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Special Article

Advances in the Brazilian norm for commercialization of infant foods

ABSTRACT

OBJECTIVE: To assess the advances in the Brazilian norm for commercialization of infant foods from 1988 to 2002, comparing the different texts with each other and with the International Code of Marketing of Breast-Milk Substitutes.

METHODS: This was a descriptive study based on data collected from documents, reports, ordinances and resolutions from the Brazilian Ministry of Health. The versions utilized in the comparison were from 1992 and 2002.

RESULTS: Comparative analysis made it possible to identify important advances in the legislation. In 1992, liquid and powdered milk were included in the scope, along with teats and dummies (pacifiers), and also warning phrases in advertising and on product labeling. In 2002, regulations for products were published by the National Agency for Sanitary Surveillance, thereby strengthening supervisory actions and including regulations for baby foods, nutrient formulae for high-risk newborns, and nipple protectors. The phrases used in commercial advertising and on product labeling, including dummies, teats and bottles, became Ministry of Health warnings. The labeling was defined according to product types, on the basis of more restrictive rules.

CONCLUSIONS: Significant modifications in the control over the marketing of products aimed at mothers during the lactation period. However, there are still some legislative questions that would make it possible to improve the Brazilian norm, in order to protect breastfeeding. There is also a need for the government to implement systematic monitoring routines to supervise this legislation.

KEYWORDS: Legislation, food. Breastfeeding. Weaning. Bottle feeding, standards. Infant food, standards. Infant formula, legislation & jurisprudence. Teats, standards.

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INTRODUCTION

The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) have long recognized that exclusive breastfeeding is the ideal feeding method for infant growth and development, especially during the first six months of life. However, either because of the influence of external factors or because of the women's own characteristics, many mothers introduce new products to babies at an earlier time than is recommended. The risks of death due to pneumonia and diarrhea are, respectively, five and seven times greater among babies that are not breastfed during the first five months of life, in underdeveloped countries.[4] Moreover, the American Academy of Pediatrics states that breastfeeding has the potential for reducing the annual cost of healthcare by around US$ 3.6 billion in the United States alone.[2] Breastfeeding is also important in the prevention of obesity.[5]

Among the various reasons why breastfeeding is abandoned is the influence from the advertising of baby formulae and whole milk utilized in homemade formulae, and the supplementary foods and cereals for feeding infants, which are usually given in bottles.[9] Jelliffe,[6] concerned about early use of bottle-feeding, created the term "commerciogenic malnutrition" to describe the marked influence of the baby food industry on infant health.

The influence of the marketing utilized by companies on infant feeding practices and its consequences relating to early weaning and infant malnutrition and mortality have been a cause for concern within WHO and UNICEF. In consequence, they held a Joint Meeting on "Infant and Young Child Feeding" in Geneva in 1979.* The outcome from the meeting was a recommendation to create a set of norms that would be grounded in ethical principles, to guide the commercial promotion of breast-milk substitutes. From this, the International Code of Marketing of Breast-Milk Substitutes was developed and approved in 1981, by the World Health Assembly (WHA).[15]

The principal objective of the International Code is to contribute towards supplying safe and adequate nutrition for infants, by means of protecting and promoting breastfeeding and regulating the commercial promotion of breast-milk substitutes. The Code applies to all breast-milk substitutes whether these are formulae, milks or supplementary foods, and to bottles, teats and dummies (pacifiers).[15]

By 2005, 64 countries had adopted measures for implementing the International Code. Among these was Brazil, which adopted a norm in 1988 that covered practically all the provisions of the Code.** However, there are still at least ten countries in which no measures have been taken, and also many others in which the Code is voluntary or only includes the measures partially.[13]

Data from a study carried out in the Brazilian state capitals and the federal district in 1999 showed that the exclusive breastfeeding rate for the first six months was less than 10%,*** while the recommended rate is around 100%.[7] The use of feeding bottles is widespread in Brazil, with a frequency of 62.8% among children less than one year old,[3] thus showing a need to stimulate breastfeeding in this country. On the other hand, in this same study, it was observed that 52.9% of the children less than one year old were using dummies.[3] At the time this study was conducted (1981), the importance of the use of dummies in causing teat confusion and contributing towards early weaning was unclear.[14] Thus, in the 1990s, norms for advertising of dummies were created and inserted in the national codes, in the form of regulations.

The norm for commercialization of infant foods (NCIF – first text) was published as National Health Council (CNS) resolution no. 5 of December 20, 1988. It was drawn up by several partners, among which were the Brazilian Pediatrics Society (SBP) and the Brazilian Association for Infant Foods (ABIA).

