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Infant formulas for infants in Brazil: A study of legislation and literature

Fórmulas infantis para lactentes no Brasil: um estudo da legislação e da literatura

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ABSTRACT

Introduction: Nutrition in the first months of life is crucial for child development, and breastfeeding is widely recommended by institutions such as the World Health Organization (WHO) and the Brazilian Ministry of Health. However, in situations where breastfeeding is not possible, infant formulas have emerged as an essential alternative. In this context, understanding the Brazilian regulatory framework for these formulas is fundamental to ensuring food safety and product quality. **Objective:** To describe how Brazilian legislation regulates the formulation, commercialization, microbiological quality, and use of infant formulas (IF) for infants, as well as to analyze the implications of this regulation for public health and the infant food market. **Method:** This is a narrative review study of the literature and national legislation regarding IF. Resolutions from the National Health Surveillance Agency (Anvisa), federal laws, and technical standards were consulted, in addition to scientific articles published between 2014 and 2024 in databases such as SciELO, LILACS, PubMed, and Google Scholar. The descriptors used were "infant formulas," "nutritional composition," and "Brazilian legislation." **Results:** The analysis showed that Brazil has a robust set of regulatory instruments, including Law No. 11,265/2006 (NBCAL) and Resolutions RDC No. 43, 44, and 45/2011, which regulate the composition, labeling, and commercialization of IF, as well as RDC No. 429/2020, which defines rules for nutritional labeling. RDC No. 724/2022 is also noteworthy, as it establishes strict microbiological standards. Reviewed studies indicated that, although most IF partially comply with current legislation, nonconformities were mainly related to labeling and nutritional composition. **Conclusion:** The analyzed studies revealed at least one nonconformity with current legislation, highlighting the need for infant formula manufacturers to adapt their products to the relevant regulations and for health authorities to intensify inspections to ensure greater effectiveness in law enforcement, thus guaranteeing product quality and protecting infant health.

KEYWORDS: Infant Feeding; Infant Formulas; Child Development

RESUMO

Introdução: A nutrição nos primeiros meses de vida é crucial para o desenvolvimento infantil, sendo o aleitamento materno amplamente recomendado por órgãos como a Organização Mundial da Saúde (OMS) e o Ministério da Saúde do Brasil. No entanto, nas situações em que a amamentação não é possível, as fórmulas infantis surgem como alternativa essencial. Nesse contexto, compreender o marco regulatório brasileiro dessas fórmulas é fundamental para assegurar a segurança alimentar e a qualidade desses produtos. **Objetivo:** Descrever como a legislação brasileira regulamenta a formulação, comercialização, qualidade microbiológica e uso das fórmulas infantis (FI) para lactentes, bem como analisar as implicações dessa regulação para a saúde pública e para o mercado de alimentos infantis. **Método:** Trata-se de um estudo de revisão narrativa da literatura e da legislação nacional referente às FI. Foram consultadas resoluções da Agência Nacional de Vigilância Sanitária (Anvisa), leis federais e normas técnicas, além de artigos científicos

publicados entre 2014 e 2024 em bases como SciELO, LILACS, PubMed e Google Acadêmico. Utilizaram-se os descritores "fórmulas infantis", "composição nutricional" e "legislação brasileira". **Resultados:** A análise evidenciou que o Brasil dispõe de um conjunto robusto de instrumentos normativos, entre eles a Lei nº 11.265/2006 (NBCAL) e as RDC nº 43, 44 e 45/2011, que regulamentam a composição, rotulagem e comercialização das FI, bem como a RDC nº 429/2020, que define regras para a rotulagem nutricional. Também se destaca a RDC nº 724/2022, que estabelece padrões microbiológicos rigorosos. Estudos revisados indicaram que, embora a maioria das FI apresente conformidade parcial com a legislação, foram observadas não conformidades principalmente relacionadas à rotulagem e à composição nutricional. **Conclusões:** Os estudos analisados apresentaram ao menos uma não conformidade com o que diz a legislação vigente, apontando, assim, a necessidade de as empresas de fórmulas infantis adequarem seus produtos às legislações pertinentes e dos órgãos sanitários intensificarem a fiscalização, garantindo maior efetividade no cumprimento das leis, assegurando a qualidade desses produtos e protegendo a saúde infantil.

