

## PERU

### SUPREME DECREE No. 009-2006-SA<sup>1</sup>

#### THE PRESIDENT OF THE REPUBLIC

*(Note: I have highlighted in blue the major differences with the previous law of 2013. There are also a few minor differences, notably in attribution of roles to various bodies.)*

#### WHEREAS

Within the framework of the International Code of Marketing of Breastmilk Substitutes, the World Health Assembly has adopted Resolutions WHA 39.28, WHA 47.5, WHA 49.1 and WHA 54.2 that update the definitions and speak of the importance of breastfeeding, as well as the provision of breastmilk substitutes when strictly necessary;

Supreme Resolution No. 014-2002-SA approves the “Guidelines for a Sectoral Policy for the 2002-2012 Period and the Fundamental Principles for the Sectoral Strategic Plan for the Quinquennium August 2001-July 2006” and the First General Guideline: Health Promotion and Prevention of Illness includes the promotion of good nutrition to contribute to the prevention of nutritional risks and harm;

In that context, it is necessary to approve the Infant Feeding Regulation, the content of which should be in accordance with the definitions and guidance of the World Health Organization, as well as with the guidelines mentioned above; and

[The President of the Republic]

In conformity with paragraph 8 of article 118 of the Political Constitution of Peru, [and with] the Law on Executive Power approved by Legislative Decree No. 560 and Law No. 26842 – General Health Law

#### HEREBY DECREES:

**Article 1:** Approve the Infant Food Regulation which contains four titles, eleven chapters, sixty one articles, six complementary, transitional and final provisions and one annex with definitions.

**Article 2:** Repeal all provisions contrary to this Supreme Decree.

**Article 3:** This Supreme Decree shall be countersigned by the Minister of Economy and Finance, the Minister of Health, the Minister for Women and Social Development, the Minister for Education and the Minister for Labour and Employment Promotion.

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<sup>1</sup> A Decreto Supremo is a law decreed by the President of the Republic, i.e. it has not gone through Parliament.

Done at the Government House in Lima on the fifteenth day of the month of June of the year two thousand and six.

ALEJANDRO TOLEDO  
Constitutional President of the Republic

FERNANDO ZAVALA LOMBARDI  
Minister of Economy and Finance

PILAR MAZZETTI SOLER  
Minister of Health

ANA MARÍA ROMERO-LOZADA LAUEZZARI  
Minister for Women and Social Development

JAVIER SOTA NADAL  
Minister for Education

CARLOS ALMERI VERAMENDI  
Minister for Labor and Employment Promotion

## **INFANT FEEDING REGULATION**

### **TITLE ONE: GENERAL PROVISIONS**

#### **CHAPTER I**

#### **REGULATION**

##### **Article 1 – Goal**<sup>2</sup>

The goal of this regulation is to achieve effective attention and care to the feeding of girls and boys up to the age of twenty-four months, by means of promotion, protection and support of breastfeeding and guidance for appropriate complementary feeding practices. It further ensures the correct use of breastmilk substitutes when these are necessary, on the basis of adequate information and appropriate means of marketing and distribution.

##### **Article 2 - Scope**

Shall be subject to this Regulation

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<sup>2</sup> Translator's note: I have used square brackets [ ] to indicate words that are not in the original Spanish text, but which make the English more correct or easier to understand. Otherwise, I have translated all the text as it is in Spanish, i.e. with redundant repetitions (e.g. girls and boys) and mistakes in use of terminology and grammar, so that the English reader can appreciate the original Spanish text as it is.

- 1) The health institutions and health workers, within the national territory, who provide care to pregnant women, mothers, girls and boys from before their birth.
- 2) Factories and distribution centers of breastmilk substitutes and complementary infant foods, in so far as they are concerned.
- 3) Physical and legal persons who directly or indirectly are related to or participate in the marketing of breastmilk substitutes and complementary infant foods, in so far as they are concerned.

### **Article 3 - Content**

This Regulation establishes provisions on:

- 1) Feeding of girls and boys from zero to twenty-four months old, stressing the promotion, protection and support of breastfeeding.
- 2) The responsibilities of the health care system, pharmacies and other points of sale, manufacturers and marketing personnel for products referred to in this Regulation.
- 3) Marketing procedures for breastmilk substitutes for infants, girls and boys up to the age of twenty-four months.

