

BOLIVIA

EXECUTIVE DECREE No. 0115 of 06 May 2009 on

Regulation of Law No 3460 of 15 August 2006 on

Promotion of Breastfeeding and Marketing of Breastmilk Substitutes

EVO MORALES AYMA

Constitutional President of the Republic

CONSIDERING that:

Paragraph 1 of Article 35 of the Political Constitution of the State affirms that the State, at all its levels, shall protect the right to health, by promoting public policies aimed at improving the quality of life, collective wellbeing and free access of all people to health care services.

Article 75 of the Political Constitution of the State provides that users and consumers have the right to supplies of foods, medicines and products in general, that are not harmful, are of adequate and sufficient quality and quantity, with opportune and efficient supply, as well as trustworthy information about the nature and contents of products and services that they use.

Articles 61 and 62 of the General Labour Law of 8 December 1942 provides that during the period of lactation women shall have short breaks throughout the day, totalling not less than one hour and that companies that employ more than 50 people shall have crèches, according to plans that shall be established. That Article 63 of the General Labour Law prescribes that employers who have women and children in their service shall take the necessary measures to ensure their physical health and comfort at work.

Article 8 of Law No 3131 of 8 August 2005, on the Exercise of the Medical Profession, sets as doctors' main roles the promotion of health, prevention of disease, recovery of health and rehabilitation of patients. That Law No 1737 of 17 December 1996 on Medications, regulates the manufacture, elaboration, importation, marketing, quality control, registration, selection, acquisition, distribution, prescription and dispensing of medicines for human consumption, special medications, medical devices and others.

Breastmilk is the first food that a human being receives and that, therefore, to reinforce the practice of exclusive breastfeeding up to six months of age of a newborn is indispensable so as to reduce infant malnutrition. That Law No 3460 of 15 August 2006 on Promotion of Breastfeeding and Marketing of Breastmilk Substitutes aims to promote, protect and support the practice of exclusive breastfeeding up to six months of age and continued breastfeeding up to two years of age, with a view to improving the physical and mental health of the mother-child dyad by means of protection, support and promotion of natural breastfeeding and by regulation of the marketing of breastmilk substitutes and other related products, as well as to regulate and control information, distribution, advertising, sales and other inherent aspects of marketing of breastmilk substitutes, complementary foods, feeding bottles, teats and dummies.

It is necessary to establish technical and administrative mechanisms to apply the provisions of Law No 3460 on Promotion of Breastfeeding and Marketing of Breastmilk Substitutes, which is considered to be a State policy.

THE COUNCIL OF MINISTERS DECREES:

Regulation of Law No 3460 of 15 August 2006 on Promotion of Breastfeeding and Marketing of Breastmilk Substitutes

CHAPTER I – GENERAL PROVISIONS

ARTICLE 1 – AIM: In the framework of the provisions of Law No 3460, this Decree aims to adopt the regulatory provisions to promote, support, encourage and protect breastfeeding, so as to ensure every child's right to receive the best food and every woman's right to breastfeed.

ARTICLE 2 – SCOPE: This Regulation shall be applicable to:

- a) Public and private institutions which must promote among all their staff a culture of support and recognition of the transcendental importance of exclusive breastfeeding of girls and boys up to six months age and continued breastfeeding up to at least two years, and to consider the necessary logistics for this purpose.
- b) Natural and juridical persons, manufacturers and marketers, importers and distributors, industries, pharmacies, health care providers, distribution and marketing channels, media, organizations and others that, directly or indirectly, are related to the manufacture, importation, distribution, marketing and promotion of breastmilk substitutes.

