

# Labeling and commercial promotion of infant formulas retailed in Brazil

## Rotulagem e promoção comercial de fórmulas infantis comercializadas no Brasil

Mariana Morais Baldani<sup>1</sup>  
Grazieli Benedetti Pascoal<sup>1</sup>  
Ana Elisa Madalena Rinaldi<sup>1</sup>

<sup>1</sup> Universidade Federal de Uberlândia, Faculdade de Medicina, Curso de Nutrição. Uberlândia, MG, Brasil.

Correspondence  
Ana Elisa Madalena Rinaldi  
E-mail: [anaelisarinaldi@gmail.com](mailto:anaelisarinaldi@gmail.com)

### Abstract

**Objective:** This study aimed to analyze the conformity of labeling and commercial promotion with the current legislation on infant formulas marketed in Brazil. **Methodology:** Thirty two labels of four different brands of infant formula (n=15), follow-on formula (n=4) and toddler formula (n=13) were analyzed. The labels were checked according to the Collegiate Discharge Resolution (RDC) 222/02, 259/02, 360/03, 42/11, 43/11, 44/11 and 46/11; Brazilian Norm for Commercialization of Food for Infants and Young Children, Nipples, Pacifiers and Baby Bottles (NBCAL, acronym in Portuguese) ; Rule 157/02; Decree 986/69 and Laws 10,674/03, 11,265/06, 11,474/07. **Results:** Nonconformities were identified in 34.7% of the formulas, 43.7% for general labeling requirements and 56.2% for commercial promotion. Concerning general labeling, 28.1% of products presented irregularities in nutritional information, and 21.8% in the product designation. Regarding commercial promotion, all (100%) infant formulas showed nonconformities to commercial sale. In addition, inadequate illustrations were observed in 40.6% of the products; in 65.6% the words “Premium” and “Supreme” were identified which may indicate similarity with breast milk; and 93.7% of the products identified phrases that give false concept of advantage and / or safety. Other non-conformities were related to nutritional composition (3.1%), health indications (6.2%), and inadequate use of nutrition allegations (68.7%). **Conclusions:** The results indicate the compliance of NBCAL by the industries as to nutritional labeling. However, there is the necessity to

adequate commercial promotion criteria and reinforce mainly the supervision by the responsible organs.

**Keywords:** Food labeling. Commerce. Infant formula. Breastfeeding

## Resumo

*Objetivo:* Analisar a conformidade da rotulagem e a promoção comercial às legislações vigentes de fórmulas infantis comercializadas no Brasil. *Metodologia:* Foram analisados 32 produtos de quatro marcas comerciais de fórmulas infantis para lactentes (n=15), de seguimento para lactentes (n=4) e de crianças de primeira infância (n=13). Os produtos foram analisados segundo às Resoluções da Diretoria Colegiada (RDC) 222/2002, 259/2002, 360/03, 42/2011, 43/2011, 44/2011 e 46/2011; Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras (NBCAL); Portaria 157/2002; Decreto 986/1969 e Leis 10.674/2003, 11.265/2006, 11.474/2007. As inconformidades foram expressas em frequências relativas. *Resultados:* Foram identificadas inconformidades em 34,7% das fórmulas, sendo 43,7% quanto às exigências de rotulagem geral e 56,2%, quanto à promoção comercial. A respeito da rotulagem geral, 28,1% dos produtos apresentaram erros na informação nutricional e 21,8% na designação do produto. Quanto à promoção comercial, todas (100%) as fórmulas infantis apresentaram não conformidades à venda mercantil. Adicionalmente, em 40,6% dos produtos foram observadas ilustrações inadequadas; em 65,6% foram identificadas as palavras “Premium” e “Supreme” que podem indicar semelhança com o leite materno; em 93,7% dos produtos foram identificadas frases que dão falso conceito de vantagem e/ou segurança. Outras irregularidades foram quanto à composição nutricional (3,1%), indicações de saúde (6,2%) e uso inadequado de alegações nutricionais (68,7%). *Conclusões:* Os resultados indicam o cumprimento da NBCAL pelas indústrias no que tange à rotulagem nutricional, porém há necessidade de adequação no critério promoção comercial e principalmente reforço na fiscalização pelos órgãos responsáveis.