### **Article 4 - Lead Authority**

The Ministry of Health shall be the authority responsible for regulating the appropriate use and consumption of breastmilk substitutes and complementary infant foods, as well as for authorizing and monitoring systems of information on the nutrition and feeding of mothers, girls and boys, within the national territory. For this purpose coordination shall be established between public and private institutions related to the goal of this Regulation.

## **CHAPTER II** **MONITORING BODIES**

### **Article 5 – Responsible Authority**

The Ministry of Health, through its departments and the Regional Directorates for Health, within the national territory, shall ensure compliance with the provisions of this Regulation and, for this purpose, investigate and sanction any infringements thereof.

### **Article 6 – Role and functions of the Responsible Authorities**

1. Ensure that the content of media messages is consistent with the standards set by this Regulation.
2. Request the support of State entities, national and international organizations for technical cooperation or any interested person, as long as there is no conflict of interest with the promotion and protection of breastfeeding, to achieve compliance with the provisions of this Regulation and other directives that are issued in pursuance of this Regulation.
3. Request information and data in public and private health facilities, as well as in pharmacies, points of sale and places of distribution, about the products within the scope of its competence.

4. Assign responsibility for monitoring [implementation] of this Regulation to the officials it shall designate.

#### **Article 7 – Breastfeeding Committees**

Public and private health care facilities that offer maternity and newborn services shall be under obligation to have a Breastfeeding Committee composed of at least three people appointed by the highest authority in said health establishments.

Regional Health Directorates shall ensure compliance with the functions of the Breastfeeding Committees within their jurisdiction.

#### **Article 8 – Role of the Breastfeeding Committees**

The main function of these committees is to promote and to ensure compliance with this Regulation. For that purpose they shall:

- 1) Every six months present their establishment with a report on the situation of breastfeeding and complementary feeding practices within their jurisdiction.
- 2) Monitor the implementation of this Regulation and report any violations to the competent authorities.

#### **Article 9 –Health quality control**

The control of quality and safety of breastmilk substitutes and other complementary infant feeding products subject to registration shall be the responsibility of the General Directorate of Environmental Health (DIGESA). The control of quality and safety of feeding bottles and teats shall be the responsibility of the General Directorate of Medicines, Supplies and Drugs (DIGEMED).

#### **Article 10 – Control of advertising**

The control of advertising of products within the scope of this Regulation shall be the responsibility of the National Institute for Competition and Intellectual Property (INDECOPI), in accordance with its institutional rules.

## **TITLE TWO** **FEEDING OF GIRLS AND BOYS UP TO TWO YEARS OLD**

### **CHAPTER I** **BREASTFEEDING AND COMPLEMENTARY FEEDING**

#### **Article 11 - Feeding**

The feeding of girls and boys from zero to two years of age is based on doctrinal concepts and procedures that must be adhered to by institutions and health workers in the country so as to protect the health and nutritional condition of said children.

## **Article 12 – Preparation of pregnant women for breastfeeding**

Health facilities that provide prenatal care to women shall:

1. Take necessary steps to ensure that every pregnant woman is informed about the importance and benefits of breastfeeding for girls and boys, as well as the mother.
2. Every pregnant woman shall be informed of the benefits of breastfeeding and encouraged by staff or health workers to take the decision to breastfeed her daughter or son up to two years of age and exclusively for the first six months, with the introduction of appropriate complementary foods from that age on.
3. Every pregnant woman shall be informed about the benefits of immediate skin-to-skin contact with the newborn, rooming in and the techniques of breastfeeding, so as to bolster her confidence in her own ability to breastfeed.
4. Healthcare facilities shall promote a culture of support and recognition of the importance of breastfeeding for human development, providing information to the people and training throughout schools, women's clubs, literacy campaigns, civic and other groups, so that women are aware, from adolescence on, of the importance of care and attention to maternity and breastfeeding.

## **Article 13 – Maternal nutrition**

Providing every pregnant woman with prenatal care and advice on her food and nutrition needs is a priority and, therefore:

1. Healthcare facilities shall carry out activities, including orientation sessions with advice on feeding of pregnant women and lactating mothers.
2. Any pregnant woman or lactating mother who qualifies for food assistance shall receive preferential care ensuring an adequate consumption of energy from macro and micronutrients.