CHAPTER II – DEFINITIONS

ARTICLE 3 – DEFINITIONS: For the purposes of this Regulation and in addition to the definitions established in Law No 3460, the following definitions shall apply:

- a) **Sponsorship:** Any financial, logistic or material support offered or given to health care workers or health care services providers.
- b) **Health care worker:** Any professional, administrative, technical or support staff, as well as volunteers, who work in a health care facility.
- c) **Health care institution:** Any organization, institution or establishment, of the public or private sector, whether municipal, social security, private or non-profit, churches, armed forces, and police which is authorized by law to provide health care to the people.
- d) **Company:** Any natural or juridical person, industry, importer, distributor or marketer, including pharmacies, supermarkets, shops, street stands and others which, directly or indirectly deal with the manufacture, importation, distribution, marketing and promotion of breastmilk substitutes, complementary foods and medical devices.

- e) **Promotion:** Any method to encourage the purchase, use or consumption of a product or service, including visits by doctors, gifts, free samples, coupons, discounts, prizes, premiums and other promotional methods.
- f) **Advertising:** Any form of communication carried out by natural or juridical persons, through radio, cable TV, internet, press, cinema, posters, banners, leaflets or any other means of private or public mass dissemination, aimed at directly or indirectly inducing the use or consumption of a product or service.
- g) **Breastmilk substitute:** In accordance with Law 3460, a breastmilk substitute is any product marketed, presented or offered as a partial or total replacement for breastmilk, regardless of its nutritional value, including infant formula, follow-up or growing-up formula, special formula and others. Milk-based products marketed, presented or offered for children above two years of age shall not be considered breastmilk substitutes.
- h) **Complementary food:** In accordance with Law 3460, a complementary food is any prepared or manufactured food specifically meant for children from six months to two years of age, and used as a complement to breastmilk, so as to satisfy the nutritional needs of infants.
- i) **Medical device:** Is any article, instrument, apparatus or device, including its components, parts or accessories, manufactured, sold or recommended for use in the care of human beings or animals during pregnancy or birth, or after it, including newborn care. For purposes of the Law and its Regulations, it refers to bottles, teats and pacifiers.

CHAPTER III - INFORMATION AND EDUCATION

ARTICLE 4 – INFORMATION AND EDUCATION PROGRAMMES: The Ministry of Education and all human resources training institutions, both public and private (universities, technical colleges, health schools and others), in coordination with the Ministry of Health and Sports, shall include in their curricula at primary, secondary, technical and superior level, contents about food and nutrition that include immediate, exclusive breastfeeding up to six months and continued breastfeeding up to two years of age, its management, with an intercultural human rights focus.

ARTICLE 5 – PERSONS RESPONSIBLE FOR INFORMATION AND EDUCATION: The Ministry of Health and Sports, the Ministry of Education, the departmental prefectures and municipal governments, shall provide information, education and training to the people, through professional groups, school groups, women's clubs, mothers' clubs, civic groups and others, at health fairs, health programs, literacy campaigns and others, so that citizens, from childhood on, are aware of the importance of care and attention to maternity and breastfeeding.

ARTICLE 6 – COMMERCIAL INFORMATION MATERIALS ABOUT BREASTMILK SUBSTITUTES: In accordance with the provisions in Chapter IX of Law No 3460, production, distribution and dissemination of information, educational materials and others, about breastmilk substitutes for commercial purposes, by manufacturers, distributors and marketers shall be prohibited.

ARTICLE 7 – INFORMATION AND EDUCATION MATERIALS ABOUT INFANT AND YOUNG CHILD NUTRITION: Informational and educational materials, regardless of their presentation, dealing with the feeding of infants and young children, shall be written in national and local languages and include clearly and visibly each of the following aspects:

- a) The advantages of breastfeeding and the superiority of breast milk;
- b) Information on the proper feeding of pregnant and nursing women;

