

COSTA RICA - REGULATIONS 1995

REGULATION OF LAW N°7430
“Law on the Promotion of Breastfeeding”
THE OFFICIAL GAZETTE
Wednesday 13 September 1995

DECREE No. 24576-S

THE PRESIDENT OF THE REPUBLIC and
THE MINISTER OF HEALTH

In compliance with the faculties bestowed on them by articles 140 paragraphs 3) and 18) of the Constitution, Paragraph two of Law No 6227 of 2 May 1978 called “General Law on Public Administration”: 1, 2, 4 and 113 of Law No 5395 of 30 October 1973 called “General Law on Health” and article 32 of Law No 7430 of 21 October 1994 called “Law on the Promotion of Breastfeeding”;

WHEREAS

1. It is an essential function of the State to ensure the health of the people, and it is therefore incumbent on the Ministry of Health to set the national health policy and to plan, regulate and coordinate all public and private health activities;
2. The purpose of the "Law on the Promotion of Breastfeeding" No. 7430 is to promote safe and adequate nutrition for infants through family education and protection of breastfeeding; and to achieve the objectives of said Law it needs to be regulated:

Hereby **DECREE** this
Regulation of the Law on the Promotion of Breastfeeding

CHAPTER I – General provisions

Article 1 – For purposes of this Regulation, the following definitions shall apply:

Infant: A child up to the age of twelve months completed.

Breastmilk substitute: Any food marketed or presented as a partial or total replacement of breastmilk, whether suitable for the purpose or not.

Marketing as a breastmilk substitute: A product shall be deemed to be marketed as a breastmilk substitute when:

- a. The advertising, promotion or label indicates that it replaces or can replace breastmilk.
- b. The advertising, promotion or label includes images, pictures or drawings of infants being fed with a bottle.
- c. The promotion, advertising or information services indicate or lead to believe that the product is intended for babies under six months.
- d. The advertising, promotion or label contains written or graphic instructions to feed the product by bottle.

Infant formula: Any breastmilk substitute industrially formulated in accordance with the applicable Codex Alimentarius standards and adapted to the physiological characteristics of infants up to six months old, to satisfy their nutritional needs. It includes foods prepared at home.

Modified milk: Any product industrially formulated in accordance with the Codex Alimentarius standards, adapted to the physiological characteristics of infants, to satisfy their special nutritional needs.

Follow-up formula: Any milk or similar food with high protein content, of animal or plant origin, industrially formulated in accordance with the applicable standards and intended for children older than six months.

Complementary food: Any manufactured or formulated product that complements breastmilk or infant formula when either is no longer sufficient to satisfy the nutritional needs of an infant. Such a food may also be called “weaning food” or “breastmilk supplement”.

Health worker: Any person, professional or not, working as paid staff or as volunteer in a unit of the health care system.

Health care unit: Any governmental, semi-governmental or private institution or organization that directly or indirectly provides health care services, including childcare centres, crèches and similar services.

(T.N. Up to here the definitions are the same as in the Law.)

[From here on other definitions that are not in the Law appear. The expression “designated products” – taken from the Model Law – is used from here onwards several times, but is not defined. Towards the end of the Regulation other words are used to refer to products covered by the Law and Regulation that are not among the defined terms either.]

Advertising: Any kind of presentation, by whatever means, intended to directly or indirectly promote the sale or use of a **designated product**, including any type of advertising, such as in a publication, by television, radio, film, video, telephone or other means of communication, by exhibition of signs, posters or goods, by exhibition of images or models, or by any other means.

Distributor: Any person dealing in marketing wholesale or retail a **designated product**, including any person who provides information services or public relations services for any **designated product**.

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 designated product.

Manufacturer: A physical or legal person 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 **designated product**.

Promotion: Any means of presentation or of familiarization of a person with a designated product, or any method to encourage a person to purchase a **designated product**.

Related utensils: Any utensil such as feeding bottle, teat, dummy, nipple shield and similar ones.

Article 2 – Shall be subject to the provisions of this Regulation all physical or legal persons who, directly or indirectly, are related to or participate in family education and protection of breastfeeding or who carry out **activities to promote breastfeeding (sic)**, by means of marketing, advertising, promotion and distribution of breastmilk substitutes and complementary foods, when these are marketed as BREASTMILK SUBSTITUTES, and related utensils.

