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# Inadequate labeling of allergenic food: the risk for individuals with food hypersensitivity

Inadequação da rotulagem de alimentos alergênicos: risco para indivíduos com hipersensibilidade alimentar

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## Abstract

Objective: To analyze labeling adequacy of allergenic foods in accordance with Resolution no. 26, of July 2, 2015. Methodology: The agreement of allergen declarations was evaluated on 221 labels of processed foods commercialized in three distinct supermarket chains. The products were subdivided into ten food groups (breads and cereals; fish and crustaceans; eggs and derivatives; oily seeds; milk and derivatives; soybeans and derivatives; pastas; sweets, cakes and biscuits; meats and processed meats and alcoholic beverages) and were categorized as "inadequate" when they failed to meet any criteria set forth in the resolution. In order to detail the inadequacies, the following classifications were adopted: incorrect location of the declaration on the label, incomplete declaration and/or inadequate formatting and nonexistent declaration. Results: The evaluated food labels showed that 31.7% (n=70) were identified as inadequate. Of these inadequacies, it was observed that 48.6% were classified as "Nonexistent Declaration". It was also observed that the inadequacies were found in the ten food groups. Conclusion: National regulatory labeling norms have innovated regarding the protection of allergic consumers, however, there are still several irregularities in their compliance. Investigations of this nature are relevant to public health and must be carried out to demand supervision and implementation of the current legislation.

Keywords: Food labeling. Food hypersensitivity. Food legislation.

#### Resumo

*Objetivo:* Analisar a adequação da rotulagem de alimentos alergênicos de acordo com a Resolução n.º 26, de 02 de julho de 2015. Metodologia: Verificou-se a concordância das declarações de alérgenos em 221 rótulos de alimentos industrializados comercializados em três redes distintas de supermercados. Os produtos foram subdivididos em dez grupos de alimentos (pães e cereais; peixes e crustáceos; ovos e derivados; sementes oleaginosas; leites e derivados; soja e derivados; massas; doces, bolos e biscoitos; cárneos e embutidos e bebidas alcoólicas) e foram categorizados como "inadequados" quando descumpriram qualquer critério estabelecido na resolução. Para detalhar as inadequações, foram adotadas as seguintes classificações: localização incorreta da declaração no rótulo, declaração incompleta e/ou formatação inadequada e declaração inexistente. Resultados: Do total de rótulos avaliados, 31,7% (n=70) foram identificados como inadeguados. Destas inadeguações, observouse que 48,6% foram classificados como "Declaração inexistente". Observou-se, ainda, que foram encontradas inadequações nos dez grupos de alimentos avaliados. Conclusão: As normas regulamentadoras nacionais de rotulagem dispõem inovações na perspectiva de defesa do consumidor alérgico; no entanto, ainda se observam diversas irregularidades no seu cumprimento. Investigações desta natureza são relevantes para a saúde pública e devem ser realizadas para exigir a fiscalização e implementação das legislações vigentes.

Palavras-chave: Rotulagem de alimentos. Hipersensibilidade alimentar. Legislação sobre alimentos.

### Introduction

Food labeling became mandatory in Brazil with the creation of the Agência Nacional de Vigilância Sanitária (ANVISA - National Sanitary Surveillance Agency) in 1999. This body establishes the necessary reports for labels to ensure the quality of products with adequate information for consumers.<sup>1,2</sup>

According to the Resolution of the Collegiate Board of Directors (RDC) No. 259/2002, which approves technical regulation for the labeling of packaged foods, labeling is any inscription, legend, image or any descriptive or graphic material, written, printed, recorded in relief or lithographed or glued onto the food packaging. Moreover, the label is one of the tools of communication between the nutritional properties of a product and its consumers and thus an important element for public health.<sup>3,4</sup>