**Palavras-chave:** Rotulagem de alimentos. Fórmulas infantis. Aleitamento materno.

## Introduction

In the 1970s, rates of early weaning, malnutrition and mortality increased,<sup>1</sup> mainly due to the intense use of infant formulas. At the same time, in that decade, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) recommended breastfeeding for health promotion and attention to child nutrition because of the diverse evidence of protection from breastfeeding to diarrheal diseases and child malnutrition.<sup>2</sup> In 1981, WHO also developed the International Code of Marketing of Breast-milk Substitutes and encouraged signatory countries to develop codes in order to curb excessive industry advertising and protect mothers from information that discouraged them from breastfeeding.<sup>2</sup>

In Brazil, due to the low rates of breastfeeding and disclosure of its benefits to society, the pro-breastfeeding actions began in 1980, with emphasis on the National Breastfeeding Incentive Program (PNIAM, acronym in Portuguese),<sup>3</sup> in 1981; and the Standard for Commercialization of Foods for Infants (NCAL, acronym in Portuguese),<sup>4</sup> in 1988. From 2002 on, pacifiers and baby bottles were inserted in the scope of NCAL, being then called “Brazilian Norm for Commercialization of Food for Infants and Young Children, Nipples, Pacifiers and Baby Bottles” (NBCAL).<sup>4</sup> NBCAL is defined as “a set of rules that regulates the commercial promotion and labeling of foods and products intended for newborns and children up to 3 years of age, such as milk, baby food, pacifiers and baby bottles”, whose objective is to ensure the appropriate use of these products in a way that does not interfere with the practice of breastfeeding.<sup>5</sup>

In this way, NBCAL became regulated by Ordinances 2,051 (11/08/2001),<sup>6</sup> RDC 221 (08/05/2002)<sup>7</sup> and RDC 222 (08/05/2002).<sup>5,8</sup> Later, in 2006, Law 11,265 (01/03/2006)<sup>9</sup> was drawn up, but sanctioned only in 2015.

Law 11,265 regulates the marketing of foods for infants and young children and also of related childcare products.<sup>9</sup>

The *International Baby Food Action Network* - IBFAN, founded in 1979 and headquartered in Brazil in 1983, was also created to protect and encourage breastfeeding and to warn about risks of using infant formulas in childhood. In addition, IBFAN supervises the implementation of the International Code of Marketing of Breast-milk Substitutes and the legislation involved.<sup>10</sup> IBFAN Brazil monitors compliance with NBCAL<sup>10</sup> and for more than two decades these laws have often been disobeyed by the commercialization of artificial milks.

The current status of the International Code of Breast-milk Substitutes in a number of WHO signatory countries is set out in a WHO publication,<sup>11</sup> noting in particular the diversity of products under this regulation, their legal format and the age groups for which children's products are destined and consequently regulated.

In Brazil, NBCAL has been a Law since 2015, and it is relevant to check the status of infant formula labels regarding legal specifications. This work aims to analyze the conformity of the labeling and commercial promotion of infant formulas with Brazilian legislation in force.

## Methods

This study had a cross-sectional character, whose object of analysis constituted infant formula labels for healthy infants. The product labels were displayed in 12 commercial establishments (retail and / or wholesale) located in Uberlândia (Minas Gerais, Brazil), between April and August 2016.

The study was developed in two phases: the first one was to survey all infant formulas retailed in Brazil for healthy infants, on the websites of the companies responsible for their manufacture. At this stage, four companies were identified responsible for the manufacture of healthy infant formulas. The second phase consisted in the analysis of the conformity of labels with the current legislation, regarding general labeling, nutrition labeling and commercial promotion.

According to the specific legislation<sup>12-14</sup> on this topic, infant formulas are classified according to the age of the child. “Infant formulas” are intended for infants between 0 and 5 completed months; “follow-on infant formula” are intended for infants between 6 to 11 completed months and “infant formulas for young children” are intended for children between 12 to 36 months.