## **Article 14 – Breastfeeding**

Natural breastfeeding is ideal for the growth and development of infants. It is also an integral part of the reproductive process and has important implications for the health of mothers.

The worldwide public health recommendation is that, in order to achieve optimum growth, development and health, during the first six months of life infants should be fed exclusively with breastmilk. From then on and in order to satisfy their growing nutritional needs, infants should receive appropriate nutritionally safe complementary foods, without abandoning breastfeeding up to two years of age.

## **Article 15 – Support to mothers for successful initiation of breastfeeding**

1. All public and private healthcare facilities shall provide rooming in 24 hours per day for mother and infant immediately after delivery.
2. They shall furthermore ensure immediate skin-to-skin contact by putting the newborn to her/his mother's breast within the first hour of life, after a vaginal partum. In case of cesarean partum skin-to-skin contact shall be established as early as possible.
3. Immediately after childbirth, the mother shall receive the necessary support in appropriate techniques for initiating and maintaining breastfeeding, thus strengthening her confidence in her own capacity to breastfeed.

4. Every mother shall receive support to breastfeed her newborn sufficiently frequently. The mothers of premature hospitalized girls or boys shall be allowed into their rooms and support shall be provided so that the newborn is fed with her/his mother's milk.
5. Every mother shall be informed of the importance of exclusive breastfeeding during the first six months and continuation of breastfeeding up to two years, complemented with solid foods. She shall equally be informed about the risks of administering liquids or milks other than breastmilk.

#### **Article 16 – Exceptional circumstances for prescription of breastmilk substitutes, other liquids and preparations**

Only in exceptional circumstances and when there is a medical prescription for it shall preparations with breastmilk substitutes or other liquids prepared by the health care services be administered, following these rules:

1. The prescription [given] by a professional [medical] doctor shall be registered in the clinical history [of the child], with supporting evidence for the therapeutic decision.
2. Staff of mother and child healthcare services and health workers in general shall warn mothers that the use of feeding bottles with milk, water or tea reduces the production of mother's milk and their use increases the risk that the girl or boy may become ill.
3. Demonstrating the preparation of breastmilk substitutes shall be done on an individual basis, stressing the importance of using boiled water and sterilized utensils.
4. The preparation of breastmilk substitutes for the exceptional cases that have been prescribed by a doctor shall be done in a closed place not exposed to the look of other mothers.

#### **Article 17 – Complementary foods and feeding practices**

Foods and food products to be used as complementary feeding of girls or boys up to the age of 24 months shall satisfy the following requirements:

1. Complementary feeding shall be initiated from the sixth month of life [completed].
2. Foods and or industrial food products used for complementary feeding shall conform to the legal standards for preparation, packaging, storage and transport in appropriate conditions, so as to ensure their quality and nutritive integrity.

## **CHAPTER II BREASTFEEDING PROMOTION**

#### **Article 18 – Breastfeeding promotion**

With the purpose of ensuring optimal growth and development, health workers and healthcare facilities, both public and private, shall be responsible for activities to promote and protect breastfeeding and for the feeding of infants and girls and boys up to two years of age.

#### **Article 19 – Message**

[The message of] promotion of breastfeeding and infant feeding of girls and boys up to two years of age shall be simple, appropriate and easy to understand by the groups to whom it is

addressed, so as to develop knowledge that translates into health practices.

#### **Article 20 – Activities**

Promotional activities aimed at mothers, families and the community should be carried out in the following manner:

1. Awaken the interest of pregnant women, mothers of minors up to two years, fathers, families, health workers and members of the community at large to the changes in attitude regarding breastfeeding and complementary feeding, with information materials, demonstrations, visual aids, recreational activities and others.
2. Encourage the creation of social support groups for breastfeeding, with the participation of voluntary and community organizations, strengthening the training of leaders who shall encourage mothers to participate; mothers will also be referred to such activities by the healthcare system.

#### **Article 21 – Community education in health and infant nutrition**

Education for health and infant nutrition aimed at communities should:

1. Safeguard and strengthen appropriate community practices and customs regarding breastfeeding and nutrition.
2. Identify traditional birth attendants, health promoters and community leaders to motivate, involve and empower them, giving them the necessary resources to fulfill their role and to integrate them as appropriate breastfeeding and complementary feeding promoters.
3. Incorporate an intercultural approach and mainstream gender and the rights of the child issues.
4. Target educational messages to mothers as well as the couple and the family in general so that, by becoming aware of the importance of their role, they support appropriate breastfeeding and complementary feeding of girls and boys.

