEL and other institutions part of the National Health System, shall boost the promotion to publicize the importance of maternal nutrition, the preparation for breastfeeding and its benefits, emphasizing its superiority over breastmilk substitutes and prevent misleading messages that discourage the practice of breastfeeding.

Any person, natural or juridical, related to health care, should promote the practice of breastfeeding, by complying with the legal technical instruments issued by the Ministry.

### **Right to information**

Art. 14 - All people, especially pregnant women and nursing mothers are entitled to receive timely, accurate and understandable information about the benefits of breastfeeding, breastfeeding techniques, potential pitfalls and solutions.

### **Obligation to inform**

Art. 15 - The Ministry shall ensure that all staff in health facilities, public and private, responsible for the care of mothers and infants, have the information and education on breastfeeding as the natural food.

### **Participation of the Education Sector**

Art. 16 - The Executive Branch of the Education Sector shall incorporate into curricula content on breastfeeding, from early education to higher education.

### **Authorization**

Art. 17 - The Ministry shall authorize all information, educational, promotional and advertising material related to infant feeding, including exclusive breastfeeding until six months, and work towards prolonged breastfeeding until two years of age.

## **CHAPTER II - SUPPORT TO BREASTFEEDING**

### **Infant feeding in special situations**

Art. 18 – Health professionals in public and private institutions shall prescribe breast milk for infant feeding, and only in special situations may breastmilk substitutes be prescribed.

### **Special cases**

Art. 19 - In special cases or at the request of the mother, food from human milk banks or breastmilk substitutes may be considered, after the attending medical staff have assessed the case and according to a protocol or technical guidance authorized by the Ministry.

Such technical guidance authorized by the Ministry shall consider all aspects that prevent or contraindicate breastfeeding, as well as maternal, neonatal and socioeconomic circumstances.

### **Human Milk Banks**

Art. 20 - Human milk banks shall be responsible for collecting, analyzing, pasteurizing and conserving breastmilk, its classification, quality control and distribution to infants unable to receive direct breastfeeding from their mothers.

The donation of human milk shall be free. No public or private institution nor any individual may set a monetary cost for obtaining or distributing it.

The State and all public, autonomous and private institutions shall promote the donation of human milk for children who can not have access to it.

### **Responsible authority**

Art. 21 - The Ministry shall ensure the implementation and enforcement of human milk banks.

## **TITLE IV - PROTECTION OF BREASTFEEDING**

### **CHAPTER I - MARKETING OF BREASTMILK SUBSTITUTES**

#### **Information content**

Art. 22 – Authorized information shall cover the importance of breastfeeding and shall contain objective, scientific data about breastmilk substitutes.

The information shall be written in Spanish, in a clear, objective and consistent manner based on scientific studies.

#### **Prohibition of advertising**

Art. 23 - Advertising of breastmilk substitutes that discourages breastfeeding shall be banned.

#### **Specific prohibitions**

Art. 24 - The following promotional activities are banned:

- a) The free distribution of breastmilk substitutes;
- b) The distribution of breastmilk substitutes through contests or other promotional measures;
- c) The sale or free distribution of promotional items;
- d) Activities, sponsorship or events that promote the consumption of breastmilk substitutes;

- e) Sweepstakes and contests that offer prizes, gifts or other benefits that promote the consumption of breastmilk substitutes;
- f) Promotion at point of sales, through special offers, tied sales, coupons, discounts, rebates or other incentives, and,
- g) Direct or indirect contact with pregnant women or mothers of infants, with the aim of promoting breastmilk substitutes.

## CHAPTER II – PACKAGING AND LABELLING

### Labeling of substitute products

Art. 25 - The container of any **substitute product** shall have a label that can not be detached from it without being destroyed. The label of each substitute product shall be designed so as not to discourage breastfeeding. It shall provide the necessary information for correct use of the product.

The label shall not contain any photographs, design or any other graphic representation, except those used to illustrate the method of preparation of the product and it shall be written in Spanish. It must also contain the name and address of the manufacturer or importer and, when applicable, the name of the distributor. It shall not use terms like "maternalized", "humanized", "breastmilk equivalent", or the like.

### Feeding bottles

Art. 26 - The labels of feeding bottles shall include:

- a) A statement of the superiority of human milk for infant feeding.
- b) A warning about potential health risks from use of the bottle and the negative consequences of its use on breastfeeding.
- c) The materials used in their manufacture.
- d) Instructions for cleaning and sterilization.