- c) The value of immediate breastfeeding exclusively for the first six months and continued breastfeeding, with complementary foods up to two years;
- d) How to start and maintain exclusive and prolonged breastfeeding;
- e) How and why bottle-feeding and early introduction of complementary foods negatively affect the infant;
- f) The importance of introducing complementary foods when the infant turns six months;
- g) That complementary foods can be easily prepared at home.
- h) For the feeding of 'infants in special medical conditions receiving breastmilk substitutes via feeding bottle', materials shall also include the following points: - Instructions for preparation and proper use of the product, including cleaning and sterilization of utensils; - How to feed infants with a cup; - The risks posed to health by bottle feeding, and improper preparation of the product.
- i) The total estimated cost of feeding an infant with breastmilk substitutes for a period of six months.
- j) Informational and educational materials shall not: -Generate the belief that a breastmilk substitute is equivalent, comparable or superior to breast milk; -Contain the name or logo of any product defined in Law No 3460 or from a manufacturer or distributor; -Contain images or text that encourage bottle feeding or discourage breastfeeding.

ARTICLE 8 – ESTABLISHMENT OF SUPPORT GROUPS: The Ministry of Health and Sports, the departmental prefectures through the Departmental Health Services (SEDES)*¹, and municipal governments, shall promote the training of personnel to strengthen community support groups for breastfeeding, as well as monitoring and evaluation of existing groups.

ARTICLE 9 - COUNSELING SERVICES: The institutions providing health services shall strengthen support groups for breastfeeding so that, by means of a reference and counter reference system, mothers and their families can receive counselling and training in breastfeeding practices by trained staff.

ARTICLE 10 - INFORMATION SYSTEM: The Ministry of Health and Sports shall incorporate into the National Health Information System, a subsystem that allows to collect, consolidate and analyze information related to breastfeeding and complementary feeding practices in the country, so as to identify problems and make the necessary adjustments to ensure the achievement of the aims of the various public policies related to nutrition and breastfeeding.

ARTICLE 11 – EXCEPTIONS: I. If for exceptional reasons described in technical standards for health facilities, infants and lactating mothers can not be breastfed or practice breastfeeding, trained health personnel shall give a clear demonstration and accurate information on the preparation and use of breastmilk substitutes, directed exclusively to mothers, parents and family members of the infant concerned, as established in the Baby Friendly Hospital Initiative. II. This exception also extends to institutions and homes that house orphaned and/or abandoned children.

ARTICLE 12 - INFORMED CONSENT: A mother's decision not to breastfeed shall be made based on the information provided by health staff about the benefits and superiority of breastfeeding.

¹ *SEDES comes back many times throughout this document. Worth remembering it is the Departmental Health Services. Bolivia is divided into departments, equivalent to provinces or states in other countries. SEDES is the Ministry of Health at local level.

CHAPTER IV – DUTIES

ARTICLE 13- DUTIES OF HEALTH CARE PROVIDERS: With the purpose of achieving the promotion, protection and support of exclusive breastfeeding until six month and continued breastfeeding up to two years, the institutions providing health services shall have the following duties:

- a) To comply with and enforce the corresponding regulations established by the Ministry of Health and Sports.
- b) To create the conditions for hospitalized premature infants to receive the necessary support from trained personnel to be breastfed, and allow mothers and fathers (when necessary) to enter special care rooms to feed the infant with breast milk.
- c) To promote, support and encourage immediate exclusive breastfeeding until six months and extended up to at least two years.
- d) To create and ensure the physical and administrative conditions in all institutions providing health services where infants are hospitalized, to allow them to receive breastmilk during hospitalization.
- e) To make possible the formation and organization of breastfeeding support groups.

ARTICLE 14 - DUTIES OF HEALTH WORKERS: In addition to compliance with regulations established by the Ministry of Health and Sports, health workers shall have the following duties:

- a) To inform pregnant women attending antenatal care in institutions providing health service about the benefits of breastfeeding and the dangers of bottle feeding and formula milk for children under six months.
- b) To inform all pregnant women about the benefits of immediate skin to skin contact with the newborn (partial or total early attachment), rooming-in and techniques of breastfeeding and milk expression, in order to strengthen their confidence in their ability to breastfeed.
- c) To implement immediate breastfeeding within the first hour of birth in vaginal deliveries and when conditions permit (recovery from anaesthesia) in caesarean deliveries.
- d) To promote and support families, so that every expectant mother and her partner are informed about the risks arising from not breastfeeding, for the mother, the child, the family, society, the environment, productivity and the economy.
- e) To support the mother in the proper techniques for the initiation and maintenance of breastfeeding in the first six hours after delivery, strengthening her confidence in her ability to breastfeed.
- f) To ensure rooming-in of mother and child, immediately after birth and during the twenty-four hours a day.
- g) To promote breastfeeding on demand according to standards (10 times during the day and night).

