

BOLIVIA

Law 3460 of August 15, 2006

Law on Promotion of Breastfeeding and Marketing of Breastmilk Substitutes

Chapter I: General Provisions

Art. 1: The provisions of this Law are mandatory and are of social and economic interest. These activities can be performed by any duly registered individual or legal or collective entity, whether national or foreign. Its provisions are consistent with the legislation in force.

Art. 2: This Law applies to the marketing and related practices related of the following products: breastmilk substitutes, including infant formula; other milk-based products; food and beverages, including complementary foods bottle-fed or not, when they are sold or when otherwise indicated that they can be used, with or without modification, to partially or totally replace breast milk; bottles, nipples and pacifiers. It also applies to the quality and availability of the above products and information related to their use. The rules provided in this Law shall apply to both domestic products and imported products.

Art. 3: In the context of national health policies, breastfeeding is established as a priority within the comprehensive care of women and children.

Chapter II: Aims and objectives

Art. 4: This Law establishes the following aims: To promote, protect and support the practice of breastfeeding exclusively until six months of age; from six months to two years continue breastfeeding with the addition of supplementary feeding.

Art. 5: The objectives of this Law are:

- a) To contribute to the physical and mental wellbeing of the mother-child dyad, through advocacy, support, promotion and protection of breastfeeding and regulation of the marketing of breastmilk substitutes and related products.
- b) Regulate and control the information, promotion, distribution, advertising, sales and other aspects relating to the marketing of breastmilk substitutes, complementary foods, bottles, nipples and pacifiers.

Chapter II: Definitions

Art. 6: In order to facilitate understanding and proper handling of the terminology used in this Act, the following definitions shall apply:

COMPLEMENTARY FOOD: Any food manufactured or prepared which can be used to supplement breastmilk or infant formula, when either becomes insufficient to satisfy the nutritional needs of infants. This type of food is also improperly called breastmilk supplement.

MARKETING: Marketing is defined as all activities of promotion, distribution, sales, advertising, public relations, information services, data dissemination by any means, intended to promote the sale of a product.

DISTRIBUTOR: Any natural or legal person, in the public or private sector, dedicated directly or indirectly to marketing, wholesale or retail, of one or more products.

PACKAGING: Any kind of single container that is not part of the product itself (including packages and wrapping) with the specific mission to maintain quality and protect it from any deterioration or contamination, for ease of handling, transportation and marketing.

LABEL: Any kind of text, title, brand, tagline or other descriptive indication drawn, written, printed, marked, embossed or engraved, attached to a product or which accompanies or belongs to the package.

MANUFACTURER: Any natural or legal person or entity engaged in the manufacture of a product, either directly or through an agent or a person related to him under a contract.

DATE OF MANUFACTURE: Date with which the individual lots are distinguished and indicating the date on which manufacture was finished, usually expressed by month and year.

DATE OF EXPIRATION: Date printed on the packaging of a product, in clearly visible manner, designating the date until which the product is expected to meet the specifications and be safe for consumption. This date is established for each batch by adding the period of useful life to the date of manufacture. It is the not encoded date provided by the manufacturer, based on stability and safety of a product, and after which the product should not be consumed, and must be considered unmarketable.

INFANT FORMULA: Any milk product of animal or vegetable origin industrially manufactured in accordance with the requirements of the standards, intended to feed children under six months.

FOLLOW-ON FORMULA: Any milk product of animal or vegetable origin industrially manufactured in accordance with the requirements of the standards, marketed or otherwise presented as suitable for feeding infants over six months old.

SPECIAL FORMULA: Any infant formula marketed for hypersensitive infants with lactose intolerance or other metabolic disorders.

INFANT: A child of less than two years.

SAMPLE: Unit representative of a product batch.

MEDICAL SALES PROMOTER OR VISITOR: Any person who provides information or public relations for a given product.

HEALTH REGISTRATION: Procedure by which a particular product passes a strict evaluation for marketing.

HEALTH SERVICE: Any semi-state, private, church, non-governmental or other institution or a health professional, dedicated to providing, directly or indirectly, health care or health education, including childcare centres, crèches and other related services.

BREASTMILK SUBSTITUTE: Any product sold, presented or offered explicitly or implicitly as partial or total replacement for breastmilk, whether or not suitable for this purpose.

Chapter IV: The National Authority

Art. 7: The Ministry of Health, through the departmental health agencies, shall be responsible for the control, supervision and correct application of this Law and its Regulations.