PALAVRAS-CHAVE: Alimentação Infantil; Fórmulas Infantis; Desenvolvimento Infantil

INTRODUCTION

The choice of nutrients for children in the first months of life is essential for promoting the physiological processes necessary for the functional and neurological development of infants. It is now known that nutrition in the first months of life significantly impacts children's future health, including important consequences in adulthood. Therefore, it is essential to establish conditions for the safe intake of foods that meet the specific needs of the infant's body at each stage of growth[1,2,3].

Breast milk is widely recognized as the ideal food for infants, as it provides a balanced supply of essential nutrients, is available at the appropriate temperature, and is free from potential contaminants. Additionally, breastfeeding offers immunological and psychological benefits, which are key factors in reducing infant morbidity and mortality[4,3]. For these reasons, the World Health Organization (WHO), together with the United Nations Children's Fund (UNICEF) and the Brazilian Ministry of Health (MS), recommends that exclusive breastfeeding be maintained until the baby is six months old[5,6,7].

However, in certain situations, it may become necessary to use infant formula (IF), which is food designed to meet the nutritional needs of infants until the introduction of complementary foods. The introduction of IF may occur in cases of health problems—whether maternal or related to the baby—that prevent breastfeeding or even pose health risks to children under one year of age. In general, these formulations, in addition to the essential macronutrients and micronutrients required by law, may include other substances, such as functional ingredients, which are added with the aim of enhancing them and offering additional benefits to infant development[8,9,10].

The regulation of infant formula (IF) in Brazil is a relevant public health issue, especially regarding the nutrition and development of children in the first months of life. Such regulations are carried out through national legislation, which establishes safety standards for IF regarding nutritional composition, sanitary quality, labeling, advertising, and marketing of these products. In this context, the role of the State of establishing clear and rigorous standards for these products is essential to ensure food safety and the well-being of children[8].

The rationale for conducting this study is based on the importance of adequate nutrition in the first months of children's lives and the role that infant formulas can play in this context. Therefore, as previously noted, the regulation of these formulas is essential to ensure the suitability of the products, and analyzing current legislation is fundamental to understanding the State's role in ensuring food safety and preventing inappropriate marketing practices, thereby protecting children's well-being and reinforcing the promotion of breastfeeding. Given this scenario, the objective of this article was to describe how Brazilian legislation regulates the formulation, marketing, microbiological quality, and use of infant formula for infants, as well as to analyze the implications of this regulation for public health and the infant food market, and to examine how this is reported in the literature.

METHODS

This is a narrative literature review designed to provide a comprehensive overview of Brazilian legislation that regulates and controls infant formula in the country. The study included resolutions and regulatory standards of national legislation on the subject, as well as scientific articles dated primarily between 2014 and 2024, published in English and Portuguese. Incomplete works and those published in other languages were excluded from the study. The literature review was conducted between August and October 2024 using *online* database platforms, such as government *websites*, the Latin American and Caribbean Health Sciences Literature (LILACS), the Medical Literature Analysis and Retrieval System Online (Medline-PubMed), the Scientific Electronic Library Online (SciELO), and Google Scholar. The search terms used were: "infant formulas," "nutritional composition," and "Brazilian legislation."

RESULTS AND DISCUSSION

Infant formula and Brazilian legislation

Infant formulas (IFs) are foods specially formulated to meet the nutritional needs of infants and young children in situations where breastfeeding is not possible or insufficient. These are products developed as an alternative to breast milk, whose production

must be controlled and supervised to ensure they meet quality standards established both nationally and internationally[1,11].

In Brazil, due to the demand for and marketing of these products, the Brazilian Standard for the Marketing of Infant Formula (NBCAL) was established. This is a set of national standards aimed at regulating the marketing of infant formula, as well as the marketing of nipples, pacifiers, and baby bottles. Furthermore, the objective of the NBCAL is to ensure adequate nutrition for children, minimizing the risks associated with lack of breastfeeding through clear rules on the promotion and marketing of foods intended for this age group. The NBCAL was based on the International Code of Marketing of Breast-milk Substitutes recommended by the WHO in 1979, published as a Resolution of the National Health Council in 1988. The first revision of the document took place in 1992, and the second in 2002, the year in which the standard was published as Collegiate Board Resolution (RDC) No. 222 of August 5, 2002. In 2006, the NBCAL was transformed into Law No. 11,265, dated January 3, 2006, which remains in force to this day[12,13,14].