In 1990, the Ministry of Health's National Program for Stimulation of Breastfeeding (PNIAM), with support from the International Baby Food Action Network (IBFAN) and participation by ABIA, held five training courses on the norm, for healthcare professionals in the different regions of the country. These showed that there were difficulties in interpreting the text of the NCIF at that time. Therefore, a national seminar was held, at which proposals for modifications to NCIF could be discussed and forwarded. These proposed alterations were approved as the Brazilian Norm for Commercialization of Infant Food (BNCIF – second text), which was published as CNS resolution no. 31, of October 12, 1992.****

*OMS; Unicef. Reunião conjunta OMS/Unicef sobre a alimentação de lactentes e crianças pequenas: declaração e recomendações. Genebra; 1979.

**Ministério da Saúde. Resolução CNS nº 5 de 20 de dezembro de 1988 do Conselho Nacional da Saúde: normas para comercialização de alimentos para lactentes. Diário Oficial da União, Brasília (DF), 23 dez 1988.

***Ministério da Saúde. Pesquisa de prevalência do aleitamento materno nas capitais e no Distrito Federal: relatório. Brasília (DF); 2001.

****Ministério da Saúde. Resolução CNS nº 31/1992 do Conselho Nacional da Saúde: norma brasileira para comercialização de alimentos para lactentes. Diário Oficial da União, Brasília (DF), 12 nov 1993.

In 1999 and 2000, the Breastfeeding Sector of the Ministry of Health (MS), in partnership with the IBFAN network, the Public Attorneys' Office, the Consumer Protection Attorneys' Office (PROCON) and the State Sanitary Surveillance Agencies, held capacitation courses on BNCIF in eight Brazilian state capitals, accompanied by monitoring in relation to supervisory actions. The results indicated serious infractions relating to infant foods, dummies, teats and feeding bottles.[8] This triggered reflections regarding the inconsistencies and difficulties in implementing this second text of the Brazilian norm. Consequently, a new process of revising BNCIF was begun, with the formation of a work group.

Today, the combination of Ministry of Health ordinance no. 2,051, of November 8, 2001, and ANVISA – RDC resolutions 221 and 222, of August 5, 2002, constitute the Brazilian norm for commercialization of foods for babies and children in early infancy, and of teats, dummies and feeding bottles.*,**

The objective of the present study was to analyze and compare the changes in the texts in the texts of the norms that have been drawn up for products that substitute for breastfeeding, seeking justifications for their modifications and examining the prospects for improvements in the control over advertising these products.

METHODS

This was a descriptive study in which information regarding the process of drawing up the texts and setting the norms relating to the different versions of the BNCIF was collected, and the versions were compared with each other.

The history of how the Brazilian norm was created was retrieved by means of documents and reports from PNIAM,*** regarding the period from 1981 to 1992, and from the Breastfeeding Sector of the Ministry of Health, regarding the period from 1998 to 2003.

Information on the changes that took place in the Brazilian legislation for commercialization of infant foods between 1988 and 2002 was obtained by means of analyzing the articles of the norm for commercialization of infant food (NCAL), which was published in 1988; BNCIF, from 1992; and the combination of Ministry of Health ordinance no. 2,051, of November 15, 2001, and ANVISA-RDC resolution nos. 221 and 222, of August 5, 2002.

The process of revising BNCIF included participation from various segments of society, namely: Ministry of Health (Children's Health and Breastfeeding; Nutrition; and National Agency for Sanitary Surveillance – Anvisa); Ministry of Agriculture; Public Attorneys' Office; Parliamentary Advisory Service of the Federal Senate; IBFAN; UNICEF; Pan-American Health Organization (PAHO); SBP; ABIA; Brazilian Association for Child-Rearing Products (APRAPUR), which brings together companies manufacturing feeding bottles, teats and dummies, among other products; and the National Institute for Metrology, Normalization and Industrial Quality (INMETRO).

RESULTS

Out of the ten points covered in the text published in 1988, six were modified in 1992. Matters relating to objectives, definitions, education and information for the public and for health professional and personnel remained the same in BNCIF, in 1992. In the last revision (2001/2002), all points in the norm underwent important alterations. The advances in Brazilian legislation achieved over the course of these two revisions were:

BNCIF (1992)

BNCIF was an advance on NCIF in the following respects:

1) *coverage*: inclusion of powdered milk, pasteurized milk and sterilized milk (item II), and dummies (pacifiers) and closed cups with straws or spouts (item IV).
2) *commercial promotion*: inclusion of an obligatory phrase for the products described in item II, to emphasize that they should not be utilized for feeding infants during their first six months of life, except on the advice of a doctor or nutritionist; the commercial promotion of dummies was prohibited.
3) *labeling*: requirement of obligatory use of packaging and/or labeling for feeding bottles, teats or dummies, and defined the message to be inserted in the labels of these products.
4) *quality*: establishment of quality rules for dummies.
5) *samples*: manufacturers would only be able to supply samples of the products covered by the norm to doctors and nutritionists.