Chapter V: Administrative Office

Art. 8: The National Breastfeeding Committee, chaired by the Ministry of Health, consisting of entities involved in the promotion and protection of breastfeeding and the marketing of

breastmilk substitutes is hereby recognized. The establishment, purpose and activities of this Committee shall be defined in the Regulations of this Law.

Art. 9: The National Breastfeeding Committee shall fulfil the following functions:

- a) To advise the Executive Branch and other institutions involved in the care of women and children under five.
- b) To promote, protect and support breastfeeding.
- c) Ensure the implementation and enforcement of this Law.

Chapter VI: Product Registration

Art. 10: Regulatory approval of breastmilk substitutes, infant formula, follow-up formulas and special formulas shall be given as medicine, through the competent authority of the Ministry of Health.

Art. 11: Regulatory approval of complementary foods and follow-on formulas for children over two years shall be granted as food, by the National Agricultural Health and Food Safety Service (SENASAG).

Chapter VII: Labelling and Packaging

Art. 12: The label of any breastmilk substitute, infant formula, special formula or follow-on formula shall:

- a) Have a prominent and visible notice with the words "IMPORTANT NOTICE" to assert the superiority of breastmilk in feeding infants at least until six months, e.g. "BREAST IS BEST FOR YOUR BABY. EXCLUSIVE BREASTFEEDING IS RECOMMENDED UP TO SIX MONTHS "(near the product name, printed in visible size and colour).
- b) Give the analytical composition, ingredients, including additives, preservatives and others, as well as the proper use of the product.
- c) Be written in Spanish.
- d) Contain the name and address of the manufacturer.
- e) Be designed so as NOT TO DISCOURAGE breastfeeding.
- f) Contain the date of expiry, noting that the use and marketing of the product after expiry is prohibited. It shall also contain the batch number and storage conditions after the product has been opened.
- g) Bear only pictures, designs or other graphic presentations necessary to illustrate the appropriate method of preparation.
- h) Contain instructions for preparation and additional hygienic measures to be followed and the age of the child for whom its use is indicated.
- i) State that the use and marketing of this product after the expiry date is prohibited.

Art. 13: In no case shall the label of breastmilk substitutes, infant formula, special formula or follow-up milks, complementary foods, bottles, teats or pacifiers contain:

- a) Information and pictures of infants that might discourage breastfeeding.
- b) Texts, drawings or illustrations which, directly or indirectly, tend to create the belief that the product is equivalent or superior to breastmilk.
- c) Terms like "maternalised", "humanised" and the like.

d) Statements of professional associations and other organizations in support of the consumption of the product.

e) Any image other than an illustration of the product source, "vegetable or animal origin".

Art. 14: Labels of dairy products (condensed, evaporated, whole, skim, powdered or liquid milk), in addition to complying with Bolivian labelling rules, shall contain a clear and prominent warning that these products should not be used to replace breastmilk.

Art. 15: The label of complementary foods should contain:

a) The age, in completed months, after which the product can be used.

b) The analytical composition of the product, ingredients used including additives, preservatives and others.

c) Shelf life after breaking the security seal, should it be different from the date of expiry.

d) Storage requirements and conditions.

e) Name and address of manufacturer.

Art. 16: The packaging of bottles, teats and pacifiers shall include, in clear and legible manner, the following texts:

a) "There is no substitute for breastmilk."

b) "The product must be sterilized before use".

c) "The pacifier interferes with suckling, discouraging breastfeeding".

Chapter VIII: Marketing

Art. 17: No manufacturer, importer or distributor, institution or business establishment, pharmacy, public entity or private, natural or legal person, may distribute, sell, store or expose breastmilk substitutes, infant formulas, special or follow-up formulas, complementary foods or bottles, teats or pacifiers that do not fulfil the following criteria:

a) Product registration.

b) Serial number or lot number.

c) Expiry date and, optionally, the date of manufacture.

Chapter IX: Promotion and Advertising

Art. 18: No manufacturer, importer or distributor, institution or business establishment, pharmacy, public entity or private, natural or legal person, may promote or advertise any breastmilk substitutes, infant formulas, special or follow-up formulas, complementary foods or bottles, teats or pacifiers in shops, health centres, shopping outlets or elsewhere.