Currently, the marketing and regulation of these products at the national level are overseen by the Brazilian Health Regulatory Agency (Anvisa), in accordance with Law No. 11,265/2006 and RDC No. 43 of September 19, 2011, which establish standards regarding the composition, labeling, advertising, and marketing of infant formula. These laws aim to ensure the quality and safety of the products, as well as to protect breastfeeding by preventing the indiscriminate promotion of formulas to the detriment of breastfeeding[15,13]. In addition to these foundational resolutions, other resolutions addressing the topic are also in effect; in this regard, the figure below provides a graphical representation of the main resolutions regulating the various aspects of IFs at the national level, including nutritional composition, labeling, and microbiological parameters.

The following sections will discuss the main aspects of the legislation regarding the nutritional composition, labeling, and microbiological standards of infant formula.

Nutritional Composition

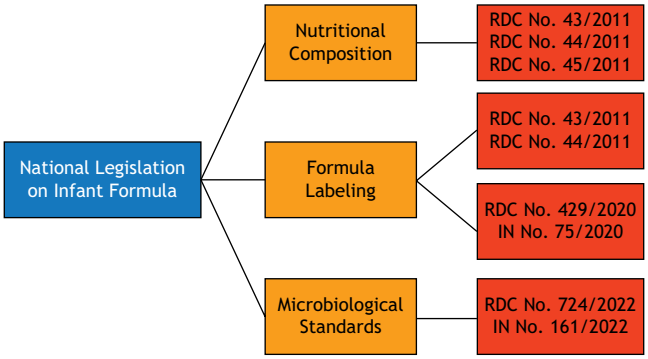
RDC No. 43/2011, RDC No. 44 of September 19, 2011, and RDC No. 45 of September 19, 2011, issued by Anvisa, regulate the production and marketing of infant formula in Brazil, with the aim of ensuring food safety and the nutritional quality of these products[15,16,29].

RDC No. 43/2011 is a legislative instrument that regulates infant formula for infants aged 0 to 6 months, intended to replace breastfeeding when it is not possible. This resolution establishes criteria for the nutritional composition of formulas, setting minimum and maximum levels of macronutrients, such as proteins, fats, and carbohydrates, as well as vitamins, minerals, and other nutrients. The resolution also addresses labeling requirements, which must be clear and provide accurate information on the product's use, while prohibiting claims that discourage breastfeeding[15].

Among the specifications for infant formula contained in RDC No. 43/2011, it is noteworthy that protein levels must be between 1.8–3.0 g/100 kcal for milk proteins and 2.25–3.0 g/100 kcal for soy isolates. As for fats, levels must remain between 4.4–6.0 g/100 kcal, with restrictions on trans and erucic fatty acids. For vitamins and minerals, the document establishes that formulas must meet specific values for healthy development, such as vitamin A, calcium, and iron[15].

RDC No. 44/2011 is a legislative instrument that applies directly to follow-up infant formulas for infants aged 6 to 12 months, a period during which the introduction of solid foods is recommended. Like RDC No. 43/2011, RDC No. 44/2011 specifies nutritional composition requirements, ensuring that these products contain the nutrients essential for proper growth and development during this stage[15,16].

The specifications of RDC No. 44/2011 state that formulas may be based on cow's milk, other animal sources, plant sources (such as soy), or mixtures, providing 60 to 70 kcal per 100 mL, in addition to containing essential nutrients such as proteins, fats, and carbohydrates within specific limits. The document further states that such formulas must contain 1.8–3.5 g/100 kcal of protein, varying according to the protein source; 4.0–6.0 g/100 kcal of fat, with trans fatty acids not exceeding 3%; and 9.0–14.0 g/100 kcal of carbohydrates, as detailed in Charts 1 and 2[16].



Source: RDC No. 43/2011[15], RDC No. 44/2011[16], RDC No. 429/2020[17], Normative Instruction No. 75/2020[18], RDC No. 45/2011[29]

Figure. Flowchart of Brazilian national legislation on infant formula.