*Agência Nacional de Vigilância Sanitária. Resolução RDC nº 221 de 5 de agosto de 2002. Diário Oficial da União, Brasília (DF), 6 ago 2002.
**Agência Nacional de Vigilância Sanitária. Resolução RDC nº 222 de 5 de agosto de 2002. Diário Oficial da União, Brasília (DF), 6 ago 2002.
***Ministério da Saúde. Programa de Incentivo ao Aleitamento Materno. Brasília (DF): Instituto de Alimentação e Nutrição; 1991.

6) *implementation*: provision for application of the measures in the Consumer Protection Code, Law No. 8,078, of September 11, 1990.*

Brazilian Norm for Commercialization of foods for foods for babies and children in early infancy, and of teats, dummies and feeding bottles (2001/2002)

This norm was an advance on the BNCIF of 1992, in relation to the following points:

1) *Objectives*: inclusion of protection for exclusive breastfeeding until the age of six months and continued breastfeeding until the age of two years or more; and regulation of the commercial promotion of foods for children in early infancy (defined as children ages from one to three years).
2) *Coverage*: inclusion of follow-on infant formula for children in early infancy, transition food for children in early infancy, nutrient formulae (NF – the so-called human milk fortifiers" that are presented or indicated for high-risk newborns), and nipple protectors.
3) *Definitions*: inclusion of the definitions of terms utilized in the texts of other articles of the norm, for example: special presentation, highlight, special exposure, or commercial promotion.
4) *Commercial promotion*: definition of obligatory phrases, preceded by the words: "The Ministry of Health warns". These warnings started to be given in specific prominent positions that were product-specific, during commercial promotions for liquid and powdered milk from a variety of animal species or those from plant origins, and for transition foods. The commercial promotion of human milk "fortifier" for high-risk newborns and of nipple protectors was prohibited.
5) *Quality*: standardization of the nitrosamine limits for feeding bottles, teats and dummies, in conformity with those established internationally.
6) *Labeling*: Rules for labeling were included, with specific warning phrases for follow-on infant formulae for children in early infancy, for nutrient formulae indicated for high-risk newborns, and for nipple protectors. Photos or pictures of infants and children in early infancy on the labels of follow-on infant formulae, liquid milk, powdered whole milk and transition foods were prohibited. Photos or pictures of children on the labels of feeding bottles, teats, dummies and nipple protectors were also prohibited. For transition foods, the age from which the food could be utilized was required on the principal panel.
7) *Educational and technical-scientific material*: establishment of rules for producing educational material about children in early infancy, in relation to feeding bottles, teats, dummies and nipple protectors. Prohibition of the production or sponsorship of educational and technical-scientific material by the suppliers and distributors of these products.
8) *Samples and donations*: samples were defined as the supply of single units of the product during the launch period, free of charge. The distribution of samples of nutritional supplements to high-risk newborns, feeding bottles, teats, dummies and nipple protectors was prohibited. The launch period for products was defined as 18 months. The distribution of samples during relaunches or changes of product brand name was prohibited.
9) *Health system and teaching and research institutions*: entities granted research aid should disclose the name of the company involved in such aid, in all the material produced.
10) *Jurisdiction and implementation*: the creation of regulations relating to infant food for babies and children in early infancy, and relating to teats, dummies, feeding bottles and nipple protectors became resolutions from Anvisa, and this body was given the power to take the sanitary measures applicable in relation to infractors. Aspects of such norms relating to professionals and the health system moved within the jurisdiction of the Ministry of Health, as indicated in Ordinance No. 2052 from the Minister.

DISCUSSION

According to a review of the literature, the present study is the first of its kind.

The objective of the norms was maintained, but the text of the first version, based on the model of the Code of 1981, was restricted to protecting babies, then defined as "children aged from 0 to 12 months". It applied to infant milks used as substitutes for breast milk, and to milk-based foods, supplementary foods, feeding bottles and teats. It was only years later that protection for breastfeeding for two years or more was seen as a recommendation.