#### **Article 22 – Media participation**

The Ministry of Health shall encourage participation of the media in the dissemination of messages that promote or increase appropriate practices of breastfeeding and complementary feeding of girls and boys up to two years of age.

### **CHAPTER III INTERSECTORAL ACTIVITIES FOR THE PROMOTION AND PROTECTION OF BREASTFEEDING**

#### **Article 23 – Coordination with the Ministry for Women and Social Development (MIMDES)**

The Ministry of Health shall coordinate with the Ministry for Women and Social Development (MIMDES) the following activities for support and participation in the promotion of appropriate feeding of girls and boys up to two years of age:

1. Develop educational activities aimed at mothers and families who benefit from Social Programs, Food Support Programs and Special Child Care Programs, especially with the

“Wawa Wasi”, in order to promote appropriate breastfeeding and complementary feeding of girls and boys up to two years of age.

2. Monitor compliance with the Code on Children and Adolescents and with the National Action Plan for Children, particularly as they relate to child nutrition.

#### **Article 24 – Coordination with the Ministry for Education and other training institutions**

The Ministry of Health shall coordinate the following activities for support and participation in the promotion of appropriate feeding of girls and boys up to two years of age:

1. With the Ministry for Education, the elaboration of appropriate provisions for the inclusion in teaching curricula at the different levels of education in the country of specific contents on breastfeeding, nutrition of girls and boys, nutrition of pregnant women and lactating mothers; the role of the family and the community in the protection and support of breastfeeding; as well as the development of educational activities for other members of the education community, such as teachers and parents, particularly for the primary education level.
2. With the universities and higher education institutions, the adoption of measures that allow to stress in the pre- and post-graduate professional training cycles a complete and adequate teaching about human feeding and nutrition, with special care for girls and boys up to two years old, particularly in the areas of medicine, obstetrics, nutrition, psychology and education, among others.
3. With training institutions in general, the implementation of administrative regulations that allow for successful breastfeeding by [female] teachers and students who are nurturing their own girls or boys.

#### **Article 25 – Coordination with the Ministry for Labor and Employment Promotion**

The Ministry of Health shall coordinate with the Ministry for Labor and Employment Promotion activities for support and participation in the protection and promotion of maternity and breastfeeding, for monitoring of the implementation of labor legislation regarding promotion and protection of breastfeeding [rights] of every working mother, particularly actions to follow up on the applicable international labor conventions ratified by the Government of Peru and those pending ratification, as well as the adaptation of national labor legislation to such international standards.

#### **Article 26 – Coordination with local governments**

The Ministry of Health shall coordinate with local governments the following activities for support and participation in the promotion of appropriate feeding of girls and boys up to two years of age:

1. Development of educational activities aimed at women and families that benefit from Municipal Programs, particularly the “Glass of Milk” Program, so as to promote appropriate breastfeeding and complementary feeding of girls and boys.
2. Monitoring the marketing of products under the scope of this Regulation in pharmacies and other points of sale.
3. Monitoring local advertising within the geographic area under their jurisdiction.

**Article 27 – Coordination with regional governments**

The Ministry of Health shall coordinate with regional governments, through the Regional Health Directorates, the following activities for support and participation in the promotion of appropriate feeding of girls and boys up to two years of age:

1. Development of guidelines aimed at promoting intersectoral activities for the promotion and protection of breastfeeding and appropriate complementary feeding, within the framework of regional policies.
2. Follow-up of monitoring indicators for the breastfeeding situation and activities to achieve an adequate compliance with the provisions of this Regulation.

**Article 28 – Coordination with INDECOPI**

The Ministry of Health shall coordinate with INDECOPI its activities to follow up implementation of the provisions of this Regulation covering advertising.

**Article 29 – Coordination with international technical cooperation organizations**

The Ministry of Health shall coordinate with international technical cooperation organizations the adoption of rules of technical cooperation that support intersectoral approaches for the promotion, protection and evaluation of appropriate breastfeeding and complementary feeding [practices] with the goal of achieving compliance with this Regulation.