RDC No. 45/2011 regulates food supplements for specific therapeutic dietary needs, which are intended for infants with medical conditions requiring a special diet, such as food allergies, intolerances, or metabolic disorders. These formulas have modifications in their composition to meet these needs, and the resolution stipulates specific rules to ensure the safety and efficacy of these products[29]. The document states that the formulas must meet specific nutritional requirements, with adjustments according to the therapeutic needs of the target population. Furthermore, all ingredients must be gluten-free, and the composition must be based on scientific evidence[29].

Chart 1 presents the nutritional composition specifications for IFs intended for infants, follow-up, and early childhood. Chart 2 presents the composition specifications for micronutrients in IFs intended for children aged 0 to 3 years. The information presented in Charts 1 and 2 was extracted from RDC No. 43/2011 and RDC No. 44/2011.

Labeling of Infant Formulas

The regulations governing infant formula labeling are clearly set forth in RDC No. 429, dated October 8, 2020, which establishes guidelines for the nutritional labeling of packaged foods; this resolution is supplemented by Normative Instruction (IN) No. 75, dated October 8, 2020. The general objective of this legislative instrument is to regulate mandatory nutritional labeling on packaged foods, with the exception of products such as mineral water and water with added salts; therefore, it applies to foods packaged in the absence of the consumer, including beverages, ingredients, food additives, processing aids, and consequently the subject of this study, which is infant formula[17,18].

According to RDC No. 429/2020, the label must contain a nutrition facts panel with information such as energy value, carbohydrates, total and added sugars, proteins, total, saturated, and trans fats, dietary fiber, and sodium, with the rules for rounding and expressing nutritional values as established by this resolution[17].

Additionally, dietary supplements, infant formula (IF), and products for special dietary uses have specific requirements. In this case, the document states that IF must follow the general nutritional labeling guidelines; however, there are exceptions regarding the nutrition declaration for this type of product. The label of infant formula must contain preparation instructions for the product and the ready-to-eat food; furthermore, the use of functional or health claims in the formulas is not permitted, except in specific cases that are provided for and follow the corresponding guidelines[17].

RDCs No. 43/2011 and No. 44/2011 establish specific labeling requirements for infant formula intended for children aged 0 to 3 years, which are: a prohibition on the use of functional property claims or health property claims; a requirement that protein sources be clearly specified; the phrase “does not contain milk or dairy products” or equivalent, if applicable; instructions for use, preparation, and storage, with an emphasis on hygiene and sterilization, in accordance with WHO guidelines;

Chart 1. Permissible limits for carbohydrates, proteins, and lipids in infant formulas intended for children aged 0 to 3 years.

CARBOHYDRATES	
Total carbohydrates	Min. 9.0 g/100 kcal (2.2 g/100 kJ) Max. 14.0 g/100 kcal (3.3 g/100 kJ)
Note: Only lactose, maltose, sucrose, glucose, maltodextrin, glucose syrup, dehydrated glucose syrup, and starches are permitted as carbohydrates in infant formulas, and their use must comply with the requirements set forth in this article.	
PROTEINS	
Hydrolyzed and non-hydrolyzed cow’s milk proteins	Min. 1.8 g/100 kcal (0.45 g/100 kJ) Max.: 3.0 g/100 kcal (0.7 g/100 kJ)
Soy protein isolates or a mixture of these with cow’s milk proteins	Min. 2.25 g/100 kcal (0.56 g/100 kJ) Max: 3.0 g/100 kcal (0.7 g/100 kJ)
FATS	
Total fats	Min. 4.4 g/100 kcal (1.05 g/100 kJ) Max: 6.0 g/100 kcal (1.4 g/100 kJ)
Hydrogenated fats and hydrogenated oils may not be used	0
Trans fatty acids	Max. 3% of total fatty acid content
Erucic acid	Max. 1% of total fatty acid content
Lauric and myristic acids	Max. 20% of total fatty acid content
Phospholipids	Max. 300 mg/100 kcal (72 mg/100 kJ)
Linoleic acid	Min. 300 mg/100 kcal (70 mg/100 kJ) Max. 1400 mg/100 kcal (330 mg/100 kJ)
Alpha-linolenic acid	Min. 50 mg/100 kcal (12 mg/100 kJ) with no maximum limit
Note: The minimum ratio of linoleic acid to alpha-linolenic acid must be 5:1 and the maximum 15:1.	

