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REGULATION OF FOOD FOR NURSING AND CHILDREN IN THEIR FIRST INFANCY IN BRAZIL: ELEMENTS FOR REFLECTION

Regulação de alimentos destinados a lactentes e crianças na primeira infância no brasil: elementos para reflexão

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ABSTRACT

Exclusive breast feeding up to six months and complementary up to two years old is recommended by the World Health Organization. However, several factors contribute to early weaning, including over-advertisement of breast-feeding substitutes and the influence of health professionals involved in the process. Understanding that this is a public health issue due to the many problems caused by this process in the health of the children involved, this article analyzes aspects of the design and implementation of regulatory frameworks in the field of promotion and exposure of foods for nursing and children in their first infancy in order to contribute to the reflection on the challenges present in the process of regulation of these products in Brazil.

Keywords

Breastfeeding; First Childhood Food; Brazilian Legislation on Food; Milk and Substitutes; Health Professionals.

RESUMO

A amamentação exclusiva até os seis meses e complementar até os dois anos de idade é recomendação da Organização Mundial da Saúde. Entretanto, diversos fatores contribuem para o desmame precoce, inclusive a propaganda excessiva dos alimentos substitutos do leite materno e a influência dos profissionais de saúde envolvidos no processo. Entendendo que se trata de uma questão de saúde pública devido aos muitos problemas acarretados por esse processo na saúde das crianças envolvidas, este artigo analisa aspectos do desenho e da implementação de marcos regulatórios no campo da promoção e exposição de alimentos destinados a lactentes e crianças na primeira infância, buscando contribuir para a reflexão sobre os desafios presentes no processo de regulação desses produtos no Brasil.

Palavras-Chave

Aleitamento Materno; Alimentos para a Primeira Infância; Legislação Brasileira sobre Alimentos; Leites e Substitutos; Profissionais da Saúde.

Introduction

According to the World Health Organization (WHO), there are three status related to breastfeeding: exclusive breastfeeding (when the infant feeds only on breast milk), predominant breastfeeding (when the infant feeds on breast milk, but also receives water, teas and juices) and breastfeeding (when the infant feeds on breast milk in addition to other milks and other foods)¹. According to the Ministry of Health (2009),

[...] in the first days, breast milk is called colostrum, which contains more protein and less fat than mature milk, that is, milk secreted from the seventh to the tenth postpartum day. Cow's milk, in turn, has many more proteins than human milk and these proteins are different from those of breast milk. The main protein in breast milk is lactalbumin and cow's milk is casein, which is difficult for the human species to digest².

Breastfeeding, in addition to supplying the infant with antibodies (IgA, IgG and IgM, among others) that help the body to protect itself against the microorganisms in the environment, also increases the emotional bonds between mother and child³. Sampaio and collaborators⁴ emphasize the importance of breastfeeding in the first hours of life and skin-to-skin contact between mother and baby. According to the authors, countries with lower breastfeeding rates in the first hours had a higher rate of neonatal mortality.

In addition to the well-known benefits brought by breast milk to the baby - decreased diarrhea, respiratory infections, allergies, hypertension, diabetes and obesity⁵ -, there are also reported decreases in the prevalence of breast cancer in the mother⁶ and a reduction in the incidence of unwanted pregnancies during lactation

¹MINISTÉRIO DA SAÚDE - MS. *Guia alimentar para crianças menores de 2 anos*. Ministério da Saúde, Organização Pan-Americana da Saúde. - Brasília-DF: Editora do Ministério da Saúde, 2005.

²MINISTÉRIO DA SAÚDE - MS. Secretaria de Atenção à Saúde. Departamento de Atenção Básica. *Saúde da criança: nutrição infantil: aleitamento materno e alimentação complementar*. Brasília-DF: Editora do Ministério da Saúde, 2009.

³*Id. Ibid.*

⁴SAMPAIO, Ádila Roberta Rocha; BOUSQUAT, Aylene; BARROS, Claudia. Skin-to-skin contact at birth: a challenge for promoting breastfeeding in a "Baby Friendly" public maternity hospital in northeast Brazil. *Epidemiol. Serv. Saude*, Brasília, v. 15, n. 2, p. 281-290, jun. 2016. Available at: https://www.scielo.br/pdf/ress/v25n2/en_2237-9622-ress-25-02-00281.pdf. <https://doi.org/10.5123/s1679-49742016000200007>.

⁵MINISTÉRIO DA SAÚDE - MS. Secretaria de Atenção à Saúde. Departamento de Atenção Básica. *Saúde da criança: nutrição infantil: aleitamento materno e alimentação complementar*, cit.

⁶GRAY, R. H. *et al.* Risk of ovulation during lactation. *Lancet*, v. 335, n. 8680, p. 25-29, Jan. 1990. [https://doi.org/10.1016/0140-6736\(90\)90147-W](https://doi.org/10.1016/0140-6736(90)90147-W).

period⁷. Black and collaborators⁸ emphasize that the risks of death from pneumonia and diarrhea are lower in children who receive exclusively breast milk in the first half-year of life.

Although several studies have demonstrated the benefits of breastfeeding and this practice is described as the first step towards healthy eating, exclusive breastfeeding for six months and continued for two years is no longer universal⁹. It is known that only 10% of babies receive exclusively breast milk in the first six months of life¹⁰.