For the organization of the information present in the legislations, two check sheets were prepared from a checklist used by the National Agency for Sanitary Surveillance - ANVISA (Board 1). One list was directed to the “Labeling of Infant Formulas “ analysis and the other to the “Labeling of Infant Follow-on Formulas for Infants and Young Children”. The commercial promotion was analyzed on the labels of all the formulas.

**Table 1.** Description of the legislation used by ANVISA to regulate general and nutritional labeling and commercial promotion. Brazil, 2016.

General and nutritional Labeling	Aspects of commercial promotion
RDC No. 4212, 4313, 4414, 4615 (19/09/2011)	RDC No. 4212, 4313 e 4414 (19/09/2011)
RDC No. 27 (6/08/2010)16	RDC No. 222 (05/08/2002)8
RDC No. 259 (20/09/2002)17	Law 11,265 (03/01/2006)9
Item 3.4.1.1.RDC No. 360 (23/12/2003)18	Law 11,474 (05/15/2007)21
INMETRO Ordinance No. 157 (19/08/2002)19	
Law 10,674 (16/05/2003)20	

In a summarized way, the RDC No. 222/2002<sup>8</sup> addresses issues of promotion of infant formulas such as the existence of expressions that may induce the use of these products by a false concept of advantage or safety. RDC No. 42/2011<sup>12</sup> provides for the technical regulation of nutrient compounds for foods intended for infants and young children. RDC No. 43/2011<sup>13</sup> provides for the technical regulation of infant formulas. RDC No. 44/2011<sup>14</sup> provides for the technical regulation of follow-on infant formula intended for infants and young children. RDC No. 46/2011<sup>15</sup> provides food additives and technology adjuncts to infant formulas for infants and young children.

For the conformity analysis of the labeling, spreadsheets containing all items in each checklist were prepared. The items were rated “0” when there was compliance, “1” when there was no compliance and “2” when it did not apply to the resolutions. In this way, it was possible to summarize the results of the analysis of all brands in absolute and relative frequencies, using Excel 2010 software.

## Results

In the first phase, after accessing the *websites* of the four companies responsible for manufacturing the formulas, 47 infant formulas were identified. Due to the unavailability of full labels on the *websites*, it was decided to identify the formulas in 12 commercial establishments (supermarkets and drugstores). In these commercial establishments, it was possible to analyze all the information available on the products. Among 47 products, 15 were discarded because they were intended for specific diet therapy. In this way, 32 products were selected to analyze their compliance with legislation.

The checklist of the labeling of infant formulas contains 44 items and the checklist of infant follow-on formulas for infants and young children contains 46 items (two additional items regarding the use of honey in infant formulas). Regarding the analysis of the checklists, 65.2% of the items (n = 30) in relation to the products were in compliance with the Brazilian legislation in force. Among the other items (n = 16), 43.7% (n = 7) presented nonconformities regarding general labeling requirements and 56.2% (n = 9) presented nonconformities regarding commercial promotion requirements.

Regarding compliance with labeling, technical regulations and nutritional information, all infant formulas were in accordance with RDC No. 27/2010,<sup>16</sup> which requires registration of the product at ANVISA. The item 3.1.a. of RDC No. 259/2002<sup>17</sup> has also been addressed on all labels, which requires that packaged foods should not use inscription, word or figure that may lead the consumer to mistake in the choice of product.

In addition, all formulas were in compliance with the requirements for the description of liquid content, origin identification, manufacturers' data, validity, food additives, description of the appropriate storage and preservation of the product, information on the presence of gluten, language, whether it was manufactured in Brazil or not, and instructions for preparation and handling of the product. All infant formulas without milk or derivatives were adequate in item II of article 40 of RDC 43/2011,<sup>13</sup> which requires on the label the warning "does not contain milk or milk products" or with equivalent phrase, according to the law. However, 9.4% (n = 3) of the formulas did not show the batch number in the product.

Protein sources were clearly identified on the labels; and nutritional compositions for fats and carbohydrates were in compliance with the legislation in all formulas. None had hydrogenated fats in the composition.