ARTICLE 15- DUTIES OF PUBLIC AND PRIVATE INSTITUTIONS: Public and private institutions shall have the following duties:

- a) To allow breastfeeding mothers to take their babies to their jobs and to study, so as to provide exclusive breastfeeding for six months.

b) To give breastfeeding mothers the rest period established in the General Labour Law, if they do not take their babies to their workplaces.

c) To adapt suitable environments in work and study places for mothers with infants under six months to breastfeed in optimal conditions.

ARTICLE 16 - DUTY TO DENOUNCE: Health personnel, non-governmental organizations, professional groups, institutions and natural or juridical persons shall be obliged to report to the health authorities at the central level and/or departmental level on any breastmilk substitutes marketing, distribution, information, promotion and advertising activities (that they have observed), as well as those relating to bottles, teats and pacifiers, contravening the principles, objectives and other provisions of Law No. 3460 and in this Regulation.

CHAPTER V - COMPETENT AUTHORITIES

ARTICLE 17 - CENTRAL LEVEL AUTHORITY: In accordance with the provisions of Article 7 of Law No 3460, the Ministry of Health and Sports shall be the competent authority at the central level, responsible for controlling the implementation of the Law and these Regulations, through the following bodies: the Nutrition Unit, the Quality and Food Safety Monitoring and Control Unit at the National Health Laboratories Institute (INLASA), and the Medicines and Health Technology Unit (UNIMED), in coordination with the National Agricultural Health and Food Safety Service (SENASAG), the National Customs and the Bolivian Police Department, according to their competence.

ARTICLE 18- DEPARTMENT LEVEL AUTHORITY: At the departmental level, the departmental prefectures, through the SEDES and in coordination with the SENASAG, the National Customs Department, the Bolivian Police Department and the National Health Insurance Institute (INASES), shall carry out surveillance and control actions for compliance with the Law and this Regulation.

CHAPTER VI - NATIONAL BREASTFEEDING COMMITTEE

ARTICLE 19 - PURPOSE OF THE COMMITTEE: The National Breastfeeding Committee shall assist the Ministry of Health and Sports throughout the country in the promotion, protection and support of exclusive breastfeeding for six months and continued breastfeeding up to at least two years.

ARTICLE 2 - MEMBERSHIP: The National Breastfeeding Committee shall consist of a chairman, secretary and accredited representative members whose powers will be determined in specific regulations approved by Ministerial Resolution of the Ministry of Health and Sports.

ARTICLE 21 - CHAIR: The Ministry of Health and Sports, through its Nutrition Unit under the Vice Ministry of Health and Promotion, shall chair the National Breastfeeding Committee.

ARTICLE 22 - TECHNICAL SECRETARIAT OF TE COMMITTEE: I. The Technical Committee on Breastfeeding Support (COTALMA) shall hold the Technical Secretariat of the National Breastfeeding Committee. II. The operation of the Technical Secretariat shall not require any budget allocation.

