

ORIGINAL ARTICLE

Analysis of labeling infant's formulas to children allergic to the protein in cow's milk

Francisca Alanna Caroline Timbó Freitas^a, Francisco Valdicélio Ferreira^b, Edilayne Gomes Boto^c, Mauro Vinicius Dutra Girão^d



^aNutricionista, Centro Universitário UNINTA, Sobral, Ceará 62020-000, Brasil;

^bNutricionista, Mestrando em Biotecnologia Universidade Federal do Ceara, Sobral, Ceará 62020-000, Brasil;

^cNutricionista, Centro Universitário UNINTA, Sobral, Ceará 62020-000, Brasil;

^dBiólogo, Mestre em Engenharia de Pesca, Centro Universitário UNINTA, Sobral, Ceará 62020-000, Brasil;

Corresponding author
celionutri@gmail.com

Manuscript received: July 2023

Manuscript accepted: September 2023

Version of record online: December 2023

Abstract

Introduction: breastfeeding is the most effective way to feed the child in the first six months of life exclusively and up to two years as a complementary form, as it provides a healthy development. However, in some situations it is impossible among them in children with food allergies such as Cow's Milk Protein Allergy (APLV). This condition can be defined as an adverse reaction of the immune system, caused by antigens present in the food that triggers the allergy.

Objective: analyze the information on the labeling of infant formulas for infants with allergies to cow's milk protein (APLV), sold in pharmacies in Sobral/CE.

Methods: cross-sectional, exploratory, quantitative and qualitative study. After data collection, the labels were analyzed based on a check list composed by the current legislation in accordance with RDC 45/2011, measuring the number of adjustments and inadequacies.

Results: of the seven formulas analyzed, five were 100% adequate, when considering all the provisions that made up the check list. Of these were FAB-1 B, FAB-1 C, FAB-1 E, FAB-1 F, FAB-2 A, they were all in accordance with the dimensions established by RDC 45/2011, it is already in relation to formulas with inadequacy we observed that FAB-1 A was 2.22% in dimension two in which the micronutrient riboflavin was above the recommended range and FAB-1 D was 2.22% in dimension two, the carbohydrate macronutrient above the recommended range. In view of this, what we observed was that most of the formulas analyzed were within the labeling standards specified in Resolution RDC 45/2011, despite the many regulatory standards that govern the labeling and marketing of infant foods, it was realized that there is still a need for regulation stricter in this regard so that the legislation is fully complied with.

Conclusion: according to what was evaluated about formulas for infants with APLV in relation to the labeling standards of the current legislation, some inadequacies were found. Therefore, this study showed a greater number of non-conformities in relation to the essential characteristics of composition and quality, despite the many regulatory standards that govern the labeling and marketing of infant foods, it is clear that they are still not fully complied with. It was found that we still need to evolve in the Elaboration, execution and inspection of the labels of formulas for infants with Allergy to Cow's Milk Protein (APLV), in order to minimize these non-conformities and offer the best food within the recommended standard, however these studies are necessary in order to better show and discuss the legislation referring to these products.

Keywords: infant care, infant formulas, food labeling, legislation, food.

Suggested citation: Freitas FACT, Ferreira FV, Boto EG, Girão MVD. Analysis of labeling infant's formulas to children allergic to the protein in cow's milk. *J Hum Growth Dev.* 2023; 33(3):376-382. DOI: <http://doi.org/10.36311/jhgd.v33.15283>

Authors summary

Why was this study done?

This study was conducted with the intent to investigate and analyze information about the labeling of infant formulas for breastfeeding infants allergic to the protein in cow's milk (CMPA), commercialized in pharmacies in the countryside of the State of Ceará.

What did the researchers do and find?

We conducted a transverse, exploratory, quantitative and qualitative study with data collection in local pharmacies, investigating the labels, for an analysis based on a checklist created by the current Brazil legislation, according to RDC 45/2011, measuring the number of adequacies and inadequacies.

Seven formulas were analyzed, and five of those were deemed as 100% adequate when all the requirements on the RDC 45/2011's checklist were taken into consideration. We observed, in the formulas deemed inadequate, that 2,22% showed the micronutrient riboflavin and carbohydrate above the recommended in the second requirement on the checklist. In the face of this, we observed that most of the formulas analyzed fit the labeling rules specified in the RDC 45/2011 Resolution.