Source: RDC No. 43/2011[15]; RDC No. 44/2011[16].

Chart 2. Permissible limits for micronutrients in infant formulas intended for children aged 0 to 3 years.

Nutrient	Unit	Minimum	Maximum	RDA
Folic acid	mcg/100 kcal	10	-	50
	mcg/100 kJ	2.5	-	12
Pantothenic acid	mcg/100 kcal	400	-	2,000
	mcg/100 kJ	96	-	478
Biotin	mcg/100 kcal	1.5	-	10
	mcg/100 kJ	0.4	-	2.4
[1] Niacin	mcg/100 kcal	300	-	1,500
	mcg/100 kJ	70	-	360
Riboflavin	mcg/100 kcal	80	-	500
	mcg/100 kJ	19	-	119
Thiamin	mcg/100 kcal	60	-	300
	mcg/100 kJ	14	-	72
Vitamin A	mcg RE /100 kcal	60	180	-
	mcg RE /100 kJ	14	43	-
Vitamin B6	mcg/100 kcal	35	-	175
	mcg/100 kJ	8.5	-	45
Vitamin B12	mcg/100 kcal	0.1	-	1.5
	mcg/100 kJ	0.025	-	0.36
Vitamin C	mg/100 kcal	10	-	30
	mg/100 kJ	2.5	-	7.5
Vitamin D3	mcg/100 kcal	1	2.5	-
	mcg /100 kJ	0.25	0.6	-
Vitamin E	mg alpha-TE /100 kcal	0.5	-	5
	mg alpha-TE /100 kJ	0.12	-	1.2
Vitamin K	mcg/100 kcal	4	-	27
	mcg/100 kJ	1	-	6.5
Calcium	mg/100 kcal	50	-	140
	mg/100 kJ	12	-	35
Chloride	mg/100 kcal	50	160	-
	mg/100 kJ	12	38	-
Copper	mcg/100 kcal	35	-	120
	mcg/100 kJ	8.5	-	29
Iron	mg/100 kcal	0.45	1.3	-
	mg/100 kJ	0.1	0.3	-
Phosphorus	mg/100 kcal	25	-	100
	mg/100 kJ	6	-	24
Iodine	mcg/100 kcal	10	-	60
	mcg/100 kJ	2.5	-	14
Magnesium	mg/100 kcal	5	-	15
	mg/100 kJ	1.2	-	3.6
Manganese	mcg/100 kcal	1	-	100
	mcg/100 kJ	0.25	-	24
Potassium	mg/100 kcal	60	180	-
	mg/100 kJ	14	43	-

Continue

Continuation

Selenium	mcg/100 kcal	1	-	9
	mcg/100 kJ	0.24	-	2.2
Sodium	mg/100 kcal	20	60	-
	mg/100 kJ	5	14	-
Zinc	mg/100 kcal	0.5	-	1.5
	mg/100 kJ	0.12	-	0.36
Choline	mg/100 kcal	7	-	50
	mg/100 kJ	1.7	-	12
Myo-Inositol	mg/100 kcal	4	-	40
	mg/100 kJ	1	-	9.5
L-Carnitine	mg/100 kcal	1.2	-	-
	mg/100 kJ	0.3	-	-

Source: RDC No. 43/2011[15]; RDC No. 44/2011[16].
LSR: Recommended Upper Limit.

an instruction that the product must be prepared with water that has been boiled and subsequently cooled to a temperature of no less than 70°C, for products requiring reconstitution; a warning to test the temperature before offering the formula to prevent burns, information on immediate consumption or refrigeration (maximum 24 hours at less than 5°C) in case of advance preparation, and instructions to discard any leftover formula; illustrations of the preparation method, a warning about health risks associated with improper handling, preparation, and storage; clear instructions on how to store the product properly after opening the package[15,16].

Microbiological Standards

Regarding the microbiological parameters that must be met in the production and marketing of infant formula, RDC No. 724 of July 1, 2022, supplemented by IN No. 161, of July 1, 2022[19,20]. These documents are Anvisa legislative instruments that form part of the agency's set of measures to ensure the quality and safety of foods intended for children, especially during developmental stages.