The causes of early weaning are diverse and involve historical, cultural, social and individual factors, such as those determined by health systems, working conditions for women, family support, individual conditions for women and infants and advertising of products intended for early childhood^{11,12}. In addition to these factors, a study demonstrated a significant association between the performance of prenatal care in a Basic Health Unit and the receipt of information about breastfeeding in the first hour of life, as well as between the type of delivery and the existence or not of contact skin to skin between mother and baby. It is worth mentioning that no mother who performed the cesarean delivery was able to have contact with the baby right after it¹³.

Piedras¹⁴, when analyzing children's food consumption, points to the dual role played by the media, through marketing and advertising, since, on the one hand, they offer consumers information about the products available in a given market, but, on the other, they also promote foods that are often unhealthy at

⁷GRAY, R. H. *et al.* *op. cit.*

⁸BLACK, Robert E.; MORRIS, Saul S.; BRYCE, Jennifer. Child survival I: where and why are 10 million children dying every year? *Lancet*, v. 1, n. 8334, p. 1148-1151, 1983. Available at: https://www.who.int/maternal_child_adolescent/documents/pdfs/lancet_child_survival_10mill_dying.pdf.

⁹AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. Promoção comercial dos produtos abrangidos pela NBCAL. *Norma Brasileira de Comercialização de alimentos para lactentes e crianças de 1ª infância, bicos, chupetas e mamadeiras*. Brasília-DF: ANVISA, 2006. Available at: http://www.associacaoportella.com.br/download/1_nbcalf.pdf.

¹⁰MINISTÉRIO DA SAÚDE. *Portaria n. 2.051, de 8 de novembro de 2001*. Available at: http://bvsms.saude.gov.br/bvs/saudelegis/gm/2001/prt2051_08_11_2001.html#:~:text=de%201992%2C%20resolva%3A%20Art.,que%20dela%20C%3%A9%20parte%20integrante. Accessed on: 13 Oct. 2020.

¹¹CYRILLO, Denise Cavallini. *et al.* Duas décadas da Norma Brasileira de Comercialização de Alimentos para Lactentes: há motivos para comemorar? *Rev Panam Salud Publica*, v. 25, n. 2, p. 134-140, 2009. Available at: <https://scielosp.org/article/rpsp/2009.v25n2/134-140/pt/>.

¹²ROLLINS, Nigel C. *et al.* Why invest, and what it will take to improve breastfeeding practices? *Lancet*, v. 387, n. 10017, p. 491-504, Jan. 2016. [https://doi.org/10.1016/S0140-6736\(15\)01044-2](https://doi.org/10.1016/S0140-6736(15)01044-2).

¹³SAMPAIO, Ádila Roberta Rocha; BOUSQUAT, Aylene; BARRROS, Claudia. *op. cit.*

¹⁴PIEDRAS, Elisa Reinhardt. Vulnerabilidade ou resistência? Um panorama da questão do consumo infantil de alimentos permeado pelo marketing e a mídia. *CMC*, v. 10, n. 29, p. 143-159, 2013. Available at: <http://revistacmc.espm.br/index.php/revistacmc/article/view/304/pdf>.

points of sale. Several authors^{15,16,17,18,19} have discussed advertising and marketing strategies in the area of infant feeding and its impact on the food consumption profile, emphasizing that the consumer's right to information cannot be overwhelmed by market interests.

The concern with the role of advertising in modulating the consumption behavior of users is pointed out by the Consumer Protection Code (Law n. 8,078/1990²⁰), which prohibits any type of misleading or abusive advertising and provides, in Article 37, that:

Art. 37. Any misleading or abusive advertising is prohibited.

§ 1st Any form of information or communication of an advertising nature, wholly or partially false, or, by any other means, even by omission, capable of misleading the consumer regarding the nature, characteristics, quality, quantity, properties, origin, price and any other data about products and services.

§ 2º Discriminatory advertising of any nature is abusive, among others, that incites violence, exploits fear or superstition, takes advantage of the child's lack of judgment and experience, disrespects environmental values, or is capable of inducing consumer to behave in a way that is harmful or dangerous to their health or safety.

§ 3 For the purposes of this code, advertising is misleading by omission when it fails to report on essential data of the product or service.

¹⁵MARTINS, Bianca Ramos; ARAÚJO, Inesita Soares de; JACOB, Silvana do Couto. A propaganda de alimentos: orientação, ou apenas estímulo ao consumo? *Ciência & Saúde Coletiva*, v. 16, n. 9, p. 3873-3882, 2011. Available at: <https://www.scielo.org/pdf/csc/2011.v16n9/3873-3882>.

¹⁶HENRIQUES, Patrícia; DIAS, Patrícia Camacho; BURLANDY, Luciene. A regulamentação da propaganda de alimentos no Brasil: convergências e conflitos de interesses. *Cad. Saúde Pública*, Rio de Janeiro, v. 30, n. 6, p. 1219-1228, jun., 2014. Available at: <https://www.scielo.br/pdf/csp/v30n6/0102-311X-csp-30-6-1219.pdf>. <https://doi.org/10.1590/0102-311X00183912>.

¹⁷NASREDDINE, L.; TAKTOUK, M.; DABBOUS, M.; MELKI, J. The extent, nature, and nutritional quality of foods advertised to children in Lebanon: the first study to use the WHO nutrient profile model for the Eastern Mediterranean Region. *Food & Nutrition Research*, n. 63, Feb. 2019. <http://dx.doi.org/10.29219/fnr.v63.1604>.