What do these findings mean?

We expect the results of this research to contribute significantly, serving as a guide to strengthen the regulatory standards that supervise the labeling and commercializing of infant food, with more rigorous inspection in the sense of providing the safest food possible, aiming not to provide any danger in the foreseeable future.

INTRODUCTION

Breastfeeding is the wisest natural strategy of bonding, affection, protection and nutrition for a child and constitutes the most sensitive, economical and effective intervention to reduce infant morbidity and mortality. Breastfeeding is the best way to feed the baby, constituting the basis for biological and emotional effects on the child's development. Among the benefits of human milk for children, we highlight its better digestibility, chemical balanced composition, lack of allergenic principles, protection from infections, besides the low cost^{1,2}.

In this context, breastfeeding is the most effective way to feed the child in the first six months of life, exclusively, and until 02 years of age as a complementary way, as it provides the supply of all the nutrients necessary for healthy development and growth. Breast milk contains lymphocytes and immunoglobulins that help the immune system fight against infections, chronic and infectious diseases³.

For the practice of breastfeeding to be successful, the support of health professionals is indispensable, helping mothers, infants and family, clarifying the management, prevention of complications, difficulties and beliefs and, mainly, reinforcing the importance of breastfeeding exclusively in the context of mother and child health².

There are some occasions when breastfeeding is not possible, among them is the manifestation of allergies in the child, in which we can highlight the Cow's Milk Protein Allergy (CMPA). This condition can be defined as an adverse reaction of the immune system, caused by antigens present in the food that triggers the allergy, in which immunoglobulins E (IgE) or T cells are involved and, in some cases, both mechanisms. It is a reproducible immunological reaction against a specific food antigen, generally proteic, being more prevalent in children than in adults, being more common in infants^{4,5}.

CMPA is the most common food allergy in early childhood children. The clinical presentation is varied depending on the type of immune response whether IgE or non-IgE mediated. In most cases, the acquisition of tolerance to Cow's Milk Proteins (CLP) occurs until the second year of life; it is an inflammatory, immunologically mediated disease that mainly affects gastrointestinal and

skin symptoms. In CMPA, there is an immunological reaction against some proteins present in CMPA, mainly beta-lactoglobulin, alpha-lactalbumin and casein, which are the most frequent food allergens in the age group up to two years of age^{6,7}.

When the child is diagnosed with CMPA, it is necessary for the mother to carry out a diet, that excludes cow's milk protein, in which it is often essential to use infant formulas, which are compounds made from protein isolated from cow's milk or soy, intact or extensively hydrolyzed amino acids, with other nutrients, in adequate amounts for the child's development and growth. These formulations are most appropriate for feeding in the first year of life, as they have a nutritional composition adapted to the infant growth rate, preventing the onset of diseases related to excess and deficiency of nutrients⁵.

The nutritional formulas used in CMPA are soy-based, extensively hydrolyzed or lactose-free protein and amino acid-based formulas. These components must be indicated on the label. Nutrition labeling is any inscription, legend, image or any descriptive or graphic material, written, printed, stamped, engraved, embossed or lithographed or pasted on the food packaging, being necessary the clarification for the consumer^{8,9}.

Due to the care inherent to this type of allergy, attention should be paid to the labels of the formulations. The importance of the information conveyed in the labeling takes on an even more relevant character, considering that the inadequacies in the acquisition or preparation of these foods can cause harm to the infant's health¹⁰.

The present study deals with the investigation of formulas indicated for children with CMPA as recommended by Anvisa's Collegiate Board Resolution 45/201111 in order to search information about the legislation and if in practice analyzing the labeling, these are found in the standard in relation to all its required composition as indicated by the resolution.

As it was described in the previous paragraphs, this research aims to analyze the labeling of infant formulas commercialized in a county in the interior of Ceará for infants with CMPA and whether they are in accordance with the current legislation RDC 45/2011¹¹, as specific

objectives classify them in terms of information. The nutritional composition on the labels, check the health record at Brazilian Health Regulatory Agency (ANVISA) and discuss the socioeconomic situation in relation to the costs of acquiring infant formula for infants with CMPA.