IN No. 161/2022 imposes strict limits on microbiological contaminants. The document distinguishes between food types such as sterile, ready-to-eat, semi-processed, and ambient-temperature-stable foods, in addition to defining terms such as "airtight packaging," "commercial sterility," and "effective heat treatment." More specifically, in Article 5, Annex III, the document establishes microbiological standards for commercially sterile foods, such as UHT milk, infant formula, and enteral formulas. This standard sets the maximum permissible limits for the presence of pathogenic microorganisms, such as *Salmonella spp.*, *Cronobacter sakazakii*, *Staphylococcus aureus*, among others, which are detailed in Chart 3[20].

Infant formulas in the literature

As discussed previously, Brazilian legislation has strict criteria regarding the nutritional composition, labeling, and microbiological standards of infant formula. In this context, several authors have conducted studies to evaluate the compliance of commercially available infant formulas with regulatory parameters, and the results of these studies will be discussed below.

In a study by Almeida[21], the nutritional quality regarding protein and mineral content was evaluated in 30 samples of infant formula and follow-up formula marketed in Brazil. Most formulas met both protein and essential mineral content requirements, complying with recommendations. All formulas exhibited good digestibility and contained essential amino acids, but most had limiting amino acids. A lack of clarity on the labels regarding the type of milk used in the formulas was noted. Regarding toxic metals, although levels of mercury (Hg), arsenic (As), cadmium (Cd), lead (Pb), and uranium (U) were within safe limits, elevated concentrations of aluminum (Al) and tin (Sn) were observed,, the presence of these contaminants in food can compromise the human body's organic functions, being of particular concern in vulnerable populations, such as infants, in whom the effects can cause irreversible damage to physical and cognitive development.

The nutritional information on the labels of infant formula (IF) sold in Joinville, SC, was analyzed to verify compliance with Brazilian legislation. Thirteen samples were evaluated between April and May 2019, and all samples met the requirement to provide nutritional information per 100 g or 100 mL of the food. In the infant formula group, 100% of the samples were compliant. In the follow-up formula group for infants, all samples contained excessive iron (Fe), with values of 1.8 mg/100 kcal, exceeding the limit of 1.3 mg/100 kcal; excess Fe can saturate lactoferrin (Lf), reducing its bacteriostatic action and promoting the growth of pathogens, which can cause intestinal damage and microscopic bleeding capable of leading to iron-deficiency anemia, in addition to impairing the absorption of zinc (Zn) or cobalt (Co). In the group of formulas for infants, there was non-compliance

Chart 3. Microbiological standards established for infant formulas.

Specific categories	Microorganism/toxin/metabolite	n	c	m	M
a) Powdered infant formula for infants (up to six months of age), infant formula intended for specific dietary needs, nutrient formulas presented or indicated for high-risk newborns, and other foods specially formulated for infants	Salmonella/25 g	60	0	Aus	-
	Cronobacter spp./10 g	30	0	Aus	-
	Presumptive *Bacillus cereus*/g	5	1	50	5×10^2
	Enterobacteriaceae/10 g	10	0	Aus	-
	Mesophilic aerobes/g	5	2	$5x10^2$	5×10^3
b) Follow-on powdered infant formulas for infants and young children and other foods specially formulated for infants and young children	Salmonella/25 g	60	0	Aus	-
	Presumptive *Bacillus cereus*/g	5	1	50	5×10^2
	Enterobacteriaceae/10 g	5	0	Aus	-
	Mesophilic aerobes/g	5	2	$5x10^2$	5×10^3
c) Cereal-based foods for infants	Salmonella/25 g	30	0	Aus	-
	Presumptive *Bacillus cereus*/g	5	1	10^2	5×10^2
	Enterobacteriaceae/g	5	2	10	10^2
	Mesophilic aerobes/g	5	2	10^3	10^4
d) Infant transition foods not stable at room temperature (refrigerated or frozen baby food)	Salmonella/25 g	10	0	Aus	-
	Escherichia coli/g	5	2	10	10^2
	Molds and yeasts/g	5	1	10^3	10^4
POWDERED ENTERAL NUTRITION FORMULAS AND POWDERED FORMULAS FOR INBORN ERRORS OF METABOLISM					
Specific categories	**Microorganism/toxin/metabolite**	**n**	**c**	**m**	**M**
a) Formulas intended for infants up to six months of age	Salmonella/25 g	60	0	Aus	-
	Cronobacter spp./10 g	30	0	Aus	-
	Presumptive Bacillus cereus/g	5	1	50	5×10^2
	Enterobacteriaceae/10 g	10	0	Aus	-
	Mesophilic aerobes/g	5	2	$5x10^2$	5×10^3
b) Formulas intended for infants and young children between six months and three years of age	Salmonella/25 g	60	0	Aus	-
	Presumptive *Bacillus cereus*/g	5	1	50	5×10^2
	Enterobacteriaceae/10 g	10	0	Aus	-
	Mesophilic aerobes/g	5	2	$5x10^2$	$5x10^3$
c) Formulas intended for children over three years of age and adults	Salmonella/25 g	30	0	Aus	-
	Presumptive *Bacillus cereus*/g	5	1	50	5×10^2
	Enterobacteriaceae/g	5	0	10	-
	Mesophilic aerobes/g	5	2	$5x10^2$	$5x10^3$