¹⁸THEURICH, Melissa A. et. al. Commercial complementary food use amongst European infants and children: results from the EU Childhood Obesity Project. *Eur J Nutr.*, v. 59, n. 4, p. 1679-1692, Jun. 2020. <https://doi.org/10.1007/s00394-019-02023-3>.

¹⁹SMITH, Rachel; KELLY, Bridget; YEATMAN, Heather; BOYLAND, Emma. Food marketing influences children's attitudes, preferences and consumption: a systematic critical review. *Nutrients*, v. 11, n. 4, p. 875, Apr. 2019. <https://doi.org/10.3390/nu11040875>.

²⁰BRASIL. *Lei n. 8.078, de 11 de setembro de 1990*. Dispõe sobre a proteção do consumidor e dá outras providências. Available at: http://www.planalto.gov.br/ccivil_03/leis/l8078compilado.htm. Accessed on: 13 Oct. 2020.

The same concern can be observed in the Brazilian Advertising Self-Regulation Code²¹, which indicates that an advertisement should not exploit the consumer's lack of experience or knowledge or benefit from its credulity. Annex H of the same code emphasizes, which deals with advertising for food, soft drinks, juices and similar drinks, the need for advertising to refrain from encouraging or highlighting excessive consumption, or even, to present situations that encourage the excessive consumption of a product.

Abrantes and Tabai²², analyzing the adequacy of infant formula labels to Brazilian legislation, observed the existence of problems such as the absence of warnings required by the Ministry of Health on labels, as well as the use of inappropriate phrases, expressions and illustrations. The authors warn of the harmful potential of inadequate labeling in infant formulas, since it can stimulate early weaning by presenting breastmilk substitutes as ideal products for infant feeding.

In addition to breastfeeding, the introduction of new foods slowly and gradually after six months of age is part of the ten steps to healthy eating defined by the Infant Feeding Guide. Huh and collaborators²³ demonstrated that, in children who were not breastfed or who were breastfed until the age of four months, the introduction of solid foods increases the risk of developing obesity at the age of three, which is not the case for children who received only breast milk for four months or more.

Thus, the number of studies that document the concern of scientists and public health authorities about early weaning and the indiscriminate use of breastmilk substitutes has grown in recent years^{24, 25, 26}. Although there are indications that the substitution of breast milk for other milk is an old practice²⁷, the decrease in breastfeeding has led to an increase in the production and

²¹ CONSELHO NACIONAL DE AUTORREGULAMENTAÇÃO PUBLICITÁRIA - CONAR. *Código Brasileiro de Autorregulamentação Publicitária* Available at: <http://www.conar.org.br/codigo/codigo.php>. Accessed on: 10 Jul. 2019.

²² ABRANTES, Viviane Regina Santos; TABAI, Kátia Cilene. Fórmulas para o público infantil: a promoção comercial nas rotulagens de fórmulas infantis e sua adequação com a legislação vigente. *Oikos: revista brasileira de economia doméstica, Viçosa*, v. 24, n. 2, p. 21-37, 2013. Available at: <https://periodicos.ufv.br/oikos/article/view/3663/1937>.

^{23,24} HUH, Susanna Y. et al. Timing of Solid Food Introduction and Risk of Obesity in Preschool-Aged Children. *Pediatrics*, v. 127, n. 3, p. e544-551, Mar. 2011. <https://doi.org/10.1542/peds.2010-0740>.

²⁴ BLACK, Robert E.; MORRIS, Saul S.; BRYCE, Jennifer. *op. cit.*, p.1148-1151.

²⁵ LUTTER, Chessa K. The International Code of Marketing of Breast-milk Substitutes: lessons learned and implications for the regulation of marketing of foods and beverages to children, *Public Health Nutrition*, v. 16, n. 10, p. 1879-1884, Oct. 2013. [10.1017/S1368980012004235](https://doi.org/10.1017/S1368980012004235).

²⁶ VICTORA, Cesar G. et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *Lancet*, v. 387, n. 10017, p. 475-490, Jan. 2016.

²⁷ REA, Marina Ferreira. Breast-milk substitutes: past and present. *Rev. Saúde Pública*, v. 24, n. 3, p. 241-249, 1990. Available at: <https://www.revistas.usp.br/rsp/article/view/23740/25776>. <https://doi.org/10.1590/S0034-89101990000300011>.

commercialization of formulas that replace milk in the feeding of infants and children in early childhood²⁸.

In this way, the objective of the article is to discuss the course of regulation of the marketing of milk for infants and children in early childhood in Brazil, describing the historical background, trends and main challenges.

I. Breast milk substitutes: historical background

The substitution of breast milk for other foods has been a common practice since the Neolithic Period and, since then, it has undergone numerous changes, according to the customs and circumstances of each people and each time²⁹. According to the Holy Bible, the Hebrews and Egyptians resorted to wet nurses when breastfeeding was prevented by the real mother. Later, Roman philosophers believed that, in addition to milk being the best food, breastfeeding strengthened the bonds of affection; however, the mixture of honey and cow's milk was used on the first day, and breastfeeding was only started after the 20th day. In Greece of the Middle Ages, according to Avicenna, the first food introduced was also honey and breastfeeding was only carried out days later. These practices aimed to despise colostrum, as it was believed that it was not good for the baby's health³⁰. In France, in 1668, changes occurred in relation to babies who could not be breastfed by their mothers, and there was the substitution of wet nurses for the introduction of porridge and other foods.