Art. 19: The following promotional practices for breastmilk substitutes, infant formula, follow-up and special formula, complementary foods for infants under six months, bottles, teats or pacifiers shall be prohibited:

a) The advertising of products listed.

b) Sales tactics, such as special displays, discount coupons, tied sales, prizes and gifts.

c) Free distribution of products, directly or indirectly, to health personnel or to anyone else, especially to pregnant or lactating mothers, or to institutions, except in the cases described in Articles 22 and 23.

d) Promotion in the form of financial benefits or the distribution of gifts of any kind to health workers or to the general public, bearing the name, logo, graphic representation or brand name of one of the products listed.

e) The distribution or display of written, audio or visual materials targeted to pregnant or breast-feeding women and the general public.

f) The distribution or display of written, audio or visual material in any scientific event related to child health and nutrition, bearing the logo, graphical representation or the brand name of one of the products listed.

g) Any other advertising or promotion practice that the National Committee for Breastfeeding believes to be harmful to the health and nutrition of children.

Art. 20: Information provided by manufacturers and distributors to health professionals, considering the restrictions on products covered by this Law, shall be restricted to scientific matters based on evidence, and such information shall not imply or convince that bottle feeding is equivalent or superior to breastfeeding.

Art. 21: It shall be prohibited to disseminate messages that:

a) Suggest to mothers or motivate or persuade mothers to replace breastmilk with any substitute thereof, be it infant formula, special formula or follow-up formula.

b) Discourage breastfeeding, through comparisons with other practices.

c) Associate breastmilk substitutes, infant formula or special formula with breastfeeding, using phrases or labels such as "Maternalised" or "Humanized".

d) Use statements such as "best", "safe", "effective", "no risk", etc. in relation to formulas, special formulas or follow-up formulas.

e) Suggest the use of breastmilk substitutes, formulas, special formulas or follow-up formulas.

Chapter X: Donations

Art. 22: Donating breastmilk substitutes, directly or indirectly, to any institution providing care to children under two years, shall be possible only when that institution has received specific authorization from the Ministry of Health.

Art. 23: Only organizations or institutions that care for infants who can not opt for breastfeeding may use breastmilk substitutes from donations, prior approval by the relevant authorities.

Chapter XI: Breastfeeding Subsidy

Art. 24: The breastfeeding subsidy* given (by the State or employer) to breastfeeding or pregnant mothers may not contain breastmilk substitutes, infant formulas and special formulas.

Art. 25: Institutions, public or private companies, which deliver the breastfeeding subsidy are required to inform pregnant and breastfeeding mothers that this subsidy is intended to promote the health and nutrition of the recipient and its use is not intended for infants under six months. The marketing of breastfeeding subsidies to the public is prohibited.

Art. 26: When any type of milk is included in the breastfeeding subsidy, the label must contain text to inform breastfeeding mothers that the product is to promote the health and nutrition of the recipient and is not intended for infants under six months.

Chapter XII: Prohibitions and Sanctions for Health Workers

Art. 27: Health personnel serving in public or private institutions or working in scientific organizations or in associations concerned with the health and nutrition of children shall not:

- a) accept gifts or financial or other benefits from a manufacturer or supplier, as a mechanism to promote the use of breastmilk substitutes.
- b) Be a mediator in the distribution of breastmilk substitutes or in the dissemination of (promotional) messages to people with children under two years.
- c) Act in a manner contrary to the provisions of this Law.

In case of breach of the provisions of this Article, the sanctions established by law shall apply.

Chapter XIII: Offences and Penalties

Art. 28: Any infringement by noncompliance with the provisions of this Law and its regulations shall be punished in accordance with the applicable rules.

The Ministry of Health shall have the duty to ensure compliance with all existing rules that relate to the scope of this Act.

Chapter XIV: Final Provisions

First: Any provisions contrary to this Law are repealed.

Second: The Executive Branch shall draft the regulations of this Law within 90 days from its publication.

* The **breastfeeding subsidy** is a package of products delivered to pregnant women with health insurance for 17 months for her own and her baby's feeding. Its value is equivalent to one national minimum wage. The 12 new products included in the packages are yogurt (which can keep more than a week); rice, palmettos, instant dry soup, natural peanut jam, fortified gelatine, canned peas, chocolate bars, three new varieties of cheese and yogurt in sachets. In total, the parcel will contain up to 40 products, depending on the region, if urban or rural. (La Paz, August 30, 2012)

Note: This explanation of what the "breastfeeding subsidy" is was found by JPA on the internet. It comes from an article in a local newspaper describing the new products included in that package. Nowhere in the law is there a definition of this *sui generis* "breastfeeding subsidy". I am not aware of any other country that provides this type of support to mothers.

Translation by J-P Allain, ICDC, 26 February 2016