**Article 30 – Coordination with non-governmental organizations for development**

The Ministry of Health shall coordinate with non-governmental organizations working for development interested in promoting and protecting breastfeeding any activities for support and participation in the promotion of appropriate feeding of girls and boys up to two years of age, as long as such activities do not pose a conflict of interest with the sources of funding of said NGOs.

**TITLE THREE  
BREASTMILK SUBSTITUTES AND COMPLEMENTARY FOODS**

**CHAPTER I  
MARKETING**

**Article 31 – Manufacturing**

The production of breastmilk substitutes and complementary infant foods for children up to 24 months of age shall respect international standards set for the purpose.

**Article 32 – Marketing**

The marketing of breastmilk substitutes and complementary foods for girls and boys up to two years old shall abide by the goals and technical requirements established in this Regulation and by the rules on content of informational and advertising materials.

### **Article 33 – Products [Scope]**

The following products shall be subject to the marketing rules, within the national territory:

1. Breastmilk substitutes, which are foods marketed or presented as total or partial replacement of breastmilk.
2. Infant formulas, milk or non-milk based complementary foods, including complementary foods that are marketed or indicated as suitable to partially or totally replace breastmilk, with or without modification.
3. Includes feeding bottles, teats and dummies.

## **CHAPTER II PACKAGING AND LABELLING**

### **Article 34 – Relevance of breastfeeding**

The Ministry of Health shall adopt the appropriate measures to ensure that breastmilk substitutes and similar products, both national and imported, adapt the information on the use of said products in such a way as not to lead to the abandonment of breastfeeding.

### **Article 35 – Labeling of breastmilk substitutes**

The label of breastmilk substitutes shall be in Spanish language and contain the following information:

- a) The commercial name [brand name] of the product.
- b) The ingredients, excipient and/or additives (indicating their Codex Alimentarius code, if appropriate).
- c) The composition and analysis of the product, including the specific origin of proteins, fats and others. If the product contains less than 1 milligram of iron per 100 kilocalories, the label shall state visibly “Requires additional iron”.
- d) The necessary storage conditions.
- e) The batch number and date of expiry, taking into account climatic and storage conditions.
- f) Instructions for preparation, hygienic measures and the age group for which the product is indicated.
- g) A legible printed inscription, printed close to the name of the product, which states: **IMPORTANT WARNING: “BREASTMILK IS THE BEST FOOD FOR INFANTS.”**
- h) Health registration number.
- i) Name and address of the manufacturer. In the case of imported products, the name and address of the importer, which may appear on an additional label.

### **Article 36 - Restrictions**

Labels of breastmilk substitutes or industrialized infant foods shall not contain information that may encourage the use of a feeding bottle, nor any of the following:

1. Pictures of girls or boys.

2. Illustrations, photos, text or images of toys or humanized shapes of animals, vegetables or objects that may idealize the product or cause confusion regarding its properties.
3. Expressions such as “maternalized milk”, “humanized milk” or any similar expression, or so-called health claims of the product.

#### **Article 37 – Labeling of feeding bottles and others**

Labels of feeding bottles, dummies and teats shall not contain any information that may encourage their use, nor pictures of girls and boys, nor images that may idealize their use.

### **CHAPTER III INFORMATION**

#### **Article 38 – Information on feeding a girl or boy**

The Ministry of Health, through its technical and executive departments, shall provide mothers, families and the community in general with objective, complete and consistent information on appropriate feeding of girls and boys during the first years of life.

#### **Article 39 – Limitations on information to health workers**

The information on products within the scope of this Regulation that manufactures and distributors provide to health workers in public and private establishments responsible for the care of mothers and girls or boys shall be limited to scientific facts proven by science-based medicine and shall not state nor create a belief that bottle feeding is equivalent or superior to breastfeeding.

#### **Article 40 – Information and educational material**

Information and educational material, whether printed, audio or visual, dealing the feeding of infants, girls or boys up to two years old, intended for the general public and especially for mothers, shall include information on the following matters:

1. The superiority and benefits of breastfeeding.
2. The importance of [adequate] nutrition of the future mother, her physical and psychological preparation for breastfeeding and maintenance thereof.
3. The negative impact on breastfeeding of introducing partial bottle-feeding.
4. The difficulties that may arise from a decision not to breastfeed the girl or boy.
5. When such material refers to bottle-feeding of infants it shall include the following information:
  - The cost of bottle-feeding.
  - The social implications of its use.
  - The health risks it entails for the baby.