In the beginning of the 18th century, there was a decrease in infant mortality in England due to the breastfeeding of babies in the first days of life, which was attributed to the ingestion of colostrum³¹. However, the recommendation of the use of cow's milk to replace breast milk by the English pediatrician Michael Underwood³² dates from 1784. Still in the 18th century, with the beginning of the Industrial Revolution, there was a paradigm shift regarding infant feeding. With the migration of women from the countryside to the cities, the consequent change in the way of obtaining food and the exploitation of human labor, women were forced to work. Along with this, the lack of techniques for preserving milk meant that the introduction of new foods occurred earlier and earlier. Thus, at the end of the 19th century, some authors reported high rates

²⁸CASTILHO, Sílvia Diez; BARROS FILHO, Antônio de Azevedo. The history of infant nutrition, *Jornal de Pediatria*, v. 86, n. 3, p. 180-189, 2010. Available at: https://www.scielo.br/pdf/jped/v86n3/en_a04v86n3.pdf. <http://dx.doi.org/10.2223/JPED.1984>.

²⁹*Id. Ibid.*

³⁰*Id. Ibid.*

³¹*Id. Ibid.*

³²BARNES, L. A. History of infant feeding practices. *Amer. J. clin. Nutr.*, v. 46, n. 1, p. 168-170, 1987. <http://dx.doi.org/10.1093/ajcn/46.1.168>.

of malnutrition and mortality related to decreased breastfeeding³³. In that same period, pasteurized, condensed and evaporated milk was created, used as a substitute for breast milk. However, all had disadvantages and did not provide enough nutrients for the adequate growth of infants. According to Rea, Platt reported that, in 1872, children showed unsatisfactory growth due to the use of condensed milk and some warnings were imposed. In 1894, in Sweden, there was a proposal to insert the word “skimmed” in the packaging of this type of milk, which characterized the first initiative to insert warning phrases for the protection of the health of infants and children³⁴. In 1867, Leibig developed the first marketable infant formula, consisting of wheat flour, malt and potassium bicarbonate, which should be mixed with hot milk. In 1874, the “first complete artificial formula for infant feeding” was launched, which contained powdered milk, wheat flour and sugar to be added in water; however, this mixture was not well accepted, since it used contaminated water (the chlorination of the water started only in 1880). In 1883, the evaporation process of goat milk³⁵ was developed and, in 1885, the composition of breast milk was described and its low percentage of proteins in relation to cow’s milk was proven. While food was improving, in 1845 glass bottles and rubber nipples were patented³⁶.

At the beginning of the 20th century, the use of boiled milk and its diluted forms increased, as did the addition of cereals to evaporated milk and the mixture of syrups to pasteurized milk. Even then, the food industry grew and began to strengthen the bond with health professionals in order to increase the demand for breast milk substitutes³⁷. Due to this relationship with brands, doctors helped to institutionalize the adoption of powdered milk and its indiscriminate use has increased, including in maternity hospitals and hospitals, throughout the century³⁸.

In addition, with the social changes resulting from the use of the contraceptive pill and the feminist movement and aiming to increase profit, the industry started to massify the promotion of substitutes, which, once again, resulted in decreased breastfeeding and the introduction of new food early. With the creation of more soluble recipes, powder formulas are currently dominant on the³⁹market.

³³CASTILHO, Sílvia Diez; BARROS FILHO, Antônio de Azevedo. *op. cit.*, p. 180-189.

³⁴REA, Marina Ferreira. *op. cit.*

³⁵*Id. Ibid.*

³⁶CASTILHO, Sílvia Diez; BARROS FILHO, Antônio de Azevedo. *op. cit.*, p. 180-189.

³⁷GREINER, Ted. *The planning, implementation and evaluation of a project to protect, support and promote breast-feeding in the Yemen Arab Republic*. Thesis for: PhD. International Nutrition, Cornell University, Advisor: Michael Latham, July 1983. <http://dx.doi.org/10.6084/M9.FIGSHARE.1331103>.

³⁸REA, Marina Ferreira. *op. cit.*

³⁹CASTILHO, Sílvia Diez; BARROS FILHO, Antônio de Azevedo. *op. cit.*, p. 180-189.

II. Regulation of the marketing of breastmilk substitutes: historical background

According to Jelliffe⁴⁰, the Industrial Revolution started to influence the behavior of women regarding infant feeding, as they migrated from the countryside to the cities. The same author report, in a pioneering way, how the influence of industry marketing practices, together with the new customs of the West, influenced the gradual substitution of breastfeeding with artificial formulas in developing countries and gives this phenomenon the name “commerciogenic malnutrition”.

According to Sant’Anna⁴¹, “advertising, among other communication strategies, is an important tool in the production flow process. It is able to influence and modify habits, regardless of the reasons that lead to the purchase.”