Article 3 – The Ministry of Health, the Costa Rican Social Security, the Ministry of Economy, Industry and Trade, the Ministry of Public Education and the universities shall be responsible for the control of programs for the education of families and the protection of breastfeeding, by means of which they shall regulate the appropriate use and consumption of BREASTMILK SUBSTITUTES and complementary foods for infants, via the authorization and supervision of information systems, advertising and distribution of BREASTMILK SUBSTITUTES.

(T.N. The authors have mixed up breastfeeding promotion and control of marketing of BREASTMILK SUBSTITUTES in these two articles. A prize to the lawyers and judges who can make out what this means when challenged by manufacturers.)

Article 5 - Any materials containing information on the use of BREASTMILK SUBSTITUTES shall highlight the dangers they represent for the health of children, and of their unnecessary, inappropriate and indiscriminate use.

Article 6 – Companies that market BREASTMILK SUBSTITUTES and industrialized infant foods shall adopt appropriate measures for their suitable linkage to consumers, including the following:

- a. Marketing staff for BREASTMILK SUBSTITUTES and similar products shall not have any direct professional contact with pregnant women or mothers of children less than two years of age.
- b. Manufacturers and distributors shall only donate equipment, information or education materials referring to the products under the scope of this Regulation, when authorized to do so, in writing, by the Ministry of Health, through the National Breastfeeding Committee.

Article 7 – Health care system facilities shall not allow the employment of staff provided or paid by manufacturers or distributors of products under the scope of this Regulation.

Article 8 – Labels of BREASTMILK SUBSTITUTES shall bear the following information:

- a. A statement on the superiority of breastfeeding, with the words “Breastmilk is the best food for infants”, printed in visible colour and letters of not less than 3 mm height.
- b. The ingredients used, in order of quantities.
- c. The composition and analysis of the product.
- d. Conditions needed for consumption of the product.
- e. The serial number and expiry date of the product.
- f. Instructions for preparation of the product, measures of cleanliness required and the age of the infant for whom the product is indicated.

Article 9 – Health care facilities that take care of children, from before their birth, shall emphasize actions to prepare future mothers physically, psychologically and emotionally for a good breastfeeding practice, in conformity with the established standards.

Article 10 – The Ministry of Health, through its administrative, technical and standards-setting departments, shall be responsible for the dissemination of this Regulation and for assistance in its implementation.

Article 11 – The Ministry of Health, with the assistance of the National Breastfeeding Committee, shall establish the provisions and actions to ensure implementation of this Regulation in public and private health care services.

Article 12 – Any act or omission that contravenes the provisions of Law No. 7430 and of this Regulation shall be considered a breach of health and shall be sanctioned according to the provisions of Chapter VII of the Law. Acts or omissions constituting crimes against health shall be treated as exceptions and dealt with by the courts.

Article 13 – Sanctions that may be imposed by the authorities for breaches of Law No. 7430 and of this Regulation, and those that may be decided upon by higher health authorities, are set in the General Health Law.

CHAPTER II

National Breastfeeding Committee

Article 14 – Characteristics. The National Breastfeeding Committee is attached to the Ministry of Health and is responsible for recommending breastfeeding policies and standards. It shall coordinate and promote activities to encourage breastfeeding.

Article 16 – Aims. The aims of the National Breastfeeding Committee shall be:

- a. To ensure that maternities in the country comply fully with the Ten Steps to Successful Breastfeeding, which are part of the Joint WHO/UNICEF Statement.
- b. To promote exclusive breastfeeding with breastmilk up to six months of age.
- c. To promote continued breastfeeding up to beyond two years of age.
- d. To control the marketing of breastmilk substitutes.
- e. To protect pregnant mothers from breastmilk substitutes.
- f. To encourage the creation of mother support groups, so as to support successful breastfeeding.
- g. To improve health and nutrition of women during pregnancy and breastfeeding.
- h. To promote appropriate training of health workers in these subjects.
- i. To carry out research for input into the establishment of breastfeeding promotion strategies and actions.
- j. To support the creation of suitable facilities in work places for mothers to extract breastmilk and conserve it.

Article 17 – Competence. To achieve its objectives the Committee shall have the following competence:

- a. To organize, coordinate and recommend policies and standards on breastfeeding, to be promulgated.
- b. To design and execute training programs for health workers, support groups and families, or to join other public or private bodies in doing so.
- c. To provide technical assistance to public and private institutions for the execution of standards and procedures that lead to successful breastfeeding.
- d. Analyse, study and recommend legislation to protect working mothers.
- e. To carry out or to participate in studies and surveys on issues related to its competence.
- f. To develop programs and activities aimed at regulating the advertising, promotion and distribution of breastmilk substitutes, complementary foods, when marketed as such, and of related utensils.
- g. To establish and maintain relations with other national, foreign or international bodies that have a similar purpose and to have exchange and cooperation agreements with them, when appropriate.
- h. To ensure compliance with the law.
- i. Any other competence that may be required to achieve the objective described in Article 1 of the Law No 7430.