ARTICLE 23 - COMMITTEE MEMBERS: I. The National Breastfeeding Committee shall be composed as follows: - Four representatives of the Ministry of Health and Sports, chosen from the following bodies: Nutrition Unit, Drugs and Health Technology Unit. - One representative of the Ministry of Education. - Two representatives of COTALMA. - Two representatives of the International Baby Food

Action Network - IBFAN Bolivia. - Two representatives of the International Health Action Network - AIS Bolivia. - One representative of the Bolivian Society of Gynaecology and Obstetrics. - One representative of the Bolivian Society of Paediatrics. - One representative of the National College of Dieticians of Bolivia. - One representative of the National College of Nursing. - One representative of the National Association of Biochemistry. - One representative of the Confederation of Universities of Bolivia - CUB. - One representative of the Federation of Municipal Associations of Bolivia - FAM. - One representative of the La Leche League in Bolivia - LLB. - One representative of the Bolivian Society of Public Health. - One representative of the National Chamber of Industries. - One representative of the National Chamber of Commerce. - One representative of the Association of Journalists. - One representative of the Association of Nursing Assistants. - A representative of the Ombudsman. - One representative of the Consumer Rights Defense Committee (CODEDCO). - One representative of the Federation of Neighbourhood Committees. II. The Committee may invite other institutions to treat specific issues.

ARTICLE 24 – ACTIVITIES: In compliance with Article 8 of Law No 3460, the National Committee on Breastfeeding shall undertake the following activities:

- a) To provide technical assistance to public and private institutions to implement policies and procedures that help achieving successful breastfeeding.
- b) To assess and authorize scientific information for health personnel regarding breastfeeding and products covered by Law No. 3460, in coordination with the Nutrition Unit of the Ministry of Health and Sports and the National Drug Commission.
- c) To analyze, study and recommend legislation to protect working mothers.
- d) To conduct or participate in studies and research in matters relating to their remit.
- e) To develop programs to encourage the creation of support groups for pregnant and breastfeeding mothers, in order to achieve successful breastfeeding.
- f) To promote the creation of departmental and/or regional breastfeeding committees, and similar committees in establishments of public and private health that have maternity services, gynaecology, paediatrics and intensive child care units.
- g) To recommend to the Ministry of Health and Sports policies and regulations to promote and protect breastfeeding.

CHAPTER VII - HEALTH REGISTRATION

ARTICLE 25 - HEALTH REGISTRATION OF BREASTMILK SUBSTITUTES FOR INFANTS UNDER TWO YEARS AND MEDICAL DEVICES: Prior to their marketing, breastmilk substitutes and medical devices shall obtain a health registration certificate granted by the Ministry of Health and Sports through the Unit of Medicines, as required by No 1737 Law, its Regulation and the Health Registration Handbook and other regulations issued under pharmaceutical regulations.

ARTICLE 26 - REGISTRATION OF COMPLEMENTARY FOODS: I. The health registration of complementary foods for children aged six months to two years, which contain milk and are enriched with vitamins and minerals, shall be granted by the Ministry of Health and Sports.

II. The health registration of other foods for children older than two years shall be granted by the SENASAG, in accordance with current regulations and considering the regulations issued by the Ministry of Health and Sports by Ministerial Resolution on the matter.

ARTICLE 27- FOOD SAFETY: The safety of breastmilk substitutes and complementary foods shall be monitored and controlled by the Food Quality and Safety Unit (INLASA) and Food Safety Units of the SEDES, in coordination with the relevant authorities of municipal governments. For this purpose the SENASAG shall semi-annually submit a list of registered complementary foods, including its main characteristics (name, manufacturer, registration number, national origin) to the Ministry of Health and Sports.

ARTICLE 28 - SPECIFIC TECHNICAL STANDARDS: In addition to the aforementioned standards, for the specific case of infant formulas, follow-on formulas, special formulas and complementary foods, including fortified foods, mandatory standards shall be adopted, issued by the competent Standards and Quality authority, by means of Ministerial Resolution of the Ministry of Health and Sports.

ARTICLE 29 - CONDITIONS OF PRODUCTS: Breastmilk substitutes and complementary foods, in addition to meeting the technical and legal requirements governing their preparation, packaging, storage and transportation, shall be subjected to periodic quality control by the competent health authority.

CHAPTER VIII - LABELING AND PACKAGING

ARTICLE 30 - CONTENTS OF LABELS: Labels of breastmilk substitutes, in addition to the provisions of Law No. 3460 and the regulations issued by the Standards and Quality authority, approved by Ministerial Resolution of the Ministry of Health and Sports, shall meet the following requirements:

- a) Carry the message "Breastmilk is best for your baby" written in a font size and colour that is readable at simple eyesight.
- b) Contain an instruction to consult with a health worker or a nutritionist before using the product.
- c) Indicate the composition, type and origin of the animal or vegetable proteins contained in the product, by their common name.

ARTICLE 31 – RESTRICTIONS: Labels of breastmilk substitutes, in addition to the requirements of Law No. 3460, shall not contain:

- a) Phrases that put into doubt the ability of the mother to breastfeed or that tend to create the belief that the products are equivalent or superior to breastmilk.
- b) Statements about presumed nutritional benefits, health claims of products or others that are not based on independent, verifiable and demonstrable scientific information.
- c) Artwork, photos or pictures of infants, toys or humanized forms of animals, plants or objects.
- d) Images or messages intended to promote the use of feeding bottles and other substitutes.

ARTICLE 32 - LABELING OF INFANT FORMULAS, FOLLO-UP FORMULAS, SPECIAL FORMULAS AND COMPLEMENTARY FOODS: Checking and control of labelling of infant formulas, follow-up formulas, special formulas and complementary foods, shall be performed by the corresponding units of the Ministry of Health and Sports, the SEDES, municipal governments and SENASAG.

ARTICLE 33 - AGE FOR USE OF COMPLEMENTARY FOODS: Packaging, containers and labels of complementary foods, shall clearly indicate the age as of which the product can be used. The use of text or pictures of infants, toys or humanized forms of animals, plants or objects that suggest their use for infants less than six months old is strictly prohibited.

ARTICLE 34 - LABELING OF MEDICAL DEVICES: The labels of bottles, teats and pacifiers shall bear the message "Breastmilk is best for baby" written in a font size and colour that is readable at simple eyesight.

ARTICLE 35 - ADHERENCE OF LABELS: The label of breastmilk substitutes must be difficult to remove and be part of the product packaging, in accordance with the provisions of the relevant rules.

ARTICLE 36 - LABELLING CONTROL: The Ministry of Health and Sports and SEDES, through their respective units, in coordination with municipal governments and SENASAG, shall have the responsibility to check and control the following:

- a) That breastmilk substitutes, complementary foods and medical devices comply with the labelling rules provided for in this regulation.
- b) That the labelling of dairy products in general (condensed, evaporated, whole, skim, powdered or fluid milk) contains the warning that they should not be used to replace breast milk, in accordance with the provisions of the Article 14 of Law No. 3460.

CHAPTER IX - PROMOTION AND ADVERTISING

ARTICLE 37 - BROADCASTING THE MOTTO: The Ministry of Health and Sports, in collaboration with the different media, health personnel, workers and businesses, shall promote the message "BREASTMILK IS BEST FOR YOUR BABY" and other messages that promote the practice of exclusive breastfeeding up to six months and continued up to two years with appropriate complementary feeding.

ARTICLE 38 - ADVERTISING VIA THE MASS MEDIA: The advertising of breastmilk substitutes, complementary foods for under-six-months infants and of bottles and teats that discourage breastfeeding, in any medium of mass communication, shall be prohibited.

ARTICLE 39 - INFORMATION FOR HEALTH WORKERS: The information provided by companies to health workers on products covered by Law No. 3460 and this Regulation shall be restricted to independent, verifiable and demonstrable scientific information. It shall be assessed and authorized by the Nutrition Unit of the Directorate of Health Promotion of the Ministry of Health and Sports, in coordination with the National Pharmacological Commission and the National Breastfeeding Committee, for monitoring and control purposes, before it is distributed.

ARTICLE 40 - ADVERTISING OF COMPLEMENTARY FOODS: Any printed, visual or audio advertising material for complementary foods for infants older than six months and up to two years shall include the message "BREASTMILK IS BEST FOR YOUR BABY", complying with the following features as appropriate:

- a) If the material is visual, the message shall be displayed throughout the duration of the ad.
- b) If the material is audio, the message shall be heard clearly at the beginning and end of the ad.

c) If the material is printed, the message must appear on the top near the product name in easily readable font size and colour.

ARTICLE 41 - FORBIDDEN PROMOTIONAL ACTIVITIES:

I. In accordance with Article 18 of Law No. 3460, manufacturers and distributors of breastmilk substitutes, complementary foods and medical devices shall not perform, directly or indirectly, the following activities:

a) Donation or distribution of any equipment, product or service that contains words or images that identify a product listed in Law No. 3460, a product line or a manufacturer, or promote the use of such products.

b) Distribution or delivery of samples of a product listed in Law No. 3460 to health services, health personnel, mothers of infants and their families;

c) Donation or distribution in institutions providing health services of objects such as pens, calendars, posters, notebooks, growth charts, toys and others that contain words, pictures or logos that identify the name or brand of products listed in Law No. 3460;

d) Sponsorship of events, contests or campaigns aimed at pregnant women or nursing mothers, parents of infants and children under two years, or members of their families, or relating to fertility, pregnancy, childbirth or infants and children under two years.

e) Establish contact at a professional level, directly or indirectly, with pregnant women or mothers of children under two years old, in institutions providing health services.

II. The use of images of children under two years old, in audio-visual or printed communication media or any other communication media, to promote breastmilk substitutes, complementary foods or feeding bottles, teats and pacifiers, shall be prohibited.

ARTICLE 42 - BONUSES OR GRATUITIES: Companies shall not offer or give to health workers, directly or indirectly, as a mechanism for promoting the sale or use of breastmilk substitutes and medical devices, any financial benefits, gifts, grants, sponsorships for travel to health events, meetings, conferences, departmental, national and international conferences, or research grants, nor shall they fund their participation in educational or social activities.

CHAPTER X - DONATIONS

ARTICLE 43 – DONATIONS:

I. Donation or free distribution of breastmilk substitutes to institutions providing health care to newborns and infants shall be banned, except when justified and expressly authorized with due documentation by the Nutrition Unit of the Ministry of Health Sports or by a SEDES.

II. The prohibition in Paragraph I of this Article shall not apply to organizations or institutions that care for infants who cannot be breastfed. In this case, the Nutrition Unit of the Ministry Health and Sports shall provide a duly documented justification that lists the donated products by name and the amounts authorized for donation.

III. In situations of emergency or disaster, donations of breastmilk substitutes and complementary foods for children under six to twenty-four months (are permitted) and shall be governed by national and international regulations on infant feeding.

ARTICLE 44 - SEIZURE OF BREASTMILK SUBSTITUTES, COMPLEMENTARY FOODS AND MEDICAL DEVICES: Breastmilk substitutes, complementary foods for children under two years and donated medical devices shall be confiscated or seized in the following cases:

- a) When they do not comply with the legal standards, or have been illegally imported or do not have the required sanitary registration.
- b) When they have been imported by natural or juridical persons not registered with the Ministry of Health and Sports.
- c) When they do not have the required Certificate of Customs Clearance.

CHAPTER XI - SUBSIDY BREASTFEEDING

ARTICLE 45 - PRENATAL AND BREASTFEEDING GIFT PACKS:

I. Gift packages of products given to mothers at prenatal consultations and clearly identified for that purpose shall not contain breastmilk substitutes (infant formulas, special formulas, follow-up formulas and others).

II. The labelling of products in gift packs shall not contain messages suggesting that whole milk or any other can be given to infants, nor shall it refer to the mother-child dyad.