The role of advertising in influencing choices on breastfeeding had been discussed since the 1960s⁴², when health professionals began to warn of the relationship between the advertising of breast milk substitutes and early weaning. In 1970, the United Nations (UN) promoted a discussion on the decline of breastfeeding and the commercial practices of infant foods, bringing together its agencies, pediatricians and industry representatives. An interview published in 1973 in an English magazine with two highly experienced pediatricians who worked in developing countries alerted public opinion to issues related to the decline in breastfeeding and the increase in child malnutrition⁴³; this article triggered the start of a campaign to change the industry’s promotional practices. Subsequently, the report *The Baby Killer*, translated into German as “Nestlé kills babies”, increased the journalistic repercussion of the topic⁴⁴. With increasing social pressure in the following years, WHO and the United Nations Children’s Fund (Unicef) organized in 1979 an international meeting on Infant and Infant Child Feeding, which brought recognition of the need for a code that would control inadequate infant food marketing practices.

Given this context, in order to promote awareness and greater adherence to the practice of exclusive breastfeeding, society sought to structure and standardize the marketing of milk and early childhood foods, since the advertising, promotion

⁴⁰JELLIFFE, D.B. Commerciogenic malnutrition? *Food Technol.*, v. 25, n. 2, p. 153, 1971. <https://doi.org/10.1111/j.1753-4887.1972.tb04042.x>.

⁴¹ROCHA JÚNIOR, Ismael; GARCIA, Luiz Fernando Dabul; SANT’ANNA, Armando. *Propaganda: teoria, técnica e prática*. 7. ed. São Paulo: Pioneira Thompson Learning; 2001.

⁴²MINISTÉRIO DA SAÚDE - MS. Secretaria de Atenção à Saúde. Departamento de Ações Programáticas Estratégicas. *A legislação e o marketing de produtos que interferem na amamentação: um guia para o profissional de saúde*. Brasília-DF: Editora do Ministério da Saúde, 2009. 114 p. (Série A. Normas e Manuais Técnicos).

⁴³MULLER, M. *O matador de bebês*. Campinas: Cemicamp, 1981, *apud* MINISTÉRIO DA SAÚDE - MS. Secretaria de Atenção à Saúde. Departamento de Ações Programáticas Estratégicas. *A legislação e o marketing de produtos que interferem na amamentação: um guia para o profissional de saúde*, *cit*.

⁴⁴SOKOL, E.J. *Em defesa da amamentação: manual para implementação do Código Internacional de Mercadização de Substitutos do Leite Materno*. São Paulo: IBFAN Brasil, 1999.

and exhibition of these products are seen as factors that influence early weaning, which can lead to increased rates of malnutrition and infant mortality.

One of the first international efforts to regulate the marketing of breastmilk substitutes was the publication of the I International Code for the Marketing of Breastmilk Substitutes in 1981. This document had as its main objective the provision of safe and adequate nutrition to infants, through the protection and promotion of breastfeeding and the regulation of commercial promotion of breast milk substitutes⁴⁵. After its launch, internationally were also published the Convention on Rights of the Child (1989)⁴⁶ and the Innocenti Declaration - On the Protection, Promotion and Support of Breastfeeding (1990)⁴⁷. In Brazil, several standards have been published for this purpose (Chart 1).

Chart 1. Brazilian rules on the marketing of infant foods

Standard	Issuing Body	Content
National Breastfeeding Incentive Program (PNIAM) - 1985	Ministry of Health	Action strategies in the areas of education and health, in the state control of advertising of infant foods and laws to protect the nursing mother ²¹
Standard for Marketing of Baby Food (NCAL) - 1988	National Health Council	It included the requirements recommended by the I International Code of Marketing of Breast Milk Substitutes.
Brazilian Standard for Marketing of Infant Food (NBCAL) - 1992	National Health Council	Modified the first and changed the requirements for coverage, commercial promotion, labeling, quality and distribution of samples.
Brazilian Standard for Marketing of Infant Food (NBCAL) - 2001/2002	Ministry of Health and Brazilian Health Regulatory Agency	Set of Brazilian standards that changed all points of the previous version.
Law n. 11,265/2006 ⁴⁸	Brazilian Health Regulatory Agency	Regulates the marketing of food for infants and children in early childhood and also of childcare and related products.

Source: Own preparation

⁴⁵ ARAUJO, Maria de Fátima Moura de *et al.* Advances in the Brazilian norm for commercialization of infant foods. *Rev. Saúde Pública*, v. 40, n. 3, p. 513-520, June 2006. Available at: https://www.scielo.br/pdf/rsp/v40n3/en_21.pdf. <https://doi.org/10.1590/S0034-89102006000300021>.

⁴⁶ UNICEF BRASIL. *Declaração dos Direitos da Criança*. Available at: <https://www.unicef.org/brazil/convencao-sobre-os-direitos-da-crianca>. Accessed on: 08 Nov. 2020.

⁴⁷ BIBLIOTECA VIRTUAL DA SAÚDE – BVSMS. *Declaração de Innocenti – Sobre a Proteção, Promoção e Apoio da Amamentação*. Available at: http://bvsm.s.saude.gov.br/bvs/publicacoes/declaracao_innocenti.pdf. Accessed on: 08 Nov. 2020.

⁴⁸ BRASIL. *Lei n. 11.265, de 3 de janeiro de 2006*. Regulamenta a comercialização de alimentos para lactentes e crianças de primeira infância e também a de produtos de puericultura correlatos. Available at: http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2006/lei/l11265.htm. Accessed on: 31 Oct. 2020.

