

## **NICARAGUA Law No 295 – 16 June 1999 – Translation**

### **The President of the Republic of Nicaragua**

Informs the people of Nicaragua that:

#### **THE NATIONAL ASSEMBLY OF THE REPUBLIC OF NICARAGUAY**

#### **WHEREAS**

- 1) Breastfeeding is an unequalled way of providing infants with the ideal food for health growth, being the biological, psychological and physiological basis for the normal development of infants.
- 2) The PPMB (promotion, protection and maintenance of breastfeeding) are among the important health and nutrition measures, as well as social measures, which ensure the complete development of infants.
- 3) The practice of breastfeeding has diminished considerably as a result of the increased marketing of breastmilk substitutes, so that it is necessary to promote the tradition of breastfeeding and to regulate the marketing, advertising and distribution of breastmilk substitutes that encourage their use to the detriment of adequate and efficient breastfeeding.
- 4) The World Health Assembly, of which Nicaragua is a permanent member, has recommended the adoption of standards to protect breastfeeding, by means of regulation of the marketing of breastmilk substitutes, it therefore being incumbent to issue the appropriate legal provisions for that purpose, as well as the State, civil society and NGOs carrying out efforts and activities that promote, protect and maintain breastfeeding.

In the use of his faculties has issued the following

#### **LAW ON PROMOTION, PROTECTION AND MAINTENANCE OF BREASTFEEDING AND THE REGULATION OF THE MARKETING OF BREASTMILK SUBSTITUTES**

#### **CHAPTER I**

#### **Definition, Aims and Scope**

**Art. 1** – This law is based on doctrinal and procedural concepts, aiming at protecting, promoting and maintaining breastfeeding, as well as regulating the correct use of breastmilk substitutes for infants.

**Art. 2** – The purpose of this law is to establish measures for the PPMB that will contribute to improving the nutritional status of infants, ensuring the appropriate use of breastmilk substitutes, on the basis of correct information, when they are needed, and to the marketing and distribution modalities for the following products: breastmilk substitutes, including infant formula, other milk-based products, including complementary foods, when marketed as breastmilk substitutes or when otherwise indicated as suitable to be used, with or without modification, totally or partially to replace breastmilk. It further includes the regulation of

marketing of feeding bottles, teats and dummies. It shall also apply to the quality and availability of the related products and to the information about their use.

## **CHAPTER II Generalities**

**Art. 3 – Definitions.** For the purposes of this law, the expressions used therein shall be understood to mean the following:

- a) **Breastmilk:** The fluid secreted by the mammary glands of a woman that contains the substances needed for the psychological and affective protection and healthy growth and overall development of children.
- b) **Infant:** Any girl or boy up to the age of two years.
- c) **Complementary food:** Any processed food product, locally or internationally manufactured or industrialized, including pasteurization or home-made, intended to complement the feeding of children above six months and given after breastfeeding.
- d) **Health care service:** Any institution or organization, governmental or private, that provides health care services directly or indirectly, with emphasis on pregnant women, mothers of infants and children under two years of age, including child development services or any other that include this kind of service.
- e) **Health professional and health care workers:** Health professionals are doctors, nurses, nutritionists, social workers, health care services administrators or any other professionals that carry out health promotion, protection, prevention, cure and rehabilitation actions. Health care workers are those who work in a health care service, be they professional or not, including volunteers.
- f) **Scientific information:** True information, based on confirmed data, references by studies.
- g) **Breastmilk substitute:** Any food marketed, presented or offered explicitly, **or that induces its use (sic)**, as a partial or total replacement of breastmilk, whether suited to the purpose or not.
- h) **Infant formula:** A product of animal or vegetable origin that has undergone any type of processing, transformation or addition, including pasteurization, in conformity with Codex Alimentarius rules, which by its composition is intended to substitute, totally or partially, the role of breastmilk in children less than two years old.
- i) **Manufacturer:** Any physical or legal person, in the public or private sector, whose role it is, directly or via an agent or entity controlled by or linked to it by virtue of a written or verbal contract, to manufacture any of the products included in the scope of this Law.
- j) **Marketing:** Any activity of promotion, advertising, sale, distribution, information and public relations related to the products within the scope of this Law. **Marketing of breastmilk substitutes shall be any activity that leads to [someone] replacing breastmilk [with the marketed product].**

**Marketing personnel:** Any physical or legal person whose role includes the promotion, advertising, sale, distribution, information and public relations services relating to products covered by the scope of this Law.