## CHAPTER III – QUALITY

### Recommended International Standards

Art. 27 - **Substitutes** covered by the provisions of this law, intended for sale or any other form of distribution, shall meet internationally



recommended standards, as well as quality standards.

### **Product packaging**

Art. 28 - Any **substitute product** covered by this law shall be sold in its original package or container and shall not be subdivided for retail sale.

## **CHAPTER IV – HEALTH CARE PROVIDERS**

### **Protection and encouragement**

Art. 29 - The Ministry shall take all necessary steps to protect and encourage breastfeeding. No health care provider, public or private, shall promote breastmilk substitutes, nor shall its facilities be used to expose products, posters, labels, stickers, or any other item or means of promotion related to breastmilk substitutes.

### **Scholarships**

Art. 30 - No official or health care provider, including the Social Security Institute and the Hydroelectric Commission of the Lempa River CEL shall directly or indirectly obtain from manufacturers or distributors of **substitute products** funding of scholarships, study trips, costs of attending professional conferences or any other activity with the purpose of promoting their products.

Manufacturers and distributors covered by the provisions of this law shall disclose to the institution to which a beneficiary health worker belongs any contribution made to such staff, or on her or his behalf, to finance continuing medical education.

### **Practices of health care providers**

Art. 31 - Health care providers shall promote early bonding, rooming-in, provision of counseling and breastfeeding support, while avoiding practices that discourage breastfeeding such as: the separation of mothers from their children, bottle feeding, delay in putting the infant to the breast for first time, the lack of guidance on the most common breastfeeding problems, prescribing breastmilk substitutes when this is not necessary or starting on complementary foods.

### **Counseling**

Art. 32 - Health care providers referred to in the scope of this law shall be trained to counsel mothers about breastfeeding and the correct use of **infant formula**, industrially manufactured or home made, in special circumstances set out in Article 19 of this law.

## **Samples**

Art. 33 - Health care providers shall not receive nor give samples of **infant formula**, or materials or implements for their preparation or use, to pregnant women, nursing mothers or members of their families, except in special cases covered by Article 19 of the law.

## **Donations**

Art. 34 - No health care provider shall accept donations of **breastmilk substitute products**, equipment, promotional, information or education materials.

In exceptional cases where the Ministry deems that the use of **substitutes** is indispensable, or in disaster, public calamity or national emergency situations, the guidelines previously established by the competent authority shall be followed for accepting donations of these products.

## **CHAPTER V – PROTECTION MEASURES**

### **Labor legislation**

Art. 35 - During the first six months postpartum any working woman, while breastfeeding her child or collecting milk, shall have a break of up to one hour per day for that purpose; this break may be divided into two breaks or more as agreed by the parties.

Breastfeeding breaks can not be used at lunch time and shall be counted as working time and remunerated as such.

Employers shall ensure compliance with this provision and this right shall not be compensated or replaced by any other, failing which employers shall be sanctioned as provided in this Act.

Employers shall set up a clean space within the workplace for mothers to extract and store their breastmilk.

### **Audits**

Art. 36 - The Executive, through the Ministry of Labour and Social Welfare and the Ministry of Health, shall carry out regular audits of workplaces to ensure compliance with these provisions. Non-compliance with these provisions by employers shall be sanctioned with penalties under the sanctions regime established by this law.

### **Schools**

Art. 37 - Schools and legally established universities shall comply with Article 35 of this law, so that student mothers can extract their milk.

## **TITLE V - VIOLATIONS AND SANCTIONS**

### **CHAPTER I – VIOLATIONS**

#### **Level of violations**

Art. 38 – Violations to this law shall be classified as minor, serious and very serious.

#### **Minor violations**

Art. 39 – The following shall be considered minor violations:

- a) Provision of advice on the use of breastmilk substitutes to parents of infants in special situations by persons who are not qualified.
- b) For health care providers of the public or private sector to not explain clearly the health risks of consuming breastmilk substitutes that have not been correctly prepared or of consuming them without a medical prescription.
- c) Not to comply with the obligation of promoting breastfeeding.