According to Araujo⁴⁹, the Standard for Commercialization of Infant Food (NCAL), launched in 1988, was restricted to protecting the infant (child from 0 to 12 months) and, only years later, there was a need for extend the protection to breastfeeding for two years or more. Still, in 1992, the Brazilian Standard for Marketing of Baby Food (NBCAL)⁵⁰ modified the first and changed the scope, commercial promotion, labeling, quality and sample distribution requirements. According to Araujo⁵¹, the main improvements were the inclusion of powdered, pasteurized and sterilized milk and pacifiers and teats. The Brazilian Standard for the Marketing of Baby Food (NBCAL), launched in 2001/2002, mainly establishes the National Health Surveillance Agency (Anvisa) as the responsible agency and supervisor of the trade of such products. NBCAL encompasses and gathers the following ordinance and resolutions: (i) Ordinance MS n. 2,051/2001; (ii) Resolution of the Collegiate Board (RDC) n. 221/2002⁵²; and (iii) RDC n. 222/2002⁵³.

According to Ordinance MS n. 2.051/2001, infant food means “any food sold or in any way presented as a partial or total substitute for breast and/or human milk” (Art. 3, I, Annex). The same ordinance defines transition food for children in early childhood

any industrialized food for direct use or used in homemade preparation, used as a complement to breast milk or infant formulas, introduced in the feeding of infants and young children with the aim of promoting a progressive adaptation to common foods and making this food balanced and adequate to your needs, respecting your physiological maturity and your neuropsychomotor development. Such food is also called “complementary food”. Thus, it is concluded that the use of such products will replace breast milk, which may cause nutritional problems (overweight and obesity) or diseases to the child (Art. 3, II, Annex).

⁴⁹ARAÚJO, Maria de Fátima Moura de et al. *op. cit.*

⁵⁰AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. Promoção comercial dos produtos abrangidos pela NBCAL. *Norma Brasileira de Comercialização de alimentos para lactentes e crianças de 1ª infância, bicos, chupetas e mamadeiras, cit.*

⁵¹ARAÚJO, Maria de Fátima Moura de et al. *op. cit.*

⁵²AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. *Resolução da Diretoria Colegiada n. 221, de 05 de agosto de 2002.* Aprovar o regulamento técnico sobre chupetas, bicos, mamadeiras e protetores de mamilo, anexo a esta Resolução. Available at: <http://antigo.anvisa.gov.br/legislacao#/visualizar/26964>. Accessed on: 13 Oct. 2020.

⁵³AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. *Resolução da Diretoria Colegiada n. 222, de 05 de agosto de 2002.* Aprovar o Regulamento Técnico para Promoção Comercial de Alimentos para Lactentes e Crianças de Primeira Infância, constante do anexo desta Resolução. Available at: <http://antigo.anvisa.gov.br/legislacao#/visualizar/26966>. Accessed on: 13 Oct. 2020.

With the publication of Law n. 11.265/2006 and its initial regulation by Decree n. 8,552/2015⁵⁴, revoked by Decree n. 9,579/2018⁵⁵, there were advances and setbacks. This law excluded nipple protectors from the list of products whose commercial promotion is prohibited. Furthermore, it does not consider direct or indirect contact with the health professional as a commercial promotion practice and does not mention the requirements for milk of different species. Still, regarding the labeling of products, the law is more restrictive as to the images used and more flexible as to the warning phrases of bottles, teats and pacifiers⁵⁶. Other important points of the law and its decrees are the exclusion of requirements of technical-scientific information on bottles, teats and pacifiers, the change in the description of sample distribution practices, donations and sponsorships⁵⁷, the scope of infant formulas for specific dietotherapeutic needs and the inclusion of the definition of supervisory authority, among others⁵⁸.

Thus, with the publication of the two resolutions, of Ordinance MS n. 2.051/2001 and Law n. 11,265/2006, there are the legal instruments that regulate the exhibition and sale of such products in retail trade, including establishments that sell medicines (pharmacies and drugstores).

In Brazil, in addition to NBCAL, there are other instruments that aim to promote and encourage breastfeeding:

(i) Consolidation of Labor Laws⁵⁹, which describes the right to maternity and paternity leave, day care and a break to breastfeed;

⁵⁴BRASIL. *Decreto n. 8.552, de 3 de novembro de 2015*. Regulamenta a Lei n. 11.265, de 3 de janeiro de 2006, que dispõe sobre a comercialização de alimentos para lactentes e crianças de primeira infância e de produtos de puericultura correlatos. Available at: https://www.in.gov.br/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/30174522/do1-2015-11-04decreto-n-8-552-de-3-de-novembro-de-2015-30174511. Accessed on: 10 Nov. 2020.

⁵⁵BRASIL. *Decreto n. 9.579, de 22 de novembro de 2018*. Consolida atos normativos editados pelo Poder Executivo federal que dispõem sobre a temática do lactente, da criança e do adolescente e do aprendiz, e sobre o Conselho Nacional dos Direitos da Criança e do Adolescente, o Fundo Nacional para a Criança e o Adolescente e os programas federais da criança e do adolescente, e dá outras providências. Available at: http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2018/Decreto/D9579.htm#art126. Accessed on: 10 Nov. 2020.