- k) **Retailer:** Any physical or legal person, in the public or private sector, whose role it is, directly or indirectly to market, **at retail or wholesale level**, products covered by the scope of this Law.
- l) **Distributor:** Any physical or legal person, in the public or private sector, whose role it is to store, market and distribute, at retail or wholesale level, products covered by the scope of this Law.
- m) **Supplies:** Quantities of a product provided for use, free of charge or at low cost, including those given to low-income families.
- n) **Sample:** A unit or small quantity of a product provided free of charge.
- o) **Label:** Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of any product within the scope of this Law.
- p) **Container:** Any form of packaging of products for sale by units.

### **CHAPTER III The Commission**

**Art. 4** – The National Breastfeeding Commission, administratively attached to the Ministry of Health, shall hereby be created and, throughout the text of this present Law, referred to merely as “the Commission”. Its purpose shall be to acts as the advisory, support and interinstitutional coordination body and as a forum for multidisciplinary discussion for the promotion and maintenance of breastfeeding.

**Art. 5** – The Commission shall be composed of the following members:

- a) Representative of the Ministry of Health, who shall preside
- b) Representative of the Ministry of Education,
- c) Representative of the Ministry of Labour,
- d) Representative of the Ministry of Economy and Development,
- e) Representative of the Nicaragua Social Security Institute,
- f) Representative of the Nicaragua Institute of Women,
- g) Representative of the Ministry of non-governmental organizations,
- h) Representative of the higher education institutions (universities),
- i) Representative of the Ministry of professional associations.

**Art. 6** – The Commission shall have the following functions:

- a) To promote the practice of breastfeeding, by means of a coherent and systematic educational intersectoral and interdisciplinary programme.
- b) Strengthen the breastfeeding culture and the confidence of women in their ability to breastfeed, by providing a general atmosphere of support for breastfeeding, via systematic demonstration and propagation of its practice.
- c) To lead a process that generates information on the breastfeeding situation and activities carried out in this regard at all levels.
- d) To formulate, coordinate, follow-up and evaluate activities for the promotion and maintenance of breastfeeding.
- e) To promote drafts of regulations and review of existing laws that relate to the promotion and maintenance of breastfeeding.
- f) Any other function that may be assigned to it.

**Art. 7** – The Ministry of Health, through the Commission, shall be responsible for planning, regulating and controlling the promotion, protection and maintenance of breastfeeding, as well as the regulation of the appropriate use and consumption of breastmilk substitutes and complementary foods.

**Art.** – Any physical or legal person who, directly or indirectly, is related to or participates in the marketing of products within the scope of this Law shall be subject to its provisions.

#### **CHAPTER IV Promotion**

**Art. 9** – The executing body of this present Law shall promote the healthy practice of feeding infants up to six months age exclusively with breastmilk. It shall, furthermore, encourage mothers to continue breastfeeding their children for up to at least two years of age, even after introducing complementary foods from six months onward.

**Art. 10** – The Government of the Republic of Nicaragua, through the Ministry of Health and with cooperation from other institutions and non-governmental organizations, shall be responsible for strengthening public and private initiatives aimed at promoting, protecting and maintaining breastfeeding as the most effective way of safeguarding the lives of girls, boys and women.