Regarding the abovementioned, labeling is a resource that assists in the orientation of eating habits, as well as in the prevention of adverse reactions directly associated with food, such as allergies and food intolerance.<sup>5,6</sup> In individuals allergic to food, even minimal ingested amounts are sufficient to trigger serious reactions.<sup>7</sup> The main clinical manifestations of a food allergy include mucocutaneous reactions (urticaria, angioedema, erythema, pruritus), reactions in the gastrointestinal tract (diarrhea, abdominal pain, nausea, vomiting), in the respiratory system (sternutation, rhinorrhea, cough, dyspnoea, sibilant rhonchi) and cardiovascular reactions (stunning, hypotension, syncope). However, the major concern in an allergic crisis is the anaphylaxis, a sudden and severe manifestation that may be fatal if not treated immediately.<sup>8</sup>

It is worth noting that the number of cases of food allergies has increased notably worldwide in the last decade.<sup>9</sup> In the United States, its prevalence has increased by 18% in ten years in the pediatric population; in Europe, 17 million people have some type of food allergy.<sup>7,10</sup> Recent data from the Associação Brasileira de Alergia e Imunologia (ASBAI - Brazilian Association of Allergy and Immunology)<sup>11</sup> estimate that 10 million Brazilians are afflicted by food allergies, which is equivalent to 5% of the population.

Hypersensitivity reactions may be caused by numerous foods, however, approximately 90% of reported food allergy cases are induced by eight main foods: eggs, wheat, soybeans, peanuts, nuts, milk, fish, and crustaceans.<sup>7</sup> It is worth noting that the *Codex Alimentarius*, a body of the Food and Agriculture Organization (FAO), recognizes these foods as allergens of high relevance for public health.<sup>12,13</sup>

In Brazil, regulations on the labeling of allergenic foods are recent. On July 3, 2015, RDC No. 26 was published, which provides the requirements for mandatory labeling of the main foods that cause food allergies. From this date, companies have been given a 12-month deadline for mandatory adjustments to the products covered by this resolution, including food, beverages, ingredients, food additives and coadjuvant of technology packaged in the absence of consumers.<sup>14</sup> In this perspective, adequate clarification of labeling to allergic consumers is essential, since they may use complete information that will prevent the consumption of foods that could trigger possible adverse reactions.<sup>7,15</sup>

Since one of the strategies for the treatment of food allergies consists in the exclusion of allergenic food from the diet,<sup>16</sup> the access to adequate, reliable and clear information on labeling is essential to avoid and control the risk of food hypersensitivity reactions.<sup>12</sup> In this sense, this study aimed to analyze the labeling adequacy of allergenic foods according to Resolution No. 26/2015.

# Methodology

This is an evaluative and of quantitative approach study that verified the agreement of allergen declarations in 221 labels of industrialized foods commercialized in three distinct supermarket chains, located in the municipalities of Belo Horizonte and Sabará - MG, in the period from August to October 2016.

The labels of products of various brands were analyzed under the provisions of RDC No. 26/2015 and categorized as "inadequate" when they failed to meet any criteria established in the resolution. Thus, foods containing or derived from allergenic foods listed in that resolution, in accordance with Article 6, shall bring the following mandatory declaration: "ALLERGICS: IT CONTAINS (COMMON NAMES OF FOODS THAT CAUSE FOOD ALLERGIES), ALLERGICS: IT CONTAINS DERIVATIVES FROM (COMMON NAMES OF FOODS THAT CAUSE FOOD ALLERGIES) OR ALLERGICS: IT CONTAINS (COMMON NAMES OF FOODS THAT CAUSE FOOD ALLERGIES) AND DERIVATIVES", according to each case.

When it is not possible to ensure the absence of cross-contamination by food allergens, according to Article 7, the label shall contain the declaration: "ALLERGICS: IT MAY CONTAIN (COMMON NAMES OF FOODS THAT MAY CAUSE FOOD ALLERGIES)", according to each case. Furthermore, these warnings must be legible, located immediately after or below the list of ingredients and with the formatting requirements in the declaration: uppercase, bold, color contrasting with the background of the label and size equal to or higher than the size of the letter used in the list of ingredients.<sup>14</sup>

Therefore, the inadequacies were classified as specified in Table 1.

Inadequacy	Classification
Nonexistent declaration	Labels that did not contain the mandatory declaration of allergenic ingredients.
Incomplete declaration	Labels that omitted the term "ALLERGICS".
Incorrect location of the declaration	Labels in which the information of the presence of allergens was not found immediately after the ingredient list.
Inadequate formatting of the declaration	Labels that did not conform to the formatting provided in the resolution.