⁵⁶MINISTÉRIO DA SAÚDE - MS. Secretaria de Atenção à Saúde. Departamento de Ações Programáticas Estratégicas. *A legislação e o marketing de produtos que interferem na amamentação: um guia para o profissional de saúde, cit.*

⁵⁷*Id. Ibid.*

⁵⁸MINISTÉRIO DA SAÚDE - MS. Secretaria de Atenção à Saúde. Departamento de Ações Programáticas Estratégicas. *A legislação e o marketing de produtos que interferem na amamentação: um guia para o profissional de saúde, cit.*

⁵⁹BRASIL. *Decreto-Lei n. 5.452, de 1º de maio de 1943*. Aprova a Consolidação das Leis do Trabalho. Available at: http://www.planalto.gov.br/ccivil_03/decreto-lei/del5452.htm. Accessed on: 13 Oct. 2020.

(ii) RDC n. 43/2011⁶⁰, RDC n. 44/2011⁶¹ and RDC n. 45/2011⁶², which establish the minimum requirements for identity, composition, quality and safety to which infant formulas for infants and follow-up formulas for infants and children in early childhood for specific diet-therapeutic needs, respectively, must comply;

(iii) Ordinance MS n. 1,459/2011⁶³, which establishes, within the scope of the National Health System (SUS), the Cegonha Network;

(iv) MS Ordinance n. 80/2011, which establishes the requirements for enabling Baby-Friendly hospitals, including joint accommodation, compliance with NBCAL standards, staff training, among other practices that encourage breastfeeding in the first hours of life under the SUS, revoked by the Ordinance n. 839/2014⁶⁴;

(v) Ordinance n. 1920/2013⁶⁵, which establishes, within the scope of SUS, the Brazilian Breastfeeding Network. The standard refers to a strategy to promote, protect and support the practice of breastfeeding in Primary Care; and

(vi) RDC n. 171/2006⁶⁶, which provides about the technical regulation for the operation of human milk banks.

III. Reflections and challenges

Although the benefits of exclusive breastfeeding until 6 months of age are widely publicized, only 37% of infants are fed exclusively with breast milk in under-developed and developing countries⁶⁷. Furthermore, in addition to full-term infants, the risk of early weaning is 1.67 higher in premature infants⁶⁸.

⁶⁰AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. *Resolução da Diretoria Colegiada n. 43, de 19 de setembro de 2011*. Dispõe sobre o regulamento técnico para fórmulas infantis para lactentes. Available at: <http://antigo.anvisa.gov.br/legislacao#/visualizar/28752>. Accessed on: 13 Oct. 2020.

⁶¹AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. *Resolução da Diretoria Colegiada n. 44, de 19 de setembro de 2011*. Dispõe sobre o regulamento técnico para fórmulas infantis de seguimento para lactentes e crianças de primeira infância. Available at: <http://antigo.anvisa.gov.br/legislacao#/visualizar/28725>. Accessed on: 13 Oct. 2020.

⁶²AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. *Resolução da Diretoria Colegiada n. 45, de 19 de setembro de 2011*. Dispõe sobre o regulamento técnico para fórmulas infantis para lactentes destinadas a necessidades dietoterápicas específicas e fórmulas infantis de seguimento para lactentes e crianças de primeira infância destinadas a necessidades dietoterápicas específicas. Available at: <http://antigo.anvisa.gov.br/legislacao#/visualizar/28727>. Accessed on: 13 Oct. 2020.

⁶³MINISTÉRIO DA SAÚDE. *Portaria n. 1.459, de 24 de junho de 2011*. Available at: http://bvsms.saude.gov.br/bvs/saudelegis/gm/2011/prt1459_24_06_2011.html. Accessed on: 13 Oct. 2020.

⁶⁴MINISTÉRIO DA SAÚDE. *Portaria n. 839, de 08 de setembro de 2014*. Available at: http://bvsms.saude.gov.br/bvs/saudelegis/sas/2014/prt0839_08_09_2014.html. Accessed on: 13 Oct. 2020.

⁶⁵MINISTÉRIO DA SAÚDE. *Portaria n. 1.920, de 05 de setembro de 2013*. Available at: http://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt1920_05_09_2013.html. Accessed on: 13 Oct. 2020.

⁶⁶AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. *Resolução da Diretoria Colegiada n. 171, de 04 de setembro de 2006*. Available at: <http://antigo.anvisa.gov.br/legislacao#/visualizar/27791>. Accessed on: 13 Oct. 2020.

⁶⁷VICTORA, Cesar G. *et al. op. cit.*, p. 475-490.

⁶⁸BENEVENUTO, Márcia Maria Benevenuto de Oliveira *et al.* Feeding patterns of Brazilian preterm infants during the first 6 months of life. *J Hum Lact.*, International Lactation Consultant Association, Charlottesville, n. 23, p. 269-274, Aug. 2007.

Boccolini ²¹ reports that the indicator of exclusive breastfeeding in Brazil, up to 6 months increased from 1986 to 2006, varying from 4.7% to 37.1%. However, despite the growing trend, rates are still below that recommended by WHO.

According to Monteiro:

Even with science proving the qualities of breast milk, the dissemination of the concept of weak milk and hypogalactia by advertising was efficient in spreading the idea of maternal incapacity in care without the medical eye and, therefore, the impossibility of adequate growth of the child without introducing the infant formula⁶⁹.

Also, according to the same author, the power exercised by health professionals over families is still widely used by the industry to advertise products intended to replace breast milk⁷⁰.