#### **Article 41 – Requirements for information and educational materials**

Information, educational, advertising or any other material intended for dissemination and/or marketing of foods for pregnant women, lactating mothers and breastmilk substitutes and

complementary foods for girls and boys up to two years old shall abide by the following requirements:

1. Shall not contain images of girls and boys.
2. Shall not contain illustrations, photos, text or images of toys or humanized shapes of animals, vegetables or objects that may idealize the product or cause confusion regarding its properties.
3. Shall not contain pictures of health professionals or any conventional symbol that may suggest that the products are recommended by a health authority.
4. Shall contain information on the importance of hygienic practices for the preparation of the product as well as the cleanliness of the person responsible for preparing the product.

#### **Article 42 – Prohibitions**

It shall be prohibited for manufacturers or distributors to directly or indirectly donate equipment, services or information and educational materials about products within the scope of this Regulation.

#### **Article 43 – Control and monitoring of information and educational materials**

The Ministry of Health, through its technical and executive departments, and the Regional Health Directorates, shall control and monitor information and educational materials produced or edited about feeding of infants, boys and girls, up to the age of 24 months and intended for pregnant women and breastfeeding mothers. Such materials shall comply with the rules on infant and maternal nutrition and with the Infant Feeding Regulations of the Ministry of Health, in order to be used within the national territory.

## **CHAPTER IV ADVERTISING**

#### **Article 44 - Advertising**

There shall be no advertising or any other form of promotion aimed at the general public and particularly at mothers for products recognized as breastmilk substitutes and/or products that promote the use of bottle-feeding.

#### **Article 45 - Prohibition**

It shall be prohibited to give samples of said products to any person for purposes of promotion. This provision shall be applicable in all healthcare facilities, pharmacies and any point of distribution or sale in the country.

#### **Article 46 – Messages in the media**

The Ministry of Health and INDECOPI shall monitor the content of messages disseminated through the mass media to ensure they abide by this Regulation.

The mass media shall not promote the use of breastmilk substitutes nor bottle-feeding,

directly or indirectly, through images, messages and/or texts of any kind.

**Article 47 – Advertising by companies that market industrialized infant foods, breastmilk substitutes and processed or industrialized foods**

Advertising by companies that market breastmilk substitutes and processed or industrialized foods used as complementary foods shall not lead to its use for boys and girls of less than 24 months of age, nor [should companies] promote marketing campaigns intended to discourage the practice of breastfeeding. **NEW**

## **CHAPTER V HEALTH WORKERS**

**Article 48 - Health workers**

The staff of public and private healthcare facilities responsible for mother and childcare and the persons who are particularly linked to nutrition of mothers and infants shall abide by the following rules:

1. Not pass on samples of infant formulas or samples of utensils for their preparation or use.
2. Not accept and/or intervene personally to receive samples of formulas and breastmilk substitutes for purposes of evaluation and research.
3. Not accept financial or material incentives offered by manufacturers or distributors with the aim of promoting breastmilk substitutes and products that encourage the use of feeding bottles.

**Article 49 – Restrictions on health workers**

Manufacturers and distributors of products within the scope of this Regulation that supply breastmilk substitutes to public or private healthcare facilities [that provide] maternal and child care shall declare that no health worker of said facilities shall receive any contribution in her/his name which may benefit her/him or serve to finance scholarships, travel, research subsidies, expenses for attending professional conferences and similar activities.

Health workers who violate this provision are liable to be sanctioned according to the seriousness of the fault and their respective [hierarchical] level.

## **CHAPTER VI RESTRICTIONS**

**Article 50 - Personnel**

Public or private healthcare facilities in the country shall not be permitted to employ personnel provided or paid by manufacturers or distributors of products within the scope of this Regulation.

**Article 51 – Restriction on companies marketing that promotes breastmilk substitutes**

Breastmilk substitutes and industrialized infant foods distributors and marketing companies shall not, directly or indirectly, promote the consumption of these products to pregnant

women, mothers and fathers of boys and girls up to the age of 24 months. **NEW**

**Article 52 – Demonstrations of preparations**

Demonstrations of feeding with industrially manufactured preparations shall be individual and addressed exclusively to mothers and members of families that must use them.

**Article 53 – Purchase of substitutes**

The small quantities of breastmilk substitutes that are needed for a minority of newborns and infants in maternity services and hospitals shall be purchased through the regular channels and not be acquired through free supplies.