Source: Normative Instruction No. 161/2022[20].
The letters n, c, m, M are standardized parameters used in microbiological standards defined by Anvisa.
n: Number of sample units analyzed; c: Maximum permitted number of sample units that may have a count between "m" and "M";
m: Microbiological limit considered "acceptable"; M: Maximum acceptable limit (or "safety limit").

regarding protein (33.3%), vitamin D (33.3%), and iron (66.7%), with iron levels 38.5% above the limit, vitamin D at 2.9 mcg/100 kcal (exceeding the limit of 2.5 mcg/100 kcal), and protein at 3.1 g/100 kcal[22,21].

A study was conducted to evaluate and validate an ultrasound-assisted extraction method for the simultaneous determination of calcium (Ca), copper (Cu), iron (Fe), potassium (K), magnesium (Mg), manganese (Mn), sodium (Na), and Zn in different commercial IFs (domestic and international), using inductively coupled plasma optical emission spectrometry (ICP-OES). In addition, the analytical conditions for an *in vitro* method of solubility and dialysability were evaluated, and the results of national and international food supplements were compared with those of different types of cow's milk (pasteurized, powdered, and UHT). The results showed variations in element concentrations among the samples, except for Na. When comparing the results with *Codex Alimentarius* values, all elements were within the established limits[23].

In another study[25], the authors evaluated seven infant formula samples intended for infants aged 6 to 10 months, purchased

from stores in Campo Grande, MS. The moisture, ash, carbohydrate, protein, lipid, and total energy content were analyzed using official methods. Formula F6 showed the greatest discrepancy compared to the energy value stated on the label, while formula F3 was the most accurate. The protein and lipid contents showed results like those declared on the labels, but there were significant differences in carbohydrates, as in formula F6, which showed 40.44±0.60 g/100 g in the analysis, in contrast to the 56.00 g/100 g reported.

In a study, the authors analyzed the labeling of 23 infant formulas (IF) sold in Rio de Janeiro, produced by four manufacturers, including nine intended for individuals with special needs, six recommended for infants aged 0 to 6 months, and eight follow-up IFs for infants. Compliance with the standards established by the Ministry of Health (MS) was assessed, and it was observed that 47.8% of the samples presented inadequacies related to the illustration, 21.7% of the samples were related to false claims of benefits and safety, 17.4% contained health claims, 13.0% indicated the presence of health conditions, and 8.7% featured expressions such as "baby" or similar terms[25].

In a study aimed at determining the total lipid content, fatty acid profile, and quantification of docosahexaenoic acid (DHA), arachidonic acid (ARA), linoleic acid, and α-linolenic acid in infant formula for infants aged 0 to 6 months, the nutritional compliance of the labels with Brazilian legislation was evaluated, the daily intake recommended by manufacturers compared to international guidelines; and a comparison of the formulas to breast milk. The labels were following current legislation for all nutrients analyzed. However, the daily intake recommended by manufacturers proved to be moderately unbalanced, showing excess protein, carbohydrates, and energy content, as well as deficiencies in DHA and ARA levels. This inadequacy is concerning, considering that these fatty acids are essential for children's brain, visual, and cognitive development, especially in the first years of life[26].