Pinheiro and collaborators⁷¹ report that the substitution of breast milk in low-risk infants is still a common practice. Although there are justifiable causes for this substitution, both from the child (galactosemia, phenylketonuria, preterm and underweight babies) and from the mother (use of drugs, medicines, smoking and infections), according to the WHO:

In most times when liquids other than breast milk are prescribed for children under 6 months, there is no scientific justification. In general, the reasons are due to the interference in the natural process of childbirth and birth, the lack of knowledge or the difficulty of offering appropriate help to the mother⁷².

The main causes and barriers that influence the replacement of breast milk and the consequent early weaning must also be considered. Kavle and collaborators⁷³ show that, in developing and underdeveloped countries, cesarean delivery was strongly associated with early weaning. In addition, professional and family

⁶⁹ MONTEIRO, Renata. Norma brasileira de comercialização de alimentos para lactentes e crianças de primeira infância: histórico, limitações e perspectivas. *Rev Panam Salud Publica/Pan Am J Public Health*, v. 19, n. 5, 2006. Available at: <https://www.scielo.org/article/rpsp/2006.v19n5/354-362/>.

⁷⁰ *Id. Ibid.*

⁷¹ PINHEIRO, Josilene Maria Ferreira et al. Prevalência e fatores associados à prescrição/solicitação de suplementação alimentar em recém-nascidos. *Rev. Nutr, Campinas*, v. 29, n. 3, p. 367-375, June 2016. Available at: <https://www.scielo.br/pdf/rn/v29n3/1415-5273-rn-29-03-00367.pdf>. <https://doi.org/10.1590/1678-98652016000300007>.

⁷² BOCCOLINI, Cristiano Siqueira et al. Tendência de indicadores do aleitamento materno no Brasil em três décadas. *Rev Saude Publica*, v. 51, n. 108, 2017. Available at: https://www.scielo.br/pdf/rsp/v51/pt_0034-8910-rsp-S1518-87872017051000029.pdf. <https://doi.org/10.11606/S1518-8787.2017051000029>.

⁷³ KAVLE, J.A. et al. Addressing barriers to exclusive breast-feeding in low- and middle-income countries: a systematic review and programmatic implications. *Public Health Nutrition*, v. 10, n. 17, p. 3120-3134, Dec. 2017. <https://doi.org/10.1017/S1368980017002531>.

counseling and community support have shown to have a strong influence on exclusive breastfeeding⁷⁴.

Thus, breastfeeding protection actions must take place in line with and concurrently with the promotion and support actions⁷⁵. Thus, in Brazil and in the world, codes, laws and norms were created that support women so that the act of breastfeeding is guaranteed and that establish requirements for the advertisement of breast milk substitutes. However, the creation of standards alone is not enough to guarantee the adequacy and correct adoption of procedures regarding the promotion and exhibition of foods and products for early childhood. Pinheiro and collaborators describe that, even in a hospital qualified as Baby Friendly, the incidence of breast milk replacement for unjustified reasons is still high⁷⁶.

Therefore, it is important and fundamental to ensure compliance with existing legislation through the implementation of systematic monitoring and inspection routines. It is also necessary to make health professionals aware of the importance of adopting ethical behavior compatible with protecting health and promoting child nutrition⁷⁷.

In this context, in order to form a working group to monitor compliance with the requirements defined in the booklet and in the current resolutions, Ordinance MS No. 1,449/2005 was signed. The work defined by the ordinance consisted of monitoring the advertising, publicity and commercial promotion of foods covered by NBCAL and, also, the labeling, advertising, publicity and commercial promotion of teats, pacifiers and bottles. To this end, higher education institutions, state and Federal District health surveillance and the team from the Management of Monitoring and Inspection of Advertising, Publicity, Promotion and Information of Products Subject to Health Regulatory Agency (GPROP/Anvisa) participated. The work resulted in the perception of the great ignorance of the norm on the part of professionals of sanitary and health surveillance and responsible for commercial establishments, and more than 70% of inadequacies in advertising and bottle labeling, being the lack of warning phrases a main offense⁷⁸. After 13 years of monitoring by Anvisa, no other work has been done in this regard.

Thus, it is understood that there are two aspects to be worked on. The first refers to the issues arising from the Basic Health Units and the offices, hospitals and maternity hospitals, where prenatal care and births are carried out, and the

⁷⁴ *Id. Ibid.*

⁷⁵ MONTEIRO, Renata. *op. cit.*

⁷⁶ PINHEIRO, Josilene Maria Ferreira *et al. op. cit.*

⁷⁷ ARAUJO, Maria de Fátima Moura de *et al. op. cit.*

⁷⁸ AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA - ANVISA. Promoção comercial dos produtos abrangidos pela NBCAL. *Norma Brasileira de Comercialização de alimentos para lactentes e crianças de 1ª infância, bicos, chupetas e mamadeiras, cit.*

conduct of health professionals allocated in these places, since studies have already demonstrated the relevance of the type of delivery and professional counseling on the success of exclusive breastfeeding^{79,80}. The second aspect concerns the enforcement of laws that describe the requirements for the marketing of breastmilk substitute milk, requiring state and municipal health surveillance authorities and Anvisa itself to be aware of the importance of their role in complying with the existing standards and that more studies be designed and carried out in order to verify whether these standards are sufficient and contribute to the exclusive breastfeeding rate until 6 months of age reach the rates recommended by WHO.

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⁷⁹MONTEIRO, Renata. *op. cit.*

⁸⁰PINHEIRO, Josilene Maria Ferreira *et al. op. cit.*

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