In 1985, a technical consultation conducted by WHO indicated that the numbers of infants who required breast-milk substitutes for physiological or socioeconomic reasons were low. The report indicated that it was unnecessary and potentially dangerous to make such products available, especially in maternity hospitals.**

*Lei nº 8.078 de 11 de setembro de 1990: Código de Defesa do Consumidor. Diário Oficial da União, Brasília (DF), 12 set 1990.
**WHO. Report of a joint WHO/UNICEF consultation concerning "Infant who have to be fed on breastmilk substitutes". Geneva: WHO; 1986. (WHO/MCH/NUT/86.1).

As in the International Code, the first text of the norm prohibited commercial promotion of infant milk, feeding bottles and teats. With regard to supplementary foods, the norm required a warning phrase stating that these products should not be utilized during the first six months of life, except on advice from the health services. This enabled any health professional to give guidance regarding the introduction of transition foods. This was a cause for concern, given that in São Paulo, among pediatricians interviewed regarding infant foods, it was observed that the informative and promotional material handed over by company representatives constituted the principal source of information.[10] In a study carried out in the United States, Lawrence[8] showed that more than 80% of the pediatricians and family doctors recommended the administration of supplementary liquids for breastfed children, thus demonstrating the lack of knowledge among health professionals regarding the practice of breastfeeding.

On the labeling of products within its coverage, NCIF prohibited the utilization of photos or images of children. The manufacturers could not supply samples of the products covered by the norm to health professionals and/or personnel, except at the time of the launch, or through a formal request from the professional or the institution at the time of conducting research. Although a resolution had already been published by WHA in 1986, based on the above mentioned technical consultation, the norm permitted donation of formulae to maternity hospitals, in conformity with guidance from the local sanitary authority.

The discussion on donations resulted from a resolution by the Executive Council of UNICEF, which in 1991 launched the Children's Friend Hospital. The objectives of this included the need to warn manufacturers and distributors of breast-milk substitutes to cease their donations of these products to maternity hospitals.*

The first Brazilian norm was sanctioned at a time of political transition and, for this reason, in 1989 the work was restricted to its publication. It proved to be a document of little clarity, with limited coverage, and it was difficult to understand, thus allowing various interpretations of some of its articles. The lack of involvement of companies that make teats and feeding bottles in drawing it up impeded the educational process that there should have been with infant food producers. This led the manufacturers of these products to ignore compliance with the legislation for many years in this country.

On the other hand, the text published as a Resolution in 1992 advanced in some points. There were improvements especially in the coverage, through including powdered, pasteurized and sterilized milks, which are greatly utilized for feeding children less than one year old, as breast-milk substitutes. Dummies and teats were also included, which have a negative influence on learning the correct sucking technique, thus harming the production of milk and favoring early weaning.[14]

With regard to commercial promotion and labeling, the 1992 text defined obligatory phrases for liquid and powdered milk, and for modified infant milk and supplementary foods. However, this second text took a backward step in relation to the first text, in that it permitted the utilization of photos or pictures of babies on the label, whereas the previous legislation had prohibited pictures of children and babies. The visual attraction of labels, which form part of advertising techniques, may suggest the utilization of this product for small children (from one to three years old) and, in so doing, may harm the stimulation towards continued breastfeeding in this age group. The 1992 resolution also presented an unclear text, and many conflicts again occurred in interpreting the articles with regard to the product labeling. Monitoring conducted by IBFAN has indicated that manufacturers adapted their marketing practices in order to discover gaps and ambiguities, thus sidestepping the norm that was in force.[11] These factors once again gave rise to the need to revise the legislation.

It is emphasized that the first two texts were published as resolutions from CNS, which for many years placed difficulties on the process of supervising the Brazilian norm, given that CNS is a deliberative body without an executive or supervisory role. Its powers are limited to actions relating to the formulation and control over the implementation of national health policies.** The various bodies indicated in the norms did not take on the commitment to perform supervision in the field of foods, and the body responsible for applying the norm with regard to feeding bottles, teats and dummies was not defined.

A similar situation occurred in Guatemala, where a law on the marketing of breast-milk substitutes was decreed in 1983. However, this law could only be applied in 1987, when the rules for its implementation were established, through designating and delineating the powers of the agency responsible for its application and supervision.*** In the Republic of

*Unicef. Resolução nº 1991/22 do Conselho Executivo do Unicef. Nova Iorque; 1991.
**Ministério da Saúde. Resolução CNS nº 291/1999 do Conselho Nacional de Saúde. Diário Oficial da União, Brasília (DF), 9 jun 1999.
**Guatemala. Acordo do Governo nº 841-87 de 30 de setembro de 1987: regras para a mercadização de substitutos do leite materno. Art. 14 e 15.