As regards general labeling legislation, 21.8% (n = 7) of the products did not conform to the product designation. For example, instead of "Infant Formula for Infants", it was written "Infant Formula with Iron for Infants".

According to item 3.4.1.1. of RDC No. 360/2003,<sup>18</sup> the expression “Nutritional Information” should be with all letters in ‘upper case’, but 28.1% (n = 9) products of the same brand did not meet this requirement. Only one (3.1%) formula presented an error in protein composition, since it presented content lower than 2.25g protein / 100 kcal; and another formula which presented caloric value higher than 70 kcal / 100ml of ready product, in accordance with RDC No. 43/2011.<sup>13</sup>

Twenty-two products (68.8%) presented irregular functional properties. For example: two labels presented the highlight of “Lutein”, which is not foreseen in RDC No. 43<sup>13</sup> and RDC No. 44 of 2011.<sup>14</sup> Two labels (6.3%) presented phrases or expressions of health conditions so that the products can be used, which is contrary to the laws.

In addition, item 4.3.1 of Resolution RDC No. 222/2002<sup>8</sup> and paragraph 1 of Article 10 of Law 11.265/2006<sup>9</sup> prohibit the use of illustrations, photographs or other graphic representations of infants, young children or humanized figures. In total, 40.6% (n = 13) formulas exhibited illustrations that alluded to artificial feeding by the mother, all of them of the same trademark.

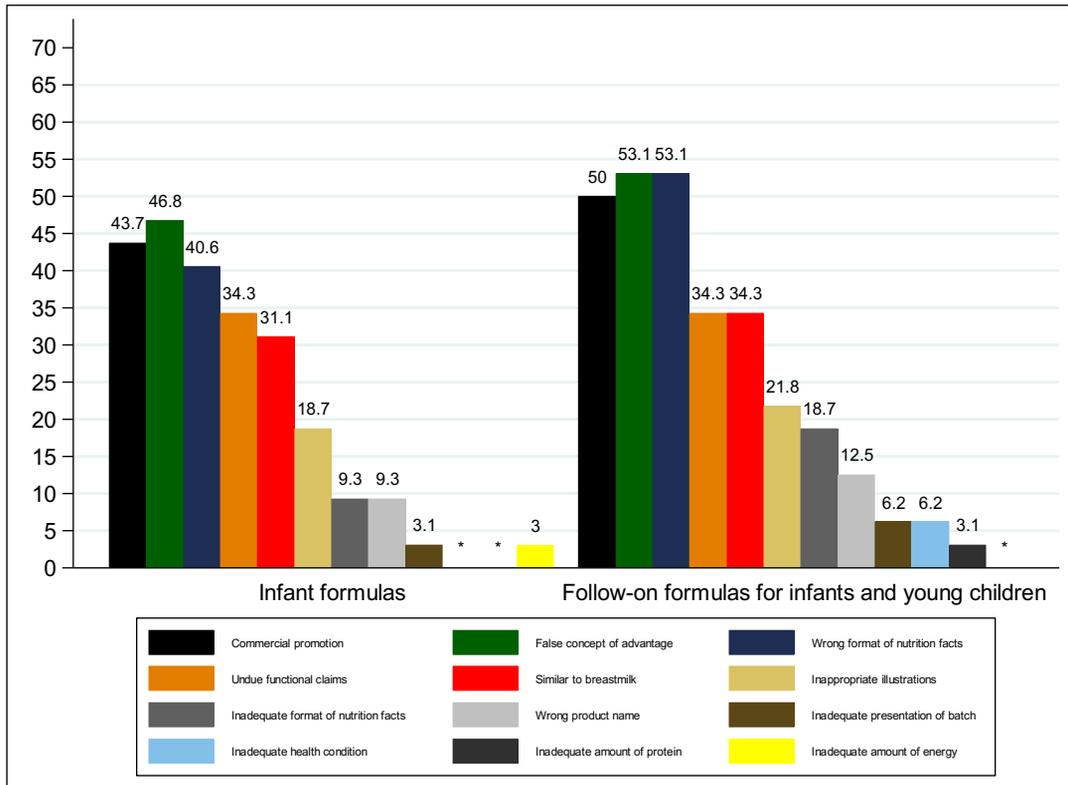
Expressions indicating product superiority were identified in 65.6% (n = 21) of the products, in addition to indicating a false concept of advantage, such as: “Premium”, “Supreme” and “ProExpert”. These expressions suggest a strong similarity with breast milk, contrary to item 4.3.2. of RDC No. 222/2002<sup>8</sup> and item II of article 10 of Law 11.265/2006.<sup>9</sup>