**Article 54 – Prohibition of donations or low-priced sales**

Donations or low-priced sales of breastmilk substitutes and other products considered in this Regulation to public or private institutions for newborn or infant care shall be banned. Only the highest authority of a healthcare facility responsible for maternal and child care shall be allowed to make a direct written request for donations, with due technical substantiation justifying its use and guaranteeing its provision only during the period that an explicitly identified girl or boy may need it.

This ban also covers pharmacies and points of sale.

**Article 55 – Exception for donated equipment and material**

Equipment and materials donated to healthcare facilities, after receiving their authorization, shall bear only the name or logo of the donating company, with no reference to text or images of any commercial product or line of products within the scope of this Regulation.

## **TITLE FOUR**

### **VIOLATIONS, SAFETY MEASURES AND SANCTIONS**

**Article 56 – Institutional responsibility**

The Ministry of Health, through its competent departments and the Regional Health Directorates, shall apply national health regulations as regards safety, violations and sanctions, in the area of quality, safety and health registration.

**Article 57 – Sanctions and safety measures for marketing and distributing companies, pharmacies and points of sale**

Persons who violate this Regulation shall be subject to sanctions that shall be applied progressively by the authorities listed in the preceding article, according to the seriousness and frequency of violations, after receiving a technical opinion from the General Directorate for Health of People. Sanctions are:

1. Written admonition.
2. Fine and temporary suspension of the marketing of a product or products for up to thirty (30) days.

3. Fine and definitive suspension of the marketing of a product or products.
4. Fines referred to in paragraphs 2 and 3 above shall be applied, starting with 10 Tributary Tax Units (10 UIT) as a minimum and 50 Tributary Tax Units (10 UIT) as a maximum.

Income from fines shall be allocated to activities to promote, protect and support breastfeeding carried out by the Ministry of Health through the corresponding technical department.

#### **Article 58 – Violations of advertising rules**

The procedure to impose sanctions for violations of the rules on advertising contained in this Regulation shall be arranged with the Commission on Repression of Unfair Competition of INDECOPI, in accordance with the regulations in force. For this purpose, the entities mentioned in Article 56 shall submit their pertinent denunciations to said Commission.

#### **Article 59 – Communicating violations**

The Ministry of Health, through its competent departments and the Regional Health Directorates, when it has been informed of a violation of this Regulation, shall communicate with the appropriate authorities for the imposition of the corresponding sanctions.

#### **Article 60 – Assistance from [other] authorities**

The judicial, political and administrative authorities shall provide the assistance that the health authority may require in order to ensure compliance with this Regulation and shall, for that purpose, resort to the powers provided in the respective legislation.

#### **Article 61 – Sanctions [imposed] on health workers**

Staff of public and private healthcare facilities responsible for maternal and child care shall be subject to administrative sanctions for non-compliance with [the provisions of] this Regulation, in accordance with procedures established in the corresponding institutional legal provisions, without prejudice to any criminal charges that may apply according to the seriousness of the case.

## **COMPLEMENTARY, TRANSITORY AND FINAL PROVISIONS**

**First** – A Multisectoral National Committee for Promotion and Protection of Breastfeeding shall be established by ministerial resolution, with the aim of contributing towards the fulfillment of policies for the protection of exclusive breastfeeding during the first six months of life of all boys and girls, as a worldwide public health recommendation, as well as towards the monitoring of use of appropriate harmless complementary foods, while recommending to continue breastfeeding up to 24 months of age.

**Second** – Within thirty (30) days of the approval of this Regulation by a Resolution of the Ministry of Health, the Form for Monitoring Breastfeeding and Complementary Feeding shall be approved.

**Third** – The provisions necessary for the enforcement of this Regulation shall be approved by a resolution of the Ministry of Health.

**Fourth** – Within six (6) months the corresponding companies shall adapt the labels referred to in this Regulation, according to the rules established therein.

**Fifth** – The Ministry of Health shall establish prohibitions relating to ingredients, inputs, additives and others, based on evidence of risks for public health, in accordance with prevailing health rules.

**Sixth** - For purposes of implementation of this Regulation, the Annex “Definitions” shall be taken into account and shall be an integral part of this Regulation.