#### **Serious violations**

Art. 40 – The following shall be considered serious violations:

- a) Promote **breastmilk substitutes** in health facilities, whether public, private, independent or otherwise, except for the reasons set forth in Article 19 of this law.
- b) Distribute promotional material containing graphics or text that in any way idealize breastmilk substitutes or induce [mothers] to use them instead of breast milk.
- c) For health workers to receive or give **breastmilk substitute products** or samples thereof to pregnant women, nursing mothers or members of their families.
- d) Carry out practices that discourage breastfeeding, such as those described in Article 31 of this law.
- e) Publicize and recommend the use of breastmilk substitutes that discourage the practice of breastfeeding.

## **Very serious violations**

Art. 41 - The following shall be considered very serious violations:

- a) To receive sponsorship or directly or indirectly to sponsor cultural, educational, political, sporting, artistic, social, scientific or community events and patron's festivities, amongst others, with the aim of promoting breastmilk substitutes that may lead to conflict of interest.
- b) To obtain from manufacturers or distributors of breastmilk substitutes funding that is not solely for continuing medical education activities.
- c) To promote breastmilk substitutes at point of sale, through special offers, tied sales, coupons, discounts, rebates or other incentives.
- d) Failure to comply with the provisions of this law on packaging and labeling.
- e) To donate or to accept donations of breastmilk substitutes in any public, private, independent or other health facility, without permission from the Ministry.
- f) To market or distribute breastmilk substitutes without the relevant health registration issued by the Ministry.
- g) Failure to comply with the provisions of Chapter V of Title IV of this law relating to protection measures.

## **CHAPTER II – SANCTIONS**

### **Sanctions**

Art. 42 – Without prejudice to possible criminal, civil or administrative penalties, the sanctions for violations of this law are:

- a) written warning for minor offenses.
- b) A fine from five to ten minimum wages in the trade and services sector for serious violations or repeated minor offenses.
- c) A fine of eleven to fifty minimum wages in the trade and services sector for very serious violations or repeated serious violations.

In addition to the fine provided in subsection c) of this article the following additional penalties shall be imposed:

- a) Suspension of the sanitary registration of products.

- b) Confiscation of products as well as promotional and educational materials.
- c) Closure of the establishment.

### **Determination of the penalty**

Art. 43 - The competent authority shall take into account the importance and gravity of the violation to determine the amount of the fine.

In the cases listed in Article 39, subparagraphs c), d) and e) of Article 40, and c) and d) of Article 41 the corresponding sanctions or fines shall apply or, where appropriate, there shall be confiscation and in addition the penalties set out in the Health Code shall be applied.

### **Closure of an establishment**

Art. 44 - When the Regional Health Bureau determines the need for closure of an establishment, in view of the gravity of the violation, it shall forward the proceedings to the Minister of Health, as appropriate, for his assessment of the relevance of such a decision.

The competent authority shall order the publication of the decision to apply the penalty, once it becomes final.

## **TITLE VI – PROCEDURES &**

### **CHAPTER I – PROCEDURES**

#### **Competence**

Art. 45 - The competent authority for the application of penalties laid down in this law shall be the Regional Director of Health of the geographical area concerned.

#### **Complaints**

Art. 46 - Any person having knowledge of one or more breaches or violations prescribed in this law shall submit a complaint with documented proof to the Director of the Health Unit of the place where the violation occurred, or to the Director of the SIBASI or the hospital, as applicable, who shall transfer the record transfer to the Regional Director of Health.

The complaint may be oral or written, shall be clear and if possible contain:

- a) A detailed account of the events that generated a violation or breach of the provisions of this law, stating the place, date and manner in

which it was committed.

b) The complainant's personal data: name, address and, if it is a juridical person, the type of entity, as well as the data of the person (or entity) who is the alleged violator.

c) The circumstances that lead to the verification of the allegations.

d) The identity and signature of complainant or the person who submits the denunciation at his request, if he does not know how or can not do it; the place and date of the complaint and to whom it was submitted.

Any verbal report shall be received for the record, to be instituted by the head of the receiving entity, and shall contain the information set out in the preceding paragraph. The complainant shall sign the record or, if unable to do so, leave the imprint of his thumb or, failing that, ask another person to sign.

### **Initiation of proceedings**

Art. 47 - The competent authority shall initiate the procedure for verification of facts, within seventy-two working hours after the violation has been denounced.

### **Audience**

Art. 48 - The competent authority shall, through the decision to initiate proceedings, summon the alleged violator for an interview, so that within a period of seventy-two working hours counted from the day following the notification, he appear to present his defense.