#### **CHAPTER V Marketing of Information and Education (sic)**

**Art. 11** - The Government of the Republic of Nicaragua, through the Ministry of Health and with cooperation from other institutions and non-governmental organizations shall be responsible for ensuring that parents, mothers and the general public [receive] objective and coherent information on feeding of infants.

**Art. 12** - Informational and educational materials, whether written, audio, visual or any other, as well as materials and equipment related to breastmilk substitutes or other products marketed as such, intended to reach pregnant women and mothers of infants and young children, shall be based on scientific facts and [include clear information on] all the following points:

- a) The benefits and superiority of breastfeeding;
- b) The health risks of the use of feeding bottles and the incorrect or unnecessary use of complementary foods and other breastmilk substitutes;
- c) Instructions for feeding with cup and spoon products under the scope of this Law;
- d) Information on the use of home-made complementary foods;
- e) The importance of hygienic practices in general and during the preparation of foods, as well as the importance of cleanliness of the person preparing the foods;
- f) Such materials shall not contain images or drawings of infants being bottle-fed;
- g) The messages shall be written in the national language and other dialects and languages.

**Art. 13** – Health professionals and health workers shall not give demonstrations, talks nor advice on infant feeding, **in the health care services**, that are detrimental to breastfeeding.

**Art. 14** – Manufacturers, distributors and retailers shall be able to donate equipment or information and education materials referring to products under the scope of this Law, only at the request and with the written authorization of the competent authority.

**Art. 15** – It shall be the duty of the Government of the Republic of Nicaragua, through the Ministries of Education and of Health and Family to promote, protect and maintain breastfeeding.

## **CHAPTER VI The General Public and Mothers**

**Art. 16** – Advertising of breastmilk substitutes and the use of bottle-feeding shall not lead to the replacement of breastfeeding.

**Art. 17** – Promoters of breastmilk substitutes and feeding bottles shall not use misleading advertising. For the purposes of this Law, misleading advertising shall mean when mothers and consumers in general are not informed about the drawbacks for the health of infants that the consumption of those products can entail.

**Art. 18** - Breastmilk substitutes may be donated only to mothers of children two years old.

## **CHAPTER VII Health Care System**

**Art. 19** – The Ministry of Health, via the Commission, shall promote, protect and maintain breastfeeding and shall ensure the implementation of this Law, facilitating information and training of health professionals and workers about their obligations.

**Art. 20** – No health care service that has programmes for children and mothers shall be used for the promotion of breastmilk substitutes or other products within the scope of this law.

**Art. 21** – The employment of personnel provided by or paid by manufacturers or distributors of breastmilk substitutes shall not be allowed in the health care service for the marketing of these products [sic].

**Art. 22** – Donations of or low-price sales of products within the scope of this law can be made to health care services only if authorized by the competent authority.

**Art. 23** – Equipment or materials donated to a health care service, after having been authorized by the competent authority, may bear the name or logo of the donating company, but shall not refer for purpose of advertising to any commercial product within the scope of this law.

## **CHAPTER VIII Health Professionals and Health Workers**

**Art. 24** - Information provided by manufacturers, retailers and distributors and by marketing staff to health professionals regarding products within the scope of this Law shall be

restricted to scientific and factual matters, and such information shall not imply or create a belief that feeding with breastmilk substitutes is equivalent or superior to breastfeeding. It shall also include the information specified in Article 12 of this Law.

**Art. 25** – Health workers and professionals shall not accept nor receive financial or material inducements offered by manufacturers, retailers or distributors with the aim of promoting products within the scope of this Law.

**Art. 26** – Health professionals and workers shall not give samples and/or originals [sic] of products within the scope of this Law to pregnant women, mothers of infants or members of their families.

**Art. 27** - Manufacturers, retailers or distributors of products within the scope of this Law may make financial contributions for scholarships, study tours, research, costs of attendance at professional conferences and similar activities, as long as these are not conditional on carrying out marketing activities for breastmilk substitutes and other products within the scope of this Law.