METHODS

This is a transverse, exploratory, qualitative and quantitative study, developed in the commercial network of pharmacies in the county of Sobral. All pharmacies with current registration in the municipal health surveillance were visited, totaling 79 pharmacies for the situational diagnosis and to check the existence and quantity of infant formulas available for consumption by infants with CMPA. We found only 03 network pharmacies that sold formulas, and only one of these units was visited.

Data collection was performed in three stages: the first was the request for authorization from the pharmacy manager to photograph the labels of formulas available for sale, as well as the values (in BRL) to the consumer of the products; in the second stage, the labels of infant formulas indicated for CMPA were photographed, and the third stage was the analysis of each label based on the RDC No. 45/2011¹¹. Only products from pharmacies that authorized the research were part of the study. Among all pharmacies that were visited, only 03 commercialized the products and accepted the research.

The sanitary registration of infant formulas for infants with CMPA was verified on the website of the Brazilian Health Regulatory Agency (ANVISA).

For data collection, we used the validated⁵ checklist

instrument that addresses infant formulas for children with specific dietary needs and follow-up on infant formulas for babies and early childhood children with dietary needs. According to the RDC 45/2011¹¹. The checklist includes three dimensions: dimension 01, which deals with the product designation, dimension 02, about the composition of the formula, and dimension 03, includes the product labeling. Dimension 01 is composed of 06 items, dimension 02 by 47 items, and dimension 03 by 19 items.

To fill out the instrument, codes were generated nominally corresponding to: compliant (C); Not compliant (NC); Not applicable (NA).

The classification of the analyzed products as elementary and semi-elemental infant formulas, as well as the commercialization values for the acquisition of infant formulas for infants with CMPA were recorded in a form built specifically for this purpose.

The data analysis is presented descriptively in numbers and percentages, quantifying the number of conformities and nonconformities. The infant formulas were classified according to the producer labeling. All data obtained with the evaluation of the checklist was organized and arranged in tables from the use of Excel and Word© programs.

RESULTS

At the end of the data presentation period, it was found 07 infant formulas for infants and early childhood children with CMPA from two producers, being producer - 1 (PRO-1) with 06 formulas and producer - 2 (PRO-2) with 01 formula.

Table 1: Infant formulas for infants and early childhood children inadequacies commercialized in Sobral-CE pharmacies

Formulas	Dimension 01		Dimension 02		Dimension 03	
	Number of items = 06	%	Number of items = 47	%	Number of items = 19	%
PRO -1 A	0	0%	1	2,22%	0	0%
PRO -1 B	0	0%	0	0%	0	0%
PRO -1 C	0	0%	0	0%	0	0%
PRO -1 D	0	0%	3	6,67%	2	10,53%
PRO -1 E	0	0%	0	0%	0	0%
PRO -1 F	0	0%	0	0%	0	0%
PRO -2 A	0	0%	0	0%	0	0%
Total of inadequacies (Average).	0	0%	0,57	1,27%	0,28	1,50%

Own authorship (2019).

Five of the seven analyzed formulas were able to achieve 100% of adequacy (PRO -1 B, PRO -1 C, PRO -1 E, PRO -1 F, PRO -2 A) when considered all dispositions that integrated the checklist, all of them were made according to the established dimensions by RDC 45/2011¹¹. Regarding the inadequate formulas, PRO -1 A presented 2,22% of the riboflavin micronutrient on dimension 2, which was above the recommended range, and PRO -1 D presented 6,67%

on dimension 2, because the carbohydrate macronutrient was above the recommended range. The same producer, on dimension 3, presented inadequacy related to the daily value (DV) on the formulas label.

Table 2 presents the formulas classified as inadequate regarding the content of vitamins, minerals and other nutrients.

Table 2: Content of micronutrients and macronutrients of the commercialized products in Sobral-CE pharmacies

Micronutrient/ Macronutrients	Below recommended range	Above recommended range
Riboflavin	-	PRO- 1 A
Vitamin A	PRO- 1 D	
Iodine	PRO- 1 D	
Carbohydrate	-	PRO- 1 D

Source: Own authorship (2019).

The greater compliance related to the current legislation was observed on dimension 1. This dimension evaluates aspects concerning how the designation of the product is and is composed of 6 items. Therefore it is possible to analyze that among the formulas the PRO -1 D obtained the greater number of inadequacies.