With respect to the commercial promotion requirements of infant formulas, all products have at least an inadequacy in legislation. However, none of them presented phrases or expressions that might cast doubt on the ability of the infant to breastfeed; all had warnings about the risks of inadequate preparation and instruction; guidelines on the dosage for dilution, use, preparation, preservation and hygiene measures, including hands, work surfaces to ready product preparation and the need for sterilization of utensils.

When searching through *websites*, all infant formulas presented undue commercial promotions, as well as other products of the same brand violating item 4.1 of Resolution RDC No. 222/2002.<sup>8</sup> However, in the commercial establishments visited, there were no irregularities.

Concerning the compulsory warning<sup>12</sup> on the labels of the formulas: “Important warning: This product should only be used to feed children under one (1) year of age with an express doctor or nutritionist advice. “Breastfeeding avoids infections and allergies and strengthens the mother-child bond”, 68.7% (n = 22) of them did not present it in the main panel as the laws demand and 93.7% formulas (n = 30) did not present the appropriate font size (the same size as the sales letter of the product).

Figure 1 shows a summary of the irregularities found from all infant formulas.



\* value equal to zero

**Figure 1.** Irregularities (%) of labeling and commercial promotion in infant formulas (n = 15) and follow-on infant formula for infants and young children (n = 17).

## Discussion

The items with the highest frequency of non-conformities in the analyzed products focus on nutritional information, general labeling requirements, false concept of advantage and / or safety, commercial sale and the manner of submitting a warning required in the field of commercial promotion.

With regard to general labeling, the resolutions relate to expressions which may be supplemented in the description of the product to the formula which is based on cow’s milk protein or soy-based protein.<sup>13,14</sup> In the case of cow’s milk protein, the terms “with milk proteins” and “with partially hydrolyzed milk proteins” were found, when the correct one is “based on cow’s milk”.<sup>13,14</sup> These technical terms may make it difficult for the consumer to understand the components of the product.

Concerning the items on commercial promotion, the irregularities have focused on the presence of illustrations that refer the consumer to the care relationship between mother and child (a bird feeding and caring for its two cubs) in all the formulas of one of the trademarks. Law No. 11,265/2006<sup>9</sup> and Resolution RDC No. 222/2002<sup>8</sup> prohibit any kind of figures that are not those necessary to illustrate methods of preparation or use of the product, with the exception of the logo. The same image was observed in 10 infant formulas in a total of 16 analyzed in the study by Silva et al,<sup>22</sup> which shows that there has been no progress to date regarding the adequacy of this item.

No expressions such as “humanized milk”, “mother’s milk” and “breast milk substitute” were found, but there were words close to the business name that have the purpose of suggesting advantages and / or superiority to other brands or even breast milk such as “Supreme”, “Comfort”, “Premium”, “Premium+”, “Pro-Expert” and “Pro-Futura”. In earlier studies these terms were not considered as expressions that suggest advantage.<sup>23,24</sup> Although there is no mention of these terms in the legislation, it is understood that the terms are used with the intention of indicating superiority of the product.

Another claim that may suggest product superiority is the presence of a functional property claim on the label, which is not allowed.<sup>13,14</sup> In this study, irregularity in letter size, different emphasis and highlighting of the product designation for DHA, ARA, taurine, FOS / GOS, nucleotides and probiotics were verified.<sup>9</sup> In two formulas, the presence of lutein has been identified, and this compound is not on the list of nutrients that can be highlighted on the label.<sup>12-14</sup> If it is claimed on food labeling, it is necessary that its ready-to-eat quantity is close to the claim, that it presents scientific support for its use<sup>25,26</sup> and no such criteria were found. The presence of functional claims has also been found in infant formulas and follow-on infant formula in a previous study,<sup>24</sup> in which the authors stated that the use of such claims may subtend that infant growth and development will only be possible because it contains these claims on products.