## **CHAPTER IX**

### **Employees of Manufacturers, Retailers and Distributors**

**Art. 28** – Staff who market products within the scope of this Law shall not, in the exercise of their profession, perform educational functions in relations with pregnant women or mothers of infants. **This shall not be interpreted as preventing such staff from being used for other functions in the health care system,** at the request and with written authorization of the competent authority.

**Art. 29** - Manufacturers, retailers or distributors shall keep a record of all products within the scope of this Law that they have distributed, for a minimum of up to six months after the date of expiry of said products. Such records shall be made available to the Ministry of Health or any other competent institution or organization, when necessary.

## **CHAPTER X**

### **Labeling**

**Art. 30** – Labels shall be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breastfeeding.

**Art. 31** – Labels of breastmilk substitutes and products within the scope of this Law shall contain the following information:

- a) The ingredients used;
- b) The composition/analysis of the product;
- c) The storage conditions required and correct use;
- d) The batch number and the date before which the product is to be consumed;
- e) Instructions for preparation and hygienic measures;
- f) The age for which the product is recommended;
- g) A statement on the superiority of breastfeeding with the following words: “BREAST MILK IS THE BEST FOOD FOR YOUR INFANT” printed in visible colors and letters of no less than 3 mm height.

- h) Products within the scope of this Law that do not satisfy all the established standards to meet the requirements and needs of an infant, but which can be modified to do so, shall carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant.

**Art. 32** – The labels of products within the scope of this Law shall not contain information that could encourage the use of a feeding bottle, such as:

- a) Pictures of infants or others that could idealize the use of a feeding bottle.
- b) Text, drawings or allusions that, directly or indirectly, tend to create the conviction that the use of a substitute is equivalent or superior to breastfeeding.
- c) Words such as “Maternalized milk, humanized milk, similar to breastmilk”, or any others of a similar nature, shall not appear on the container or label of products within the scope of this Law.

**Art. 33** – Labels of feeding bottles, teats or dummies shall include:

- a) A statement on the superiority of breastmilk to feed infants.
- b) A statement to explain that feeding with a cup and spoon is safer than using a feeding bottle.
- c) A warning of the possible health risks and harm to the practice of breastfeeding when using a feeding bottle.

**Art. 34** - Manufacturers, retailers and distributors of products within the scope of this Law shall make sure that the label affixed to each container, in a manner that it cannot be easily removed, contains a clear statement, written in visible and easily readable language, in Spanish, with the following points:

- a) The words “important warning” or their equivalent.
- b) A statement of the superiority of breastmilk.
- c) Instructions for the correct preparation, with an explanation of the health risks of inappropriate preparation [of the product].
- d) It shall not contain any photographs, drawings or other kind of presentation, apart from the basic graphic designs to illustrate the method of preparation of the product.
- e) Labels of whole milk, condensed milk, sweetened, skimmed or semi-skimmed milks and so-called follow shall contain a clear visible warning that they should not be used to feed infants.
- f) It shall not contain pictures of health professionals or workers, or any other conventional sign that may suggest that these products are recommended by health authorities.
- g) It shall not contain pictures or text that may idealize the use of commercial products within the scope of this Law, nor pictures that may create anxiety or doubt about breastfeeding or the use of homemade complementary foods.

## **CHAPTER XI Quality**

**Art. 35** – Food products within the scope of this Law intended for sale or for any other form of distribution shall comply with the Codex Alimentarius standards.

**Art. 36** – No food or product within the scope of this Law that does not comply with the food quality and safety standards of its country of origin shall be imported into this country.

**Art. 37** – Any food product within the scope of this Law shall be sold in its original container and shall not be re-packaged for retail sale.

## **CHAPTER XII Implementation and Control**

**Art. 38** – The Ministry of Health shall be responsible for the implementation of this Law. Manufacturers, retailers and distributors, as well as any other governmental or non-governmental body, shall comply with this Law.

**Art. 39** – The Ministry of Health, through the Commission, shall:

- a) Check written or audiovisual education and information materials about infant feeding intended for the general public, parents, educational institutions and health professionals and workers.
- b) Demand the correction or withdrawal of any materials that contravene the aims of this Law.
- c) Withdraw from circulation any commercial product that violates the provisions of this Law.

**Art. 40** - Independently of any other measures taken for implementation of this Law, manufacturers and distributors of products within the scope of this Law shall regard themselves as responsible for monitoring their marketing practices and for taking steps to ensure that their conduct at every level conforms to the principles and aims of this Law.

## **CHAPTER XIII Sanctions**

**Art. 41** – Violations of the provisions of the Law by a physical or legal person shall be sanctioned by the institutions responsible for the monitoring of this Law.

Sanctions shall be applied progressively, according to the seriousness and frequency of violations, as follows:

- a) Written warning.
- b) Fine of one thousand up to twenty thousand Córdoba.
- c) Temporary suspension of marketing of the product or products object of the violation.
- d) Definitive suspension of the marketing of the product or products object of the violation.
- e) Cancellation of sanitary registration [of the product or products].

**Art. 42** – Notwithstanding the sanction that may be imposed in each case, the competent health authority may seize the breastmilk substitutes and products within the scope of this Law that it considers unsuitable for consumption, for destruction or incineration, with the assistance of the police if necessary.

**Art. 43** - When it is proven that a health professional or health worker has violated a provision of this Law, the Ministry of Health shall apply progressive sanctions, as follows:

- a) Verbal admonishment.
- b) Written warning.
- c) Fine of fifty thousand Córdoba.



**Art. 44** – The Commission shall, by means of a resolution, impose the sanctions provided for in this Law, on physical or legal persons that have infringed it, after giving an audience to the violator, who shall have six days to contest the allegation(s) and present evidence.

**Art. 45** – An administrative appeal to the Commission may be submitted against a resolution imposing a sanction, within forty-eight hours of notification. The Commission shall decide [on such appeals] within five days.

**Art. 46** – If the decision is not favorable, the person sanctioned may appeal to the Ministry of Health within a period of seventy-two hours after notification. The Ministry of Health shall have ten days to decide on the matter.

**Art. 47** – The written appeals must explain the grievances of the case. If the sanctioned person does not use any of the appeals provided in law, the resolution stands, meaning the end of the administrative procedure and the sanction shall be executed.

#### **CHAPTER XIV Derogations and Final Provisions**

**Art. 48** - The Law on Promotion of breastfeeding, Decree No. 912, of 15 December 1981, published in the Official Gazette No. 292 of 23 December 1981 is hereby revoked, as is any other contrary provision.

**Art. 49** – This Law shall come into effect on the date of its publication in any social written media, without prejudice to its later publication in the Official Gazette.

This present Law on Promotion, Protection and Maintenance of breastfeeding and Regulation of the Marketing of breastmilk substitutes, approved by the National Assembly on eighteen June nineteen ninety-eight, contains the partial veto of the President of the Republic, accepted at the Third Ordinary Session of the Fifteenth Legislature.

Issued in the City of Managua, National Assembly Hall, on the tenth day of the month of June of nineteen ninety-nine.

**IVAN ESCOBAR FORNOS**, President of the National Assembly  
**VICTOR MANUEL TALAVERA HUETE**, Secretary of the National Assembly

It shall therefore be considered law of the Republic. To be published and executed. Managua, sixteenth day of June of nineteen ninety-nine.

**ARNOLDO ALEMAN LACAYO**, President of the Republic of Nicaragua.

(T. N. One USD equals 28 Córdoba. I have highlighted in yellow some incongruous departures from the text of the International Code. I think these are merely inadvertent errors from drafters who want to be sure they have covered every conceivable angle.

The original text is exceedingly long and repetitious. I have kept many of the repetitions, which are not necessary in English, to preserve the flavor of the original law.)