The commercial promotion on the packaging of 25 infant formulas was investigated, analyzing their compliance with current legislation. The products included infant formula (n = 7), follow-up formula (n = 4), soy-based formula (n = 5), lactose-free formula (n = 1), hypoallergenic formula (n = 4), thickened formula (n = 1), formula with prebiotics (n = 1), and acidified formula (n = 1). On 92% of the labels, a picture of a baby bottle appears in the preparation instructions or warnings. Information that could suggest a false advantage or safety, or question mothers' ability to breastfeed, was present on 72% of the packaging. Additionally, 52% of the products featured graphic elements such as images of babies, children, children's characters, or anthropomorphized fruits or flowers, with the aim of encouraging use[27].

A study analyzed 86 labels of products specifically for infants, including infant formula (n = 11), follow-on formula (n = 5), weaning foods (n = 7), cereal-based foods (n = 11), milk and plant-based products (n = 52), and common foods used for this age group (n = 13). The frequency of non-compliance in specific labeling was higher than in general labeling. The main irregularities included the presence of detailed illustrations, such as images of humanized babies or children, as well as expressions like "humanized milk" and *"baby,"* which suggest benefits or safety. Flaws were also found in product composition and the absence of mandatory statements. This is because *marketing* strategies for infant formula focus heavily on convenience for mothers, often resorting to the misleading promotion of breast milk substitutes. These actions include advertising in specialized magazines and technical publications, sponsorship of scientific events, use of the image of health professionals, and persuasive product labeling[28]. Chart 4 presents the main findings regarding the compliance of infant formula with legislation.

Chart 4. Studies conducted to assess the compliance of marketed infant formulas with current legislation.

Reference	Formula studied	Study topic	Did it comply with the legislation?
Almeida, 2021[21]	Infant formulas for newborns and follow-up	Nutritional quality of proteins and minerals	Partially
Oenning; Oliveira, 2020[22]	Infant formula, follow-up formula, and early childhood formula	Nutritional information on labels	No
Fioravanti, 2020[23]	Different commercial infant formulas (domestic and international)	Total mineral content	Yes
Paniago et al., 2017[24]	Infant formulas	Moisture, ash, carbohydrate, protein, lipid content, and total energy value	Partially
Albuquerque et al., 2016[25]	Infant formulas for infants, follow-up formulas, and formulas intended for special dietary needs	Labeling	No
Gontijo, 2016[26]	Infant formulas	Total lipid content, fatty acid profile, and quantification of DHA, ARA, linoleic acid, and α-linolenic acid	Partially
Abrantes; Tabai, 2013[27]	Infant formulas for infants, follow-up formulas, soy-based, lactose-free, hypoallergenic, thickened, with prebiotics, and acidified	Labeling	No
Silva et al., 2008[28]	Infant formulas, follow-on formulas, weaning foods, cereal-based foods, milk and plant-based products, and common foods used for this age group	Compliance with current legislation	No

Source: Prepared by the authors, 2024.

CONCLUSIONS

Given the importance of infant feeding for healthy development, Brazilian legislation, in line with international guidelines, establishes strict parameters to ensure that infant formula meets the specific nutritional needs of infants, guaranteeing quality and food safety. Furthermore, the protection of breastfeeding, reinforced by the NBCAL and other regulations, is a crucial measure to prevent the inappropriate promotion of infant formula at the expense of breastfeeding, which reaffirms the commitment to public health.

The studies analyzed revealed at least one instance of non-compliance with current legislation, thus highlighting the importance of maintaining strict control over the composition, labeling, and promotion of these products, ensuring a balance between providing adequate nutrition and protecting breastfeeding. At the same time, the need for continuous monitoring and updating of these standards is evident to keep pace with changes in the food market and ensure that children's health remains a priority.

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Authors' Contributions

Soares MAS, Bernardi DM - Conception, planning (study design), data collection, analysis, interpretation, and drafting of the manuscript. Farinã LO, Bender S - Drafting of the manuscript. All authors approved the final version of the manuscript.

Conflict of Interest

The authors declare that there is no potential conflict of interest with peers, institutions, politicians, or financial entities related to this study.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.

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