## **ANNEX DEFINITIONS**

*(In the original Spanish alphabetical order)*

### **Complementary feeding**

The process of introduction of additional foods different from breastmilk, which is started as of six months age.

### **Homemade food**

A food prepared at home, usually from fresh natural produce.

### **Processed food**

A food made of raw materials that have undergone changes through industrial processing. It is usually packaged for consumption and use in complementary feeding of girls and boys from 6 to 24 months.

### **Complementary infant food**

Any milk-based or not milk-based manufactured food that satisfies the requirements to complement breastmilk or local preparations intended for infants [infant formula] with the purpose of satisfying their nutritional needs.

### **Community health worker**

[Health] promoters, traditional birth attendants, pastoral [religious] health workers who carry out preventive health activities and health promotion and contribute towards access to health for a large percentage of Peruvians.

### **Marketing**

Refers to activities of promotion, sales, distribution, advertising, public relations and information services related to the products that are the subject of this Regulation.

### **Breastfeeding Committee**

A multidisciplinary team of pediatricians, nurses, nutritionists, gynecologists, obstetricians, neonatologists, social workers and others, with the purpose of ensuring compliance with the Ten Steps Towards Successful Breastfeeding and monitoring compliance with the International Code of Marketing of Breastmilk Substitutes and the Peruvian Regulation on Infant Feeding.

### **Nutritional advice**

Activity through which specific and necessary information is provided, adjusted to the local reality, so that the user mother can make her own informed decisions on her food and nutrition and that of a girl or boy from 0 to 24 months.

### **Distributor**

Any person, company or other entity in the public or private sector which is directly or indirectly involved in the distribution, at wholesale or retail level, of any of the products within the scope of this Regulation.

**Container**

Any recipient or packaging that contains and is in contact with the products that are the subject of this Regulation for their sale in units.

**Label**

Any tag, symbol, brand, image or other descriptive or graphic matter, printed, embossed, attached to a container of any of the products within the scope of this Regulation.

**Nutritional evaluation**

The health activity to determine the nutritional status of persons or users of the service. Includes anthropometric, biochemical and food consumption evaluations.

**Manufacturer**

Any natural or legal person in the public or private sector that manufactures the products included in this Regulation, either directly or through an entity controlled by or under contract with it.

**Follow-up formula**

A milk or similar food indicated or otherwise presented as suitable for infants, small girls and boys over six months, formulated industrially in accordance with the requirements of national standards and those of the Codex Alimentarius.

**Infant formula or preparation for infants**

A breastmilk substitute product formulated industrially to satisfy the nutritional needs of infants from birth and adapted to their physiological characteristics, including special formulas, in accordance with the requirements of national standards and those of the Codex Alimentarius.

**Breastfeeding support group**

A group of voluntary pregnant women and/or breastfeeding women who meet periodically for a certain time to receive information, to reflect and to support each other mutually in breastfeeding. It has a coordinator who is a mother with own positive experience of breastfeeding.

**Exclusive breastfeeding**

Feeding an infant with mother's milk exclusively, without the addition of water, juice, tea or other liquids or foods.

**Optimal breastfeeding**

The practice of exclusive breastfeeding for the first six months of life followed by the provision of appropriate safe complementary foods while continuing to breastfeed up to the age of two years.

**Infant**

A girl or boy from 0 to 24 months of age.

**Breastmilk**

The natural food to satisfy the nutritional needs of a girl or boy. Suction is a prime factor for adequate production of breastmilk. It includes exclusive breastfeeding during the first six months of life, as well as healthy and appropriate complementary feeding while maintaining

breastfeeding up to two years of age.

**Guidelines for infant nutrition**

A set of recommendations about the nutritional content that should be developed in educational activities and communications about nutrition.

**Samples**

Single or small quantities of a product provided without cost.

**Marketing personnel**

Individuals [natural persons] who carry out marketing activities for one or more products under the scope of this Regulation.

**Health workers**

Health professionals or non-professionals who work in public or non-public healthcare facilities, including adequately trained volunteers.

**Breastmilk substitutes**

Any food being marketed or presented as a partial or total replacement for breastmilk, including all formulas, whole, evaporated, modified, powdered, condensed, follow-up and similar milks, as well as commercial preparations of non-milk origin.

**Other liquids or preparations**

Foods prepared with cereals, oral glucose solutions, oral rehydration salts or other strictly medical solutions.

(7,480 words in original text)

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