Rocha⁵ researched 30 formulas analyzing the same dimension in the present study in which he observed that it had the highest average of inadequacies (16,25%), what concerns the designation of infant formulas for infants, and infant formulas for infants with specific dietary needs, all items presented inadequacies.

At the dimension 2, which is composed for 45 items, we observed 1,27% of inadequacies including the standard values for vitamins, minerals and other compounds as of Choline, Myo-Inositol and L-Carnitine, essential characteristics of composition and quality of infant formulas showed inadequacies, because of the item 8 of PRO -1 D that dealt with the minimum of total carbohydrates is found with the value above the recommended which is 9g/100kcal to 14,0g/100kcal.

On table 3 we can verify the distribution of values of each one of the infant formulas according to the pharmacies that commercialized the products.

Table 3: Values of the researched infant formulas that are commercialized in Sobral-CE pharmacies

Producers	Pharmacy 1	Pharmacy 2	Pharmacy 3
Number of formulas = 6	Number of formulas = 5	Number of formulas = 1	
PRO -1 A	134,90 BRL	132,00 BRL	-
PRO -1 B	229,99 BRL	219,99 BRL	-
PRO -1 C	46,40 BRL	65,69 BRL	-
PRO -1 D	224,99 BRL	223,49 BRL	-
PRO -1 E	89,90 BRL	179,99 BRL	-
PRO -1 F	105,99 BRL	-	-
PRO -2 A			69,99 BRL

Source: Own authorship (2019).

Another factor that was observed was the values of each formula, because it was realized that the values are different at pharmacy 2 the PRO -1 A was found with an inferior value such as PRO -1 B and PRO -1 D and in the remaining formulas at pharmacy 1 had an inferior value. However, only in pharmacy 3 it is commercialized the PRO -2 A.

We observe the elevated value of the formulas compared to the others that are not for specific dietary therapies needs, in that a lot of municipalities do not provide it, requiring that the citizen many times has to initiate legal proceedings to be able to get the infant formula, because of the very high price.

DISCUSSION

Some formulas are in disagreement and this can present risks to the infant's feeding until six months old, when the consumption is exclusive and also for older children that already consume other foods.

Facing this great significance, it was expected a 100% adequacy just like it recommends the current legislation, RDC 45/2011¹¹, mistakes were perceived at the composition and/or information conveyed on the labeling which can lead to serious health problems for the infants that use infant formulas. However, contradicting

this expectation, some of the analyzed products presented some inadequacies.

A study realized by Baldani, Pascoal and Rinaldi¹² evaluates 47 infant formulas concerning labeling compliance, technical regulation and nutritional information, it was noticed that the infant formulas were not in agreement with the legislation which requires that food must use registration, vocabulary or a figure that make the consumer not to have doubts at the time of the purchase.

Comparing the authors' results with those of the present study, it was possible to perceive that there was not total adequacy of the labeling of those products, as we found inadequacy regarding inadequate illustrations and expressions.

It is worth highlighting that the study by Bernardi *et al.*¹³, in which the study of well-being directly influences children's health and well-being, as it depends on the interaction between their genetic potential and environmental complement. An important and necessary source of energy for children's lives is carbohydrate, however its excess can cause several pathologies such as diabetes, cardiovascular problems and lead the child to overweight and obesity. Thus, adequate nutrition plays a very important role in growth, development and disease prevention.

Regarding PRO-1 D, the recommended vitamin A is from 60 mcg to 300 mcg/100 kcal, which is below what is recommended. A study by Pedraza and Queiroz¹⁴, show that the lack of Vitamin A still has high prevalence in most developing countries, causing several problems to the health of those individuals. Vitamin A is a fundamental micronutrient for physiological processes, as it acts in the proper functioning of vision, cell differentiation, epithelial tissue integrity, reproduction and the immune system, being very important during childhood, especially as recommended by the Health Ministry on children from the sixth month of life up to the age of five.

We observed an inadequacy regarding the mineral iodine, whose recommendation ranges from 10 to 60mcg/100 kcal, being also below. It is estimated that two billion people worldwide do not consume sufficient amounts of iodine daily for healthy thyroid function, as iodine is an essential mineral for the synthesis of thyroxine (T4) and triiodothyronine (T3), which are important in the fetal development, in the metabolic control of cells and in the physical and neurological growth of individuals¹⁵.