ARTICLE 46 – INFORMATION: Suppliers of gift packs shall inform beneficiaries that the donated products are intended to feed the nursing mother and are not recommended for infants less than six months old.

CHAPTER XII - RESTRICTIONS AND SANCTIONS ON HEALTH CARE SERVICES AND HEALTH WORKERS

ARTICLE 47 - RESTRICTION ON HEALTH CARE SERVICES: Institutions providing health services shall not be allowed to employ professional or administrative, technical or support staff paid by the companies.

ARTICLE 48 – RESTRICTION ON HEALTH WORKERS: Health workers shall not perform any of the following activities:

- a) To solicit or accept samples of breastmilk substitutes and utensils for their preparation or use.
- b) To carry out personal errands in order to receive samples of breastmilk substitutes for evaluation or research, as a favour to companies.
- c) To accept gifts from companies, such as posters, calendars, stationery or any other bearing the logo, emblem or brand name of a breastmilk substitute.

d) To solicit or accept from companies any benefit or financial incentives, grants, sponsorship for travel (tickets, per diem) to health events, meetings, workshops, conferences, or research grants or funding for participation in educational or social activities.

ARTICLE 49 – SANCTIONS: Violations of the provisions of Law No. 3460 and these Regulations, committed by the institutions providing health care services and/or by health workers, shall lead to administrative, criminal or civil penalties that apply according to specific regulations issued by the Ministry of Health and Sports.

CHAPTER XIII - PROHIBITIONS AND SANCTIONS ON COMPANIES

ARTICLE 50 – STAFF PAID BY COMPANIES: Companies defined in paragraph d) of Article 3 of this Regulation, their agents and/or representatives, shall not provide any staff paid by them to health care institutions.

ARTICLE 51 – SANCTIONS: Companies that violate the provisions of Law No. 3460 and this Regulation shall be subject to the following penalties:

a) Confiscation and/or seizure of products in the following cases:

1. When breastmilk substitutes, complementary foods and/or medical devices do not comply with labelling and packaging rules.
2. When they market complementary foods for children less than six months old.

b) Financial penalties for any promotion and advertising that is not allowed, according to specific regulations issued by the Ministry of Health and Sports.

CHAPTER XIV - DESTINATION OF SEIZED PRODUCTS AND SANCTIONS

ARTICLE 52 - SEIZURE OF PRODUCTS: The products seized on the grounds mentioned in paragraph a) of Article 44 of this Regulation, after passing a quality control and health registration by the Pharmaceutical Unit of the Ministry of Health and Sports, shall be donated to charities.

ARTICLE 53 – USE OF PROCEEDS FROM SANCTIONS:

I. The resources collected by way of sanctions shall be deposited in a specific account of the SEDES and become part of their respective budgets.

II. The collected funds specified in Paragraph I of this Article shall be used exclusively for advocacy, support and protection of breastfeeding, in coordination with the National and Departmental Breastfeeding Committees.

ARTICLE 54 - INSTITUTIONS AUTHORIZED TO APPLY SANCTIONS: The SEDES shall be responsible for applying the sanctions provided for in this Decree, according to specific regulations drawn up by the Ministry of Health and Sports.

TRANSITIONAL PROVISIONS

SINGLE TRANSITIONAL PROVISION

I. The development and adoption of the new Regulation of the National Breastfeeding Committee and the specific regulation on sanctions shall occur within a maximum of thirty days from the publication of this Supreme Decree.

II. The adaptation of labels and packaging of products listed in Law No. 3460 and this Regulation shall be made within a maximum of eight months counting from the publication of this Supreme Decree.

III. The adaptation of nursing spaces in places of work and study for breastfeeding mothers shall be made within one year from the publication of this Supreme Decree.

The Ministers of State in their respective offices are responsible for the implementation and enforcement of this Supreme Decree.

Issued in the Government Palace in the City of La Paz, on the sixth day of May two thousand nine.

(Signed by)

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6 May 2009

Translated by J-P Allain, ICDC, 29 May 2016