Article 18 – Management. The management of the Committee shall be the responsibility of the Board composed of seven members.

Article 19 – Membership. The Board of the National Breastfeeding Committee shall be composed of:

- a. A Chairperson
- b. A vice-chairperson
- c. A secretary
- d. Three members
- e. A treasurer.

The president shall be a representative of the Ministry of Health and the remaining members shall be appointed by a simple majority of the representatives of each of the ministries and entities that compose the Committee. They shall be of age, of good moral standing, Costa Rican by birth or naturalization, having resided in the country for more than ten years. They must have a professional degree that qualifies them for the position, with recognized field experience.

Once they have assumed their posts, they can only be removed for justifiable reasons, in accordance with the corresponding legal and regulatory provisions. Among these can be cited:

- a. To have committed any of the prohibited acts under Law No 7430 and its Regulation.
- b. Abandonment of duty.
- c. Not to be present at four consecutive or at six alternate meetings over one semester, for what the Board considers to be not justified reasons.

- d. Admitting responsibility for fraudulent or illegal acts or operations.
- e. Physical or mental incapacity to continue fulfilling normal functions, in the opinion of the Board.
- f. Absence from the country for more than one month, without permission from the Board.
- g. Being declared insolvent.

In any of these cases, a substitution [of member] for reasons of renunciation, justified removal, death or any other cause, shall be done within fifteen days for the remainder of the corresponding period.

Article 20 – Attributions of the Board: The Board shall have the following attributions:

- a. To study, analyse and recommend to the Ministry of Health the general policy on breastfeeding, within the framework of the legally defined government policy.
- b. To approve the annual plan of activities of the Committee.
- c. To study, approve and recommend to the Ministry of Health the ordinary and extraordinary budget the Committee needs in order to achieve its objectives.
- d. To establish rules of procedure for the operations of the Committee.
- e. To approve the establishment and membership of advisory subcommittees and to regulate their organisation and functions.
- f. To receive and approve the annual report of the Chairperson of the Committee.
- g. To deal with the other issues prescribed by laws and regulations.

Article 21 – Meetings: The Board shall meet on the second and fourth Thursday of each month and in extraordinary session when needed. Meetings shall be called by the Chairperson, or at the written request of four members, with a minimum of twelve hours notice. In the absence of the Chairperson, the Vice-Chairperson who shall preside shall give notice of meetings. The quorum shall be four members and decisions shall be made by an absolute majority of four members present.

Article 22 – Role of the members of the Board:

- a. The Chairperson of the Board shall:
 - a.1 Chair the Board and ensure the correct implementation of its decisions, as well as coordinate the activities of the Committee with the other public and private institutions. Furthermore, he/she shall have any other functions, which by law are reserved to the Chairperson of the Board and those that the Board may assign.
 - a.2 Prepare ordinary and extraordinary budgets of the Committee and submit them to the Board.
- b. The Vice-Chairperson of the Board shall:
 - b.1 Replace the Chairperson in her/his absence, with the same attributions and obligations.
- c. The Secretary shall:
 - c.1 Draft the record of Board meetings.
 - c.2 Prepare the agenda of Board meetings, in consultation with the Chairperson.
 - c.3 Sign the record of meetings, together with the Chairperson, once they are approved by the Board.
 - c.4 Handle the correspondence.
- d. The Treasurer shall:
 - d.1 Collaborate in the drafting of the ordinary budgets of the Committee.
 - d.2 Control the use of the budget approved by the Ministry of Health.
 - d.3 Submit, with the Chairperson, the annual budgetary report.
 - d.4 Any other functions decided by the Board.
- e. The members shall:
 - e. 1 Collaborate in all areas assigned by the Board and substitute for an absent member, except the Chairperson.
- f. The Controller shall:
 - f.1 Ensure that the Law and its Regulation, as well as the agreements, regulations and instructions issued by the Committee, are complied with.
 - f.2 Listen to complaints that reach the **association** and carry out the appropriate investigations.
 - f.3 Submit an annual report to the Board.
 - f.4 Any other functions, which the Board may assign

Article 23 – Donations. Donations made by public institutions set up as commercial companies, autonomous and semiautonomous institutions, public companies, as well as other institutions or private organisations, shall be channelled through the Pro-Breastfeeding Promotion Association or through the Technical Board of Social Medical Welfare, applying the procedures adopted for the purpose.