It was also found that in PRO -1 A, Vitamin B2 (riboflavin) has its values above the recommended, it is worth mentioning that infant formulas and milk can be considered important sources of Vitamins B2 contributing to functions in the body, such as assisting in the blood production, adjust metabolism, help with growth and act on the visual process of the nervous system¹⁶.

Also, according to the authors, excess riboflavin can occur even though it is easily eliminated through urine, in which case it can increase the risk of developing kidney stones, sensitivity to light and itchy skin. One of the aggravating factors is the labels of some producers that do not have riboflavin on their products, which makes it a limitation for who will consume it.

The check list of RDC 45/2011 on dimension 03 intends to evaluate information regarding the infant's formula labeling for children, consisting of 19 items. This dimension, which had the highest average of inadequacies (1.50%), concerns the labeling of infant formulas for infants with specific dietary needs, corresponding to items 4 and 7.2 of the RDC in which PRO - 1 D, presented specific inadequacies what deals with the percentage of daily value (%DV) and the phrase "does not contain milk or dairy products" thus being classified as inadequate.

It was also found that in dimension 3, item 1, deals with the nutritional information being declared per 100g or 100mL according to the producer's instructions, on item 2, regarding the nutritional information, it is declared per 100kcal and per 100kj, on item 3, regarding when added the nutrients DHA, ARA, Taurine, Nucleotides, and/or FOS and GOS are declared.

This way, it is also stated on item 5, which deals with probiotics added to the amounts, close to the nutritional information per 100 ml of ready-to-eat food, already on item 7.1 of dimension 3, about the protein sources of the product are clear, 7.3 of dimension 3, regarding the proper instructions for use, preparation and conservation, 7.4 of dimension 3, on the preparation of the product with boiled water and later cooled, did not present any inadequacy, as well as in items 7.5, 7.6, 7.7, 7.8, 7.9, 7.10 of dimension

3, regarding the temperature and average boiling time, immediate consumption, disposal over the rest of the product, illustrations on the preparation method, health hazards resulting from misuse and conservation of the product, respectively.

On item 08, it concerns products labeled in order to avoid confusion among other infant formulas and the formulas have a warning; if they contain probiotics and should not be consumed by premature, immunocompromised or with heart disease children, those did not apply to any of the formulas evaluated on the present work.

According to Romero, Talesnik and Harris¹⁷, they observed that some formulas they analyzed did not clearly present the animal protein present in the product. In recent years, an increase in children with CMPA has been observed, and according to the authors, the prevalence is between 2 and 7.5% in infants fed with infant formula. Absences concerning the origin of the infant formula protein can lead to the wrong indication or purchase of the formula, and it is possible to cause harm to the infant with CMPA.

On the seven formulas that were analyzed in this research, we observed that the two producers showed that all formulas are properly registered.

The Brazilian Health Regulatory Agency (ANVISA) is the body that establishes which information must appear on food labels, in order to guarantee the quality of the product regarding the health of the population. List of ingredients, expiration date and nutritional information are among the mandatory items on the labels, as well as the homemade measure. The resolution RDC 45 published in September 2011 refers to products intended for feeding infants and early childhood children. The norms resulted from a process of technical revisions of the composition criteria and established minimum and maximum limits of vitamins and minerals allowed in these formulations¹⁸.

Thus, it is necessary that, in these situations, the health professional has the ability to guide while the nutritionist can stimulate the change in the infant's eating habits with a diet free of cow's milk protein, in order to continue breastfeeding, which is essential in addition to protecting against various diseases infections, presents long-term benefits resulting from inadequate nutrition, such as obesity, hypertension and dyslipidemia, as well as type I diabetes mellitus, estimating, in the latter case, that 30% of occurrences could be prevented if 90% of children up to three months of age did not receive cow's milk¹⁸.

According to the Health Ministry, the average monthly expenditure with the purchase of milk to feed a baby in its first six months of life in Brazil varies depending on the brand of the infant formula and not breastfeeding can mean financial sacrifices for the family, and these expenses could be used for other family expenses, providing greater social well-being¹⁹.

■ CONCLUSION

It is notable the rigidity from Brazilian law about food labeling, but yet, it was possible to verify an amount of nonconformities in some infant formula package labels commercialized.

Simple information could persuade the consumer to buy an unqualified product, making the infant precociously consume products that can affect the pathology, growing and development.