**Table 1.** Classification of the inadequacies verified on the labels of the analyzed products,Belo Horizonte and Sabará - MG, 2016.

As inclusion criteria, products commercialized as of July 3, 2016 were selected, which could contain any of the main food allergens included in the annex of the abovementioned resolution (wheat, barley, rye, oat, crustaceans, eggs, fish, peanuts, soybeans, milk of mammalian animals, almonds, hazelnuts, cashew nuts, Brazil nuts, macadamias, walnuts, pecans, pistachios, nuts and natural latex). This date represented the end of the 12-month deadline set by the resolution for industries to make the necessary adjustments to the labeling of their products.

Exclusion criteria were foods commercialized without packaging, the ones packaged at the point of sale at the request of the consumer and the ones packaged, prepared or divided into food services and marketed at the establishment itself.

The products were randomly selected in commercial establishments, followed by photographic records of the pertinent information for evaluation. For categorization purposes, the products were subdivided into ten food groups: breads and cereals; fish and crustaceans; eggs and derivatives; oily seeds; milk and derivatives; soybeans and derivatives; pastas; sweets, cakes and biscuits; meats and processed meats and alcoholic beverages. The data were transcribed to a table with the help of Microsoft Office Excel 2010 software, and the statistical software IBM SPSS Statistics (Statistical Package for Social Sciences), version 19 (Chicago, Illinois, USA) was used for the descriptive analysis.

#### Results

Of the 221 analyzed labels, 38.5% (n=85) were selected in supermarket A, 33.9% (n=75) in B and 27.6% (n=61) in establishment C. Regarding the food groups, 33.0% (n=73) corresponded to the group of milk and derivatives; 13.6% (n=30) to the group of breads and cereals; 12.2% (n=27) to sweets, cakes and biscuits; 10.0% (n=22) to meats and processed meats; 7.3% (n=16) to eggs and derivatives; 6.3% (n=14) to pastas; 4.5% (n=10) to fish and crustaceans; 4.5% (n=10) to oily seeds; 4.5% (n=10) to alcoholic beverages and 4.1% (n=9) for soybeans and derivatives.

Of the total number of evaluated labels, 31.7% (n=70) were classified as inadequate. Figure 1 shows the classifications of the recorded inadequacies.



**Figure 1.** Inadequacies verified in the analyses of the information of allergens on the labels of products commercialized in different establishments (%), 2016.

It is possible to observe that the absence of declaration of allergens on the label (48.60%) was the most frequently found inadequacy. The nonconformities observed in this study may hinder and/or limit the identification of the presence of ingredients that should have a restricted consumption by individuals with food hypersensitivity. The adequacies and inadequacies according to the analyzed food groups are shown in table 2.

Food groups	Labels Inadequate* % (n)	Labels Adequates* % (n)
Fish and crustaceans	4,3 (3)	4,6 (7)
Soybean and derivatives	4,3 (3)	4,0 (6)
Meats and processed meats	5,7 (4)	12,6 (19)
Alcoholic beverages	5,7 (4)	4,0 (6)
Breads and cereals	7,1 (5)	16,6 (25)
Eggs and derivatives	7,1 (5)	7,3 (11)
Oily seeds	7,1 (5)	3,3 (5)
Pastas	10,0 (7)	4,6 (7)
Sweets, cakes e biscuits	14,3 (10)	10,6 (16)
Milk and derivatives	34,4 (24)	32,4 (49)
Total	100 (70)	100 (151)

**Table 2.** Evaluation of the adequacy of product labels by food groups, (%, n). Belo Horizonte and Sabará - MG, 2016.

\* Labels analyzed in accordance with RDC No. 26 of July 2, 2015.

It is possible to observe that inadequacies have been verified in all food groups, which implies a greater risk for allergic consumers.