CHAPTER III Advertising and Distribution

Article 24 – Advertising: Material for the dissemination or advertising of breastmilk substitutes, other products marketed as such, or related utensils, after authorisation and within the timeframe set by law, the Food Control Department of the Ministry of Health shall consult on the text with the Committee.

(T.N. It is not clear in Spanish either what this is to mean. It would appear that part of the text was lost.)

The study and analysis shall be done on the basis of standards and procedures established for that purpose. On all printed, visual or audio materials the motto “Breastmilk is the best food for infants” shall appear.

Article 25. Misleading advertising: For any type of advertising, whether printed, visual or audio, the use of a feeding bottle shall not be allowed, because of its implicit subliminal message that discourages breastfeeding.

CHAPTER VI Labelling

Article 26. This chapter applies to the labelling of all breastmilk substitutes, complementary foods and other packaged or pre-packaged milks.

Article 27. The label of breastmilk substitutes or industrialised infant foods shall not contain information that may encourage the use of feeding bottles. Neither shall in contain the following:

- a. Images of infants or other images that may idealise the use of the feeding bottle.
- b. Text, drawings or illustrations that, directly or indirectly, tend to create the conviction that the substitute is equivalent to breast milk.

Article 28. The motto “Breastmilk is the best food for infants” shall appear on labels of all breastmilk substitutes, complementary foods and other milks, on the front part of the label, near the name of the product and in letters of no less than 3 mm (three millimetres) height.

Article 29. The label must be adhered to the product in such a manner that it cannot easily be unstuck.

Article 30. Labels of related utensils shall bear the sentence “Feeding by cup and spoon is safer”, printed near the name of the product and in letters of no less than 3 mm (three millimetres) height.

Article 31. To grant authorization for the labels, the National Standards and Units Office of the Ministry of Economy, Industry and Trade shall consider the Code of Hygienic Practice for Foods for Infants and Children, of the Food Code.

CHAPTER V Information and Education

Article 32. All information, educational and promotional materials, whether printed, audio, visual or otherwise, relating to the breastmilk substitutes or other products marketed as such, as well as related utensils, intended for pregnant women, nursing mothers and health professionals, must contain the information set out in Articles 21, 22 and 23 of the Law.

This information material, prior to its distribution, must have the approval of the Ministry of Health, through the National Breastfeeding Committee, which shall ensure that it complies with the applicable rules.

Article 33. Any information, advertising, didactic or other material, dealing with the feeding of infants, children under two years and pregnant women or mothers of children under two years, must comply with the following:

- a. State that breast milk is the best food for children two years of age.
- b. Not contain pictures, drawings, sounds or messages of children under two years of age or other pictures idealizing the product or liable to mislead about the product's properties.
- c. Not contain images of health professionals or any other conventional symbol to suggest that health professionals recommend these products.
- d. Include information on the importance of hygiene practices in the preparation of the product, and the importance of cleanliness of the person responsible for the preparation thereof.

CHAPTER VI Health Workers

Article 34. Concerning the duties of the Ministry of Health and the Costa Rican Department of Social Security, Ministry of Education, universities and health workers, the Commission shall ensure that standards set by the law in Articles 24, 25, 26 and 27 are met.

CHAPTER VII Violations

Article 35. The Ministry of Health, through the National Breastfeeding Committee, shall ensure compliance with the law and coordinate with relevant agencies for the application of sanctions in cases of the infringement of the law, as established by its Articles 28, 29 and 30, subject to competence and obligations the General Health Law establishes for Health Authorities.

Article 37. This Regulation is applicable upon its publication.

Signed at the Presidency of the Republic. -San Jose, on the seventh day of August 1995.

JOSÉ MARÍA FIGUERES OLSEN (President of the Republic)
The Minister of Health, Dr. Herman Weinstok Wolfowicz

T.N. The Regulation is poorly drafted in Spanish, with many grammatical mistakes and inconsistencies. Some parts are probably copy of the Model Law or other legal texts and use expressions that are not among those defined. Some copy and paste work was done sloppily, leaving out part of the text. There is too much detail and repetition about the National Breastfeeding Committee and its role, but little or nothing about other actors, such as food inspectors. No mention of any sanctions. Any astute company lawyer would be able to counter a suit brought against the company on the basis of this Regulation.

6,813 words in Spanish

(3,730 words in English)