An important analyzed data was the presence of carbohydrate above the recommended in a formula, although other analyzed marks are according to the standards, the excessive consume of this nutrient can cause future health problems showing that the increased inspection necessity, further clarification and levy from consumers could make rules and laws be fulfilled, decreasing the damages that can be caused.

Therefore this study presented a bigger number of nonconformities relating essential characteristics of composition and quality, besides many regulatory standards that conduct infant food commercialization are not followed.

Still, we see the necessity to improve the oversight level, not just in nutritional and microbiological quality, but also on package labels to infants allergic to cow's milk protein (CMPA), in order to minimize these nonconformities.

Also stands out that some past research made by other authors detected some nonconformities in infant formulas too, proving it is a recurrent problem in this kind of product and it is necessary a routine inspection in order to improve this reality.

Authors Contribution

Idealization, collection, analysis, discussion of data and writing of the manuscript.

Ethics committee approval

Not applicable.

Financing

No Financing.

Acknowledgments

To everyone who contributed in the design and writing of this study.

Conflicts of interest

No conflicts of interest.

■ REFERENCES

1. Brasil. Associação Brasileira de Alergia e Imunopatologia, Sociedade Brasileira de Alimentação e Nutrição. Guia prático de diagnóstico e tratamento da alergia às proteínas do leite de vaca mediada pela imunoglobulina E. *Rev Bras Alerg Immunopatol.* 2012; 35(6):203-33.
2. Bueno KCN. A importância do aleitamento materno exclusivo até seis meses de idade para promoção da saúde da mãe e do bebê. 2013. 27. Monografia (Especialização)-curso de Especialização em atenção Básica em Saúde da família. Universidade federal de Minas gerais,2013.
3. Souza EACS. Reflexões acerca da amamentação: uma revisão bibliográfica. . Universidade Federal de Minas Gerais. Faculdade de medicina núcleo de educação em saúde coletiva. Belo Horizonte, 2010.
4. Brasil. Associação Brasileira De Alergia E Imunologia – ASBAI. Informações ao público: alergia alimentar – perguntas e respostas. São Paulo, 2017.
5. Rocha KF. Análise da rotulagem de fórmulas infantis para lactentes. 2016(Monografia) universidade federal do rio grande do norte centro de ciências da saúde departamento de nutrição universidade federal do rio grande do norte.
6. Dias A, Santos A, Pinheiro JA. Persistence of cow's milk allergy beyond two years of age. *Allergol Immunopathol (Madr).* 2010; 38(1): 8-12. DOI: 10.1016/j.aller.2009.07.005
7. Caldeira F, Da Cunha J, Ferreira MG. Alergia A Proteínas De Leite De Vaca. *Acta Medica Portuguesa.* 2011; 24(4):505-510.
8. Brasil. Resolução - RDC No 259, DE 20 DE SETEMBRO DE 2002. Disponível em: www.agricultura.gov.br/.../resolucao-rdc-no-259-de-20-de-setembro-de-2002.../view > acesso em 20. Mar. 2020.
9. Brasil. CONITEC. Comissão nacional de incorporação de tecnologia do Sus. 2018, Fórmulas nutricionais para crianças com alergia à proteína do leite de vaca. Ministério da Saúde,2018.
10. Albuquerque GLB, Silva EB, Rodrigues N, Cardoso FT. Avaliação da adequação da rotulagem de fórmulas infantis para lactentes. *O Mundo da Saúde, São Paulo.* 40(4): 481-489. 2016. tab, graf. DOI: 10.15343/0104-7809.20164004481489
11. Brasil. Agência Nacional de Vigilância Sanitária. Resolução RDC 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. *Diário Oficial da União, Poder Executivo,* de 19 de setembro de 2011.
12. Baldani MM, Pascoal GB, Rinaldi AEM. Rotulagem e promoção comercial de fórmulas infantis comercializadas no Brasil. *DEMETERA: Alimentação, Nutrição & Saúde.* 2018;13(2): 413-425, 2018. DOI: <https://doi.org/10.12957/demetra.2018.32911>.