According to table 3, which presents the detailed inadequacies for the ten food groups, it is noted that nine groups presented the classification "Nonexistent declaration", evidencing the negligence on the part of the companies that commercialize the most varied types of food products with allergenic ingredients. The group "Breads and cereals" stood out by presenting the declaration of allergens in all the evaluated labels, however, they proved inadequate in at least one of the investigated issues. On the other hand, the group "Soybeans and derivatives" did not declare the presence of allergenic ingredients in any evaluated label.

				Food	Food groups $[\%, (n)]$	[(u)]				
Inadequacy	Fish and crustaceans	Soybeans and derivatives	Meats and processed meats	Beers	Breads and Cereals	Eggs and derivatives	Oily seeds	Pastas	Sweets, cakes and biscuits	Milk and derivatives
Incorrect location of the declaration	25.0 (1)		75.0 (3)	25.0 (1)	20.0 (1)	20.0 (1)	40.0 (2)	14.3 (1)		62.5 (15)
Nonexistent declaration	75.0 (2)	100.0(3)	25.0 (1)	50.0 (2)		60.0(3)	40.0 (2)	71.4 (5)	70.0 (7)	37.5 (9)
Incomplete declaration	ı	ı	ı	25.0 (1)	20.0 (1)	ı	I	14.3 (1)	30.0(3)	ı
Inadequate formatting	ı	ı	ı	I	20.0 (1)	20.0 (1)	20.0 (1)	ı	ı	,
Incomplete declaration and inadequate formatting			ı	ı	40.0 (2)		ı			
Total (70)	100.0 (3)	100.0 (3)	100.0 (4)	100.0	100.0	100.0	100.0	100.0	100.0	100.0

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#### Discussion

The labels analyzed in this study presented inadequacies in relation to the recent regulations for the labeling of products containing allergenic ingredients. Jardim et al.<sup>17</sup> stated that many food industries generally do not follow certain legal requirements that control labeling. In this regard, it becomes imperative that food industries provide access to safe and useful product information which they are providing to consumers and which meet the requirements of regulations,<sup>18</sup> especially for consumers who are sensitive to food allergens. Once companies do not comply with such recommendations, the penalties established in terms of sanitary infraction, without damaging civil, administrative and penal responsibilities, may be established.<sup>14</sup>

For the approval of this new national resolution, it was necessary the demand from institutions such as ASBAI and the "Put on the Label" Campaign. This movement in social media, composed of individuals allergic to food and their families, allowed the exposure of the challenges for the interpretation of labels. The main difficulties were related to the identification of food allergens presented through technical terminologies, the declaration of many ingredients with generic terms that do not identify their origin and also the lack of declaration of some important allergic constituents in the list of ingredients. The location, contrast and size of the characters were also discussed as obstacles faced by consumers. Thus, this campaign was one of the protagonists in the recognition of the new labeling, which was discussed with Anvisa, medical entities, associations of industry and of consumer rights.<sup>11,15,19</sup>

In this area, studies also showed the consumer's difficulty in understanding the information on the labels of allergenic products. In the study carried out by Binsfeld et al.,<sup>20</sup> it was observed that 39.5% of allergic reactions to cow's milk were related to errors in the reading of labels by the consumers. This study demonstrated the importance that adequate labeling, containing information on the presence of allergens, could have in the aid of the prophylaxis of allergic reactions.

Weber et al.<sup>21</sup> evaluated the performance of parents of children on a cow's milk exclusion diet in the identification of industrialized foods with and without cow's milk. The authors observed that the terms beginning with the word "milk" were the most recognized ones. However, the terms "casein", "caseinate" and "lactalbumin" were identified by less than 25% of the respondents, emphasizing the lack of knowledge of technical terms by the population.

Another study investigated the accuracy of reading labels by parents of allergic children and found that most respondents were unable to recognize allergen ingredients in products, especially in cow's milk and soy milk.<sup>22</sup>

It is important to mention that national studies that have addressed the verification of allergen labeling regarding the new resolution are still scarce. To date, the study conducted by Freitas &

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Piletti<sup>15</sup> investigated the labeling of 15 dairy products of different brands under the criteria of RDC No. 26/2015. The authors verified that only three products reported the presence of allergens, however, they did not mention the period of the study, nor did they evaluate the