### **Refusal**

Art. 49 - Should the alleged offender or his legal representative fail to appear without good cause, within the established time, to manifest his defense, he shall be declared in rebellion.

### **Interruption of rebellion**

Art. 50 - At any stage of the proceedings before the final decision, the alleged offender or his legal representative may appear in person and stop the rebellion that has been declared and take the process forward at the stage where it is. In any case, to interrupt the declared rebellion, he shall designate a place to receive subsequent notifications.

### **Time for presentation of evidence**

Art. 51 – When the time laid down in Article 47 of this law has expired, there shall be eight days to present evidence against the charges, as well as the evidence mentioned in the complaint, in the inspection report or the report that gave rise to the proceedings or any other evidence.

Inspection, certification, expertise or any other procedures shall be ordered immediately by the competent authority. Evidence by confession may be submitted at any stage of the proceedings, provided it is before the final decision.

### **Sound criticism**

Art. 52 - Evidence presented by the alleged violators will be appreciated by the competent authority according to the rules of sound criticism.

### **Final resolution**

Art. 53 – After the time for presentation of evidence has ended the competent authority shall issue the final decision within a time period of seventy-two hours. The decision shall be based on the evidence received and applicable legislation.

Final decisions shall be sufficiently founded and include the evidence on which they are based, the identity of the alleged offender, the legal provisions that were violated, the respective penalty and shall be signed by the competent authority.

### **Enforceability**

Art. 54 - Any decision that imposes, modifies, revokes or confirms any of the sanctions provided for in this law shall be declared final and executory within the time limit set, without appeal.

## **CHAPTER II – APPEAL**

### **Admissible appeals**

Art. 55 Requests for review and appeals against a decision to impose the penalties provided in this law shall be allowed.

### **Appeal for revocation**

Art. 56 - The alleged offender or his legal representative may submit proceedings for revocation within seventy-two business hours counted from the day following the notification to the authority which issued the decision, who shall decide on such an appeal within five working days,

by modifying, confirming or revoking that decision.

### **Appeal and its procedure**

Art. 57 - Any decision of the competent authority shall be subject to the right of appeal to the Minister of Health or his substitute, within seventy two working hours counting from the day after notification.

The Minister of Health shall accept or reject the appeal filed if it does not meet the matters of fact or law that motivated the filing of the same.

### **Reopening a case for evidence**

Art. 58 - Should the Minister of Health or his substitute accept the appeal, the appellant shall be notified that the case is open for three working days for presentation of evidence.

### **Decisions on appeal**

Art. 59 - Upon expiration of the time for presentation of evidence, the Minister of Health or his substitute shall decide within a period of seventy two working hours to revoke, modify or confirm the appealed decision.

If the offender does not use any of the remedies provided in this law, the decision becomes final, administrative remedies shall be exhausted and the penalty shall be executed.

### **Payment of fines**

Art. 60 - Fines imposed on offenders under this law shall be paid to the Directorate General of Treasury, Ministry of Finance, within seven working days from the date of notification of the decision.

### **Collection through the courts**

Art. 61 - If a fine is not paid within the time limit stipulated in the preceding article, the competent authority shall certify the non-payment and forward it to the Attorney General's Office to initiate the corresponding procedures for collection.



## TITLE VII – FINAL PROVISIONS

### SINGLE CHAPTER

#### **Adapting to the law**

Art. 62 - Natural or legal persons engaged in the manufacture or marketing of formula or breastmilk substitutes shall have a period of six months from the date of the enactment of this law to conform to its provisions.

They shall have up to 12 months from the date of delivery of the electronic files, duly authorized by the Ministry of Health, to change labels and logos used in the manufacture or marketing of breastmilk substitutes.

#### **Deadline to set features**

Art. 63 - The Ministry shall have a period of sixty days from the date of enactment of this law to deliver duly authorized electronic files on labeling.

#### **Special nature of the law**

Art. 64 - The provisions of this law are of a special nature and shall therefore prevail over any other contrary provisions.

#### **Regulations**

Art. 65 – In conformity with paragraph 14 ° of Article 168 of the Constitution, the President of the Republic shall issue the regulations of this law within one hundred eighty days counted from the date of its enactment.

#### **Entry into force**

Art. 66 - This Law shall enter into force eight days after its publication in the Official Journal.

Adopted in the Blue Room of the Legislative Palace, San Salvador, on the 26th day of the month of June of the year two thousand thirteen.