13. Bernardi JR, De Cezaro C, Fisberg MR, et al. Estimativa do consumo de energia e de macronutrientes no domicílio e na escola em pré-escolares. *Jornal de Pediatria*. 86(1), 59-64. <https://doi.org/10.1590/S0021-75572010000100011>.
14. Pedraza DF, De Queiroz D. Micronutrientes no crescimento e desenvolvimento infantil. *Journal of Human Growth and Development*. 2011; 21, (1), 156-17.
15. Da Silva ARM, Melchert WR. Iodo: riscos e benefícios para a saúde humana. *Ciência e Cultura*. 71 (2), 58-60. <https://dx.doi.org/10.21800/2317-66602019000200016>.
16. Reiter MGR, de Souza CK, Ferraz NH, et al. Riscos e Benefícios da Dieta Vegetariana em Crianças. *International Journal of Nutrology*. 2018. 11, (S 01), 713. DOI: 10.1055/s-0038-1675010
17. Romero B, Talesnik E, Harris, PR, et al. Características clínicas associadas a colitis eosinofílica em lactantes con rectorragia persistente. *Revista chilena de pediatría*. 2014; 85 (6): 666-673doi: 10.4067/S0370-41062014000600003
18. Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Consulta Pública n.º 29/2014. Proposta de Resolução de Diretoria Colegiada que dispõe sobre Rotulagem de Alergênicos em Alimentos. Gerência Geral de Alimentos, 2013.
19. Brasil. Ministério da Saúde. Secretaria de Atenção à Saúde. Departamento de Atenção Básica. Saúde da criança: nutrição infantil: aleitamento materno e alimentação complementar. Brasília: Editora do Ministério da Saúde, 2009.

Resumo

Introdução: a amamentação é a forma mais eficaz de alimentar a criança nos primeiros seis meses de vida exclusivamente e até os dois anos como forma complementar, pois proporciona um desenvolvimento saudável. No entanto, em algumas situações, é impossível entre eles em crianças com alergia alimentar, como a alergia à proteína do leite de vaca (APLV). Essa condição pode ser definida como uma reação adversa do sistema imunológico, causada por antígenos presentes nos alimentos que desencadeiam a alergia.

Objetivo: analisar as informações sobre a rotulagem de fórmulas infantis para lactentes com alergia à proteína do leite de vaca (APLV), comercializadas em farmácias de Sobral/CE.

Método: estudo transversal, exploratório, quantitativo e qualitativo. Após a coleta de dados, os rótulos foram analisados com base em um check list composto pela legislação vigente de acordo com a RDC 45/2011, mensurando o número de adequações e inadequações.

Resultados: das sete fórmulas analisadas, cinco foram 100% adequadas, quando consideradas todas as disposições que compunham o check list. Destes eram FAB -1 B, FAB -1 C, FAB -1 E, FAB -1 F, FAB -2 A, todos estavam de acordo com as dimensões estabelecidas pela RDC 45/2011, já está em relação às fórmulas com inadequação observamos que FAB-1 A foi de 2,22% na dimensão dois em que a micronutriente riboflavina estava acima da faixa recomendada e FAB-1 D foi de 2,22% na dimensão dois, o macronutriente carboidrato acima da faixa recomendada. Diante disso, o que observamos foi que a maioria das fórmulas analisadas estava dentro dos padrões de rotulagem especificados na Resolução, apesar das inúmeras normas regulamentadoras que regem a rotulagem e comercialização de alimentos infantis, percebeu-se que ainda existe necessidade de regulamentação mais rigorosa nesse sentido, para que a legislação seja integralmente cumprida.

Conclusão: de acordo com o que foi avaliado sobre as fórmulas para lactentes com APLV em relação aos padrões de rotulagem da legislação vigente foram encontradas algumas inadequações. Portanto esse estudo apresentou maior número de inconformidades em relação as características essenciais de composição e qualidade, apesar das muitas normas regulamentadoras que regem a rotulagem e comercialização de alimentos infantis, percebe-se que ainda não são totalmente cumpridas. Verificou-se que ainda precisamos evoluir na Elaboração, execução e fiscalização dos rótulos das fórmulas para lactentes com Alergia a Proteína do Leite de Vaca (APLV), a fim de minimizar essas não conformidades e oferecer o melhor alimento dentro do padrão preconizado, no entanto faz-se necessários estes estudos a fim de mostrar e discutir melhor as legislações referentes a esses produtos.

Keywords: cuidado do lactente, fórmulas infantis, rotulagem de alimentos, legislação, alimentos.

©The authors (2023), this article is distributed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated.