

Law No 11265 of 3 January 2006

Regulating the Marketing of Foods for Infants and Young Children as well as Related Products for Child-Rearing

THE PRESIDENT OF THE REPUBLIC

Hereby notifies that the National Congress has decreed, and I have sanctioned, the following Law:

CHAPTER I Preliminary provisions

Art. 1^o The aim of this law is to contribute to the adequate nutrition of infants and young children by the following means:

- a) regulating the commercial promotion and appropriate use of foods for infants and young children and of feeding bottles, teats and dummies;
- b) protecting and promoting exclusive breastfeeding up to 6 (six) months of age; and
- c) protecting and promoting continued breastfeeding up to 2 (two) years of age with introduction of new foods into the diet of infants and young children.

Art. 2^o This law shall apply to marketing and related practices and to quality and information on use of the following products, whether manufactured in this country or imported:

- a) infant formula and follow-up formula for infants;
- b) follow-up formula for young children;
- c) liquid, powdered, modified and similar vegetable-based milks;
- d) transition foods and cereal-based foods for infants and young children, as well as other foods or beverages whether milk-based or not, when marketed or otherwise presented as suitable to feed infants and young children;
- e) nutrient formula presented as suitable for high-risk newborns;
- f) feeding bottles, teats and dummies.

Art. 3^o For purposes of this law, the following definitions shall apply:

1. **Breastmilk or human milk substitute food:** any food that is marketed or otherwise presented as a partial or total replacement for breastmilk or human milk;
2. **Transition food for infants and young children or complementary food:** any food manufactured for direct consumption or used in home-made preparations that is used as a complement to breastmilk or to infant formula, introduced into the diet of an infant or young child for the purpose of promoting a gradual adaptation to common foods and to favour a balanced diet adapted to its needs, taking into account its physiological maturity and neuropsychomotor development;

3. **Cereal-based food for infants and young children:** any cereal-based food suitable to feed infants after the 6th (sixth) month and young children, taking into account their physiological maturity and neuropsychomotor development;
4. **Sample:** 1 (one) unit of a product provided free of charge once only;
5. **Special presentation:** any way of presenting a product (for the purpose of its commercial promotion) with the intent of inducing purchase or sales, such as promotional packaging, fancy wrapping or packaging together with other products not under the scope of this law;
6. **Teat:** an object presented or suited to the process of nutrition suction with the aim of administering or providing food or liquids to a child;
7. **Child:** a person up to the age of 12 (twelve) years not completed;
8. **Young child or small child:** a child between 12 (twelve) months and 3 (three) years of age;
9. **Dummy:** an artificial teat to be sucked without the aim of administering food, medicine or liquids bico;
10. **Highlight:** a graphic or sound message intended to stress a certain warning, phrase or text;
11. **Donation:** a free supply of a product in a quantity greater than a sample;
12. **Distributor:** an individual or a legal entity, in the private or public sector, directly or indirectly involved in the wholesale or retail marketing or importing of any product under the scope of this law;
13. **Kit:** a set of products of different brands, shapes or sizes contained in a single package;
14. **Special exhibit:** any way of exposing a product in a manner that sets it apart from others within a commercial establishment, such as a special display window or case, at the front of a shelf, a pyramid or isle of products, on steps, or decoration of a shelf or any other form as defined in the regulations;
15. **Container:** any packaging or wrapping (of a product) intended to preserve, transport or handle a product;
16. **Importer:** any establishment or private company that imports any of the products under the scope of this law;
17. **Manufacturer:** any establishment or any private or state company involved in the manufacture of any of the products under the scope of this law;
18. **Infant formula for infants:** any product in liquid or powder form intended, when prescribed, for the feeding of infants up to the age of 6 (six) months, as a total or partial replacement of breastmilk or human milk, to satisfy the nutritional needs of this age group;
19. **Infant formula for specific dietary or therapeutic needs:** (an infant formula) whose composition has been modified to meet the specific needs (of children with) physiological or pathological temporary or permanent alterations and that is not covered under the specific technical regulations for infant formula;
20. **Follow-up formula for infants:** any product in liquid or powder form that is used upon prescription by a qualified professional, as a substitute to breastmilk or human milk, (for children) from the age of 6 (six) months onward;
21. **Follow-up formula for young children:** any product in liquid or powder form that is used as a substitute to breastmilk or human milk for young children;
22. **Infant:** a child up to the age of 11 (eleven) months and 29 (twenty nine) days;

23. **Modified milk:** any milk that is classified as modified by the competent government agency;
24. **Educational material:** any written or audiovisual material intended for the general public that aims to instruct about the appropriate use of products for infants and young children, such as leaflets, books, articles in the general press, cassette tapes, video tapes, electronic format information and others;
25. **Technical-scientific material:** any material containing substantiated information about products or related to the field of nutrition and pediatrics, intended for professionals and health workers;
26. **Marketing representative:** any professional (sales person, promoter, demonstrator, company representative or sales representative) directly or indirectly remunerated by a manufacturer, provider or importer of any of the products under the scope of this law;
27. **Commercial promotion:** all activities related to information provision and persuasion by companies involved in the production, handling, distribution or marketing (of products) with the aim of inducing the purchase or sale of a product;
28. (REFUSED)
29. **Label:** any description on the surface of a container or package of a product, as defined in the regulations;
30. **Nutrient formula for high-risk newborns:** any compound of nutrients presented or intended to supplement the feeding of premature or high-risk newborns.

CHAPTER II MARKETING AND ADVERTISING

Art. 4^o Commercial promotion of products under article 2 a), 2 e) and 2 f) above shall be banned by any means of communication, as provided for in the regulations.
Single paragraph. (REFUSED)

Art. 5^o Commercial promotion of infant foods under article 2 b), c) and d) shall include the following visual or audio highlight, according to the media used:

1. for products under sub-paragraphs b) and c) of article 2 the words *“Ministry of Health warning: Breastfeeding avoids infections and allergies and is recommended up to the age of 2 (two) years or more.”*;

2. for products under sub-paragraph d) of article 2 the words *“Ministry of Health warning: After 6 (six) months continue breastfeeding your child and add new foods.”*

Art. 6^o Marketing representatives shall not undertake activities in health units, except for communicating technical-scientific aspects of products to pediatricians and nutritionists.

Single paragraph: It shall be a duty of manufacturers, distributors and importers to inform their marketing representatives and advertising agencies they hire of the contents of this law.

Art. 7^o Manufacturers, distributors and importers shall be entitled to provide samples of products under article 2 a) and e) above to pediatricians and nutritionists when a new product is launched, in accordance with article 15 of this law.

§ 1^o For purposes of this law, a national launch shall be carried out within a maximum period of 18 (eighteen) months throughout the whole national territory.

§ 2^o The distribution of samples when a product is relaunched or its brand is changed without any significant modification in its nutritional composition shall be banned.

§ 3º The distribution of samples of feeding bottles, teats, dummies and nutritional supplements for high-risk newborns shall be banned.

§ 4º Any delivery of a sample or samples of infant formula shall be accompanied by a delivery protocol of the company, with copy for the pediatrician or nutritionist.

Art. 8º Manufacturers, distributors and importers of products under the scope of this law may provide financial or material sponsorship to scientific teaching or research institutions or associations of pediatricians and nutritionists. Any sponsorship of individuals shall be banned.

§ 1º Beneficiary institutions shall ensure that companies do not carry out any commercial promotion at events that they sponsor, restricting (their participation) to the distribution of technical-scientific material.

§ 2º Any sponsored events shall include in their information materials the following highlighted statement *“This event is sponsored by private companies, in accordance with the provisions of Law 11265 of 3 January 2006”*.

Art. 9º Donations or low-priced sales of products under the scope of this law to maternity clinics and (other) institutions that provide child care shall be banned.

§ 1º This ban shall not apply to donations or low-priced sales in situations of exceptional individual or collective need, as determined by the competent monitoring authority.

§ 2º In cases provided for under § 1º of this article, the supplies must be guaranteed for as long as the infant(s) need them.

§ 3º The name and logo of the donator shall be permitted (on such supplies), but no advertising of products shall be allowed.

§ 4º Donations for purposes of research shall be allowed only upon presentation of a research protocol approved by the Ethics Committee of the institution in which the professional works, and in compliance with the regulations published by the competent authorities.

§ 5º Products donated for research purposes shall contain on the front part of the label the following highlighted statement: *“Donation for research, in accordance with the law”*.

CHAPTER III LABELING

Art. 10. On containers or labels of infant formula and follow-up formula for infants the following shall be banned:

I – The use of photos, drawings or other graphic representations, apart from those necessary to illustrate the method of preparation or use of the product, except the use of a brand or logo as long as it does not contain an image of an infant, young child or any other humanized image;

II – The use of names or expressions that may suggest a strong resemblance of the product with breastmilk, as provided for in the regulations;

III – The use of words or expressions that can cause mothers to doubt their ability to breastfeed their child;

IV – The use of expressions or names that may identify the product as the most appropriate to feed infants, as provided for in the regulations;

V – The use of information that may induce (consumers) to use the product based on a wrong concept of advantage or safety;

VI – The use of words or expressions that indicate health conditions for which the product may be appropriate (T.N. health claims);

VII – To promote the products of the manufacturer or those of other companies.

§ 1º The labels of such products shall have in their main part, in a clearly visible and readable form, as provided for in the regulations, the following highlighted text: *“Ministry of Health warning: This product should be used only to feed children under one year of age on the express indication of a doctor or nutritionist. Breastfeeding prevents infections and allergies and strengthens the bond between mother and child.”*

§ 2º The labels of such products shall have a highlighted text warning of the risks of inappropriate preparation and instructions for the correct preparation of the product, including measures of hygiene (cleanliness) that need to be observed and the correct dilution, if appropriate.

Art. 11. On containers or labels of infant formula and follow-up formula for young children the following shall be banned:

I - The use of photos, drawings or other graphic representations, apart from those necessary to illustrate the method of preparation or use of the product, except the use of a brand or logo as long as it does not contain an image of an infant, young child or any other humanized image, as provided for in the regulations;

II – The use of names or expressions that may suggest a strong resemblance of the product with breastmilk, as provided for in the regulations;

III – The use of words or expressions that can cause mothers to doubt their ability to breastfeed their child;

IV – The use of expressions or names that may identify the product as the most appropriate to feed infants, as provided for in the regulations;

V – The use of information that may induce (consumers) to use the product based on a wrong concept of advantage or safety;

VI – The use of sequential brand names found on follow-up formulas for infants;

VII – To promote the products of the manufacturer or those of other companies.

§ 1º The labels of such products shall have in their main part, in a clearly visible and readable form, the following highlighted text: *“Ministry of Health warning: This product should not be used to feed children under one year of age. Breastfeeding prevents infections and allergies and is recommended up to two years of age or beyond.”*

§ 2º The labels of such products shall have a highlighted text warning of the risks of inappropriate preparation and instructions for the correct preparation of the product, including measures of hygiene (cleanliness) that need to be observed and the correct dilution; the use of pictures of feeding bottles shall be banned.

Art. 12. The containers or labels of infant formula for specific dietary or therapeutic needs shall contain information on the characteristics of the food, but shall not indicate health conditions for which the product may be used.

Single paragraph: The provisions of article 8 of this law shall apply to these products.

Art. 13. On containers or labels of liquid milks, powdered milks, modified milks and similar vegetable-based milks the following shall be banned:

I - The use of photos, drawings or other graphic representations, apart from those necessary to illustrate the method of preparation or use of the product, except the use of a brand or logo as long as it does not contain an image of an infant, young child or any

other humanized images or those that may induce (consumers) to use the product for those age groups;

II – The use of names or expressions that may suggest a strong resemblance of the product with breastmilk, as provided for in the regulations;

III – The use of words or expressions that can cause mothers to doubt their ability to breastfeed their child;

IV – The use of expressions or names that may identify the product as the most appropriate to feed infants, as provided for in the regulations;

V – The use of information that may induce (consumers) to use the product based on a wrong concept of advantage or safety;

VI – To promote the products of the manufacturer or those of other companies intended for infants.

§ 1º The labels of such products shall have in their main part, in a clearly visible and readable form, as provided for in the regulations the following highlighted text:

I – For skimmed or partially skimmed milk, with or without the addition of essential nutrients: *“Ministry of Health warning: This product should not be used to feed children except on the express indication of a doctor or nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years of age or beyond.”*

II – For full milks or similar milks, vegetable-based or mixed, whether enriched or not: *“Ministry of Health warning: This product should not be used to feed children under one year of age except on the express indication of a doctor or nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years of age or beyond.”*

III – For modified milk, vegetable- or animal-based: *“Ministry of Health warning: This product should not be used to feed children under one year of age. Breastfeeding prevents infections and allergies and is recommended up to two years of age or beyond.”*

§ 2º Condensed and sweetened milks shall not be indicated in any way as suitable to feed infants and young children.

Art. 14. The container or label of any transition food or cereal-based food for infants and young children and those of food or beverage, whether milk-based or not, when market or presented at suitable to feed infants and young children, shall not:

I - Contain photos, drawings or images of young children;

II - Contain words or expressions that can cause mothers to doubt their ability to breastfeed their child;

III – Contain expressions or names that may identify the product as appropriate or the preferred product to feed infants under six months of age;

IV – Contain information that may induce (consumers) to use the product based on a wrong concept of advantage or safety;

V – Promote infant formula, milks, milk-based products or cereals that can be administered with a feeding bottle.

§ 1º The age as of which such a product can be used shall appear on the front part of the label.

§ 2º The labels of such products shall have in their main part, in a clearly visible and readable form, the following highlighted text: *“Ministry of Health warning: This product should not be used to feed children under six months of age except on the express indication of a doctor or nutritionist. Breastfeeding prevents infections and allergies and is recommended up to two years of age or beyond.”*

Art. 15. The container or label of any nutrient formula for high-risk newborns shall not:

I - Contain photos, drawings or other graphic representations, apart from those necessary to illustrate the method of preparation or use of the product, except the use of a brand or logo as long as it does not contain an image of an infant, young child or any other humanized images;

II – Contain names or expressions that may suggest that breastfeeding needs to be complemented, supplemented or enriched;

III – Contain words or expressions that can cause mothers to doubt their ability to breastfeed their child;

IV – Contain expressions or names that may identify the product as the most appropriate to feed infants, as provided for in the regulations;

V – Contain information that may induce (consumers) to use the product based on a wrong concept of advantage or safety;

VI – Promote the products of the manufacturer or those of other companies.

§ 1º The labels of such products shall have in their front part the following highlighted text: *“This product should be used only as supplementary feeding for high-risk newborns, on doctor’s prescription. For use exclusively in hospital units.”*

§ 2º The labels of such products shall have in their main part, in a clearly visible and readable form, as provided for in the regulations, the following highlighted text: *“Ministry of Health warning: Breastmilk contains the essential nutrients needed for the child’s growth and development during the first years of life.”*

§ 3º The labels of such products shall have a highlighted text warning of the risks of inappropriate preparation and instructions for the correct preparation of the product, including measures of hygiene (cleanliness) that need to be observed and the correct dilution, if appropriate.

§ 4º The products referred to in this article shall be used exclusively by hospitals and shall not be marketed outside the healthcare services.

Art. 16. Packaging or labels of feeding bottles, teats and dummies shall not:

I - Contain photos or images of children, nor humanized drawings;

II - Contain words or expressions that can cause mothers to doubt their ability to breastfeed their child;

III – Contain words, expressions or illustrations that may suggest similarity between the product and the breast or nipple;

IV – Contain expressions or names that may identify the product as suitable for infants, as provided for in the regulations;

V – Contain information that may induce (consumers) to use the product based on a wrong concept of advantage or safety;

VI – Promote the products of the manufacturer or those of other companies.

§ 1º The labels of such products shall have in their main part the following highlighted text: *“Ministry of Health warning: A breastfed child does not need feeding bottles, teats or dummies. The use of a feeding bottle, teats and dummies hampers breastfeeding.”*

§ 2º Feeding bottles, teats and dummies shall only be marketed when wrapped or packaged.

Art. 17. Labels of samples of products under the scope of this law shall have on their front part the following text: *“Free sample for professional assessment. Not for distribution to mothers, pregnant women and family members.”*

CHAPTER IV EDUCATION AND PUBLIC INFORMATION

Art. 18. The public authorities in the areas of health, education and research and associations of pediatricians and nutritionists shall participate in the dissemination of information on infant and young child feeding as well as in the training of human resources.

Art. 19. Any educational or technical-scientific material, in whatever form, that deals with infant and young child feeding shall abide by the provisions of this law and shall include explicit information on the following points:

I – The benefits and superiority of breastfeeding;

II – Guidance on appropriate nutrition for pregnant and lactating women, emphasizing how to prepare and maintain breastfeeding up to the age of two years or more;

III – The negative impact on breastfeeding of using a feeding bottle, teat or dummy, in particular the difficulty of reversing a decision not to breastfeed and the inconvenience of ensuring proper preparation and cleanliness of breastmilk substitutes;

IV – The financial implications of choosing to use breastmilk substitutes instead of breastfeeding, in addition to the harmful effects on the health of infants from the unnecessary or incorrect use of artificial foods;

V – The importance of developing educational and cultural habits that strengthen the use of foods of the daily family diet.

§ 1º Educational or technical-scientific materials shall not contain images or text, including pictures or statements from health professionals and health authorities, that recommend or could lead to the use of dummies, teats and feeding bottles or the use of other foods to replace breastmilk.

§ 2º Educational materials that deal with infant feeding shall not be produced nor sponsored by distributors, providers, importers or manufacturers of products under the scope of this law.

Art. 20. Institutions responsible for education and training of health professionals shall include knowledge of this law and strategies for its implementation in curricula dealing with infant feeding.

Art. 21. To encourage and spread the practice of exclusive breastfeeding up to six months and continued breastfeeding up to two years and more shall be one of the priority competences of health professionals.

Art. 22. Primary and secondary schools shall promote knowledge about this law.

CHAPTER V GENERAL PROVISIONS

Art. 23. Public authorities, under the guidance of the Ministry responsible for health, shall have the duty to ensure knowledge, implementation, monitoring and control of this law and compliance therewith.

Single paragraph: The appropriate public bodies, at all levels, shall work together with civil society entities to ensure knowledge and compliance with the provisions of this law.

Art. 24. Infant foods shall comply with the quality standards provided for in the regulations.

Art. 25. Feeding bottles, teats and dummies shall not contain more than 10 (ten) parts per billion of any N-nitrosamines and, of all such substances together, no more than 20 (twenty) parts per billion.

§ 1º The appropriate public authority shall establish, when necessary, a ban or restriction on any other substances deemed harmful to public health which is the aim of this law.

§ 2º The provisions of this article shall come into force as soon as the appropriate laboratories have been certified by the competent authority.

Art. 26. Manufacturers, importers and distributors of food shall have a period of 12 (twelve) months from the date of publication of this law to make the necessary changes and adaptations in order to comply with it.

Single paragraph: For manufacturers, importers and distributors of teats, dummies and feeding bottles the period referred to in this article shall be 18 (eighteen) months.

Art. 27. The competent national public authority shall establish, when necessary and appropriate, new categories of products and shall regulate their production, marketing and advertising, so as to fulfill the aim of this law as provided in article 1.

Art. 28. Violations of the provisions of this law shall be subject to the penalties provided in Law No 6437 of 20 August 1977.

Single paragraph: For the fulfillment of the aims of this law, the provisions of Law No 8078 of 11 September 1990 and its modifications, of Decree-Law No 986 of 21 October 1969, of Law No 8069 of 13 July 1990 and of other regulations published by the competent public authorities, shall also apply, where appropriate.

Art. 29. The Executive Power shall establish regulations for (the implementation of) this law.

Art. 30. This law shall come into force on the date of its publication.

Brasília, 3 January 2006; 185th year of Independence and 118th year of the Republic.

LUIZ INÁCIO LULA DA SILVA

Luiz Paulo Teles Ferreira Barreto

Luis Carlos Guedes Pinto

Saraiva Felipe

Ivan João Guimarães Ramalho

Definitions used in this law, in English alphabetical order:

Breastmilk or human milk substitute food: any food that is marketed or otherwise presented as a partial or total replacement for breastmilk or human milk;

Cereal-based food for infants and young children: any cereal-based food suitable to feed infants after the 6th (sixth) month and young children, taking into account their physiological maturity and neuropsychomotor development;

Child: a person up to the age of 12 (twelve) years not completed;

Commercial promotion: all activities related to information provision and persuasion by companies involved in the production, handling, distribution or marketing (of products) with the aim of inducing the purchase or sale of a product;

Container: any packaging or wrapping (of a product) intended to preserve, transport or handle a product;

Distributor: an individual or a legal entity, in the private or public sector, directly or indirectly involved in the wholesale or retail marketing or importing of any product under the scope of this law;

Donation: a free supply of a product in a quantity greater than a sample;

Dummy: an artificial teat to be sucked without the aim of administering food, medicine or liquids bico;

Educational material: any written or audiovisual material intended for the general public that aims to instruct about the appropriate use of products for infants and young children, such as leaflets, books, articles in the general press, cassette tapes, video tapes, electronic format information and others;

Follow-up formula for infants: any product in liquid or powder form that is used upon prescription by a qualified professional, as a substitute to breastmilk or human milk, (for children) from the age of 6 (six) months onward;

Follow-up formula for young children: any product in liquid or powder form that is used as a substitute to breastmilk or human milk for young children;

Hihglight: a graphic or sound message intended to stress a certain warning, phrase or text;

Importer: any establishment or private company that imports any of the products under the scope of this law;

Infant formula for infants: any product in liquid or powder form intended, when prescribed, for the feeding of infants up to the age of 6 (six) months, as a total or partial replacement of breastmilk or human milk, to satisfy the nutritional needs of this age group;

Infant formula for specific dietary or therapeutic needs: (an infant formula) whose composition has been modified to meet the specific needs (of children with) physiological or pathological temporary or permanent alterations and that is not covered under the specific technical regulations for infant formula;

Infant: a child up to the age of 11 (eleven) months and 29 (twenty nine) days;

Kit: a set of products of different brands, shapes or sizes contained in a single package; (this definition is not used in the text)

Label: any description on the surface of a container or package of a product, as defined in the regulations;

Manufacturer: any establishment or any private or state company involved in the manufacture of any of the products under the scope of this law;

Marketing representative: any professional (sales person, promoter, demonstrator, company representative or sales representative) directly or indirectly remunerated by a manufacturer, provider or importer of any of the products under the scope of this law;

Modified milk: any milk that is classified as modified by the competent government agency;

Nutrient formula for high-risk newborns: any compound of nutrients presented or intended to supplement the feeding of premature or high-risk newborns.

Sample: 1 (one) unit of a product provided free of charge once only;

Special exhibit: any way of exposing a product in a manner that sets it appart from others within a commercial establishment, such as a special display window or case, at the front of a shelf, a pyramid or isle of products, on steps, or decoration of a shelf or any other form as defined in the regulations; (this definition is not used in the text)

Special presentation: any way of presenting a product (for the purpose of its commercial promotion) with the intent of inducing purchase or sales, such as promotional packaging, fancy wrapping or packaging together with other products not under the scope of this law; (this definition is not used in the text)

Teat: an object presented or suited to the process of nutrition suction with the aim of administering or providing food or liquids to a child;

Technical-scientific material: any material containing substantiated information about products or related to the field of nutrition and pediatrics, intended for professionals and health workers;

Transition food for infants and young children or complementary food: any food manufactured for direct consumption or used in home-made preparations that is used as a complement to breastmilk or to infant formula, introduced into the diet of an infant or young child for the purpose of promoting a gradual adaptation to common foods and to favour a balanced diet adapted to its needs, taking into account its physiological maturity and neuropsychomotor development; **(this definition is not used in the text)**

Young child or small child: a child between 12 (twelve) months and 3 (three) years of age;

jpa, 4Apr07