Regarding the presence of words that may indicate health promotion for infants and children, we identified the presence of the expressions “Active” and “Sensitive” that are in opposition to subsection VI of Art. 10 of Law 11,265/2006.<sup>9</sup> In the case of the formula that had the word “Active”, next to it there was the “prebiotics” claim that suggests solving the intestinal problem of the infant. The formula that presented the word “Sensitive” had the complement “with partially hydrolyzed protein”, which presupposes to solve the problem of absorption of the nutrient by infants with the digestive system still in development.

Still based on the false concept of advantage and safety, in a single infant formula was written “... is a formula developed for infants from birth to 6 months of life,” contrary to item 4.3.4 of the RDC 222/2002.<sup>8</sup> A study carried out in 2008 found the same irregularity.<sup>22</sup>

All formulas have the compulsory warning<sup>6</sup> on recommending the use of the formula by a doctor or nutritionist and on the benefits of breast milk. The irregularities observed in the products were concentrated on the inadequate formatting for the identical characters and with the same letter size of the sales designation, as determined by Law 11,474/2007.<sup>21</sup> In the study carried out by Silva et al.<sup>22</sup> and by Chater<sup>24</sup> there has also been no proper care as to the mode of presentation, causing the warning to go undetected, which reveals the lack of progress on this issue over the years.

A relevant point to be highlighted and celebrated with the advancement of NBCAL in Brazil, seen in the analysis of products, was the absence of phrases or expressions that might cast doubt on the ability of mothers to breastfeed their children (RDC No. 222/2002<sup>8</sup>; Law 11,265/2006<sup>9</sup>); warnings about the risks of improper preparation and instructions for the correct preparation (RDC No. 222/2002<sup>8</sup>; Law 11,265/2006<sup>9</sup> and Res. RDC No. 44/2011<sup>14</sup>); guidelines on the hygiene measures to be observed and the dosage for dilution, if necessary (RDC No. 222/2002<sup>8</sup>; Law 11,265/2006<sup>9</sup>); appropriate instructions for use, preparation and storage of the product, including information on hand hygiene and work surfaces, and the need for sterilization of utensils (RDC No. 44/2011<sup>14</sup>).

Compared to the literature,<sup>22,24,27-29</sup> the commercial promotion items are being adapted to the legislation, but in a slower way than those of technical regulation regarding general and nutritional labeling. The study carried out by Cyrillo et al<sup>30</sup> states that the knowledge of the Brazilian Standard of Food Marketing for Infants, even among health professionals, is restricted. Although this study was conducted in the previous decade, it is possible that the prescription of these products by professionals still persists. However, a relevant point to be analyzed is the distribution of free samples of infant formulas to these professionals, which is also prohibited by NBCAL.

It is believed that one of the main limitations of our work is the lack of analysis on the issues of price reduction, combined sales and product highlights on shelves in the commercial establishments visited. These items should be analyzed because price is one of the items that facilitate the purchase of these products, especially as they are products with high cost and with high demand of consumption by infants and young children. In addition, it is necessary to investigate and understand the mothers' understanding of the labels of these formulas.

From the results observed in the present study, it can be stated that the general and nutritional labeling proposed in NBCAL are being respected, except for minor irregularities. However, we caution against the fact that there are still inconsistencies in the commercial promotion present in the products of infant formulas. It is important to emphasize that the heart of NBCAL is the protection to the mothers regarding the advertisements of the formulas, which may confuse them regarding the superiority of the mother's milk and it is precisely this item that was more violated in the products.

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## Contributors

Baldani MM performed the data collection, data analysis and drafted the manuscript; Pascoal GB contributed in the drafting of the manuscript and in the final review, and Rinaldi AEM was responsible for the conception of the objective of the work, guided the collection and analysis of the data, contributed in the writing and final revision of the manuscript.

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