Cameroon, the local code is monitored by the Ministry of Health, which can submit cases to the Attorney General's Office for penalties to be applied.* In some countries, interministerial committees have been created to be held responsible for implementing the code, as is the case of China.[13] Thus, for the legislation to be applied, a body responsible for its supervision is needed, which did not occur in Brazil with regard to the initial two texts.

From 1999 onwards, with support from a consultant in the Public Attorneys' Office of the Federal District, the Ministry of Health started to have a dialogue with the industry and to impose the rules on infracting companies. The results from the monitoring carried out by the Ministry of Health in the years 1999 and 2000** guided the second revision of BNCIF, with the publication of new ordinances that had wider coverage and were better drafted.

The principal advance took place in 2002, when two ANVISA RDC resolutions were promulgated: No. 221, which dealt with teats, dummies, feeding bottles and nipple protectors; and No. 222, which made provisions regarding baby food and food for children in early infancy. With the publication of these two documents from ANVISA, Brazil started to have a body with constitutional powers for supervising and inspecting foods and products related to individuals' health. This enabled surveillance of commercial promotion practices and correction of any irregularities found.

This set of rules, which has been in force in this country since May 2003, altered all the points in the previous version of the norm. In addition to presenting a clearer and more objective text, it sought to take into consideration new products and marketing strategies utilized within the industry, such as the use of the Internet and merchandising.

The International Code was approved as the minimum recommendations to be followed,*** thus giving room for each country to expand its breastfeeding protection measures. Consequently, the inclusion of products destined for children in early infancy in the new revision of the norm, enabled protection for breastfeeding practices continuing for two years or more, in conformity with Brazilian recommendations and the international recommendations from WHO. Nutrient formulae indicated for high-risk newborns and nipple protectors, which were present on the Brazilian market without regulation, were also included with clear and restrictive rules.

The obligatory phrases relating to commercial promotion were defined as warning phrases from the Ministry of Health, and became specific for each product. This strengthened the messages to be put across, since the Ministry of Health is the highest authority in the country regarding health. The same took place with regard to the labels for all the products considered within the coverage of the norm, for which the sizes of the letters in the warning were also defined. Photos or pictures of babies were prohibited, both for foods indicated for this age group and for powdered and liquid milk. And for feeding bottles, teats, dummies and nipple protectors, pictures and photos of children under 12 years of age were prohibited on these products.

Even though some countries prohibit the distribution of samples, as is the case of the Philippines and Cameroon,[12] the Brazilian legislation achieved an advance in the sense of defining samples as "product units distributed on a single occasion", during the launch period for the product, which was defined as 18 months throughout the national territory. The distribution of samples of nutritional supplements (so-called breast-milk fortifiers) to high-risk newborns was prohibited, along with samples of feeding bottles, teats, dummies and nipple protectors. This greater rigor may contribute towards avoiding the distribution of free samples of infant formulae and supplementary foods to pregnant women in hospitals and maternity hospitals. During the 1980s, a Canadian study[3] had already shown that the receipt of samples in maternity hospitals was related to early weaning.

Both the initial drafting and the two revisions of the norm took place within a democratic process, with participation by all the segments involved in this matter. This was important, because it made it possible for the industry to ratify compliance with the country's legislation.

The present analysis has shown that some points of the current norm could still be revised, thereby allowing improvement of this legislation and providing greater protection for exclusive and continued breastfeeding in Brazil. For example, the question of sample distribution and food advertising relating to children in early infancy should be addressed: this is an age group that also ought to be protected so as to give priority to the recommendation that complementary breastfeeding should continue until the age of two years or over.

*Cameroon. Arrete Interministeriel nº 40 portant sur lê reglementation de la commercialisation des substituts du lait maternel; 1993. Art. 19.
**Ministério da Saúde. Relatório de monitoramento da Norma Brasileira de Comercialização de Alimentos para Lactentes 1999/2000: relatório. Brasília (DF); 2001.
***WHO. World Health Assembly Resolution 34.22 [preâmbulo]. Geneva; 1981.

On the other hand, it is important to establish a social commitment within the Brazilian government, in its different levels of health management, and for manufacturers, distributors and health professionals, with regard to ensuring compliance with this legislation, thus contributing towards adequate nutrition for babies and children in early infancy. The government has the responsibility to implement systematic monitoring routines to supervise compliance with this legislation, in order to detect and punish infractors. Even though the norm has been in force for 16 years and the Anvisa systems for supervision and for applying infraction penalties are in operation, many infractions are still being detected today. For health professionals, there is a duty to adopt ethical behavior that is compatible with protecting children's health and nutrition. For manufacturers and distributors, there is a duty to faithfully observe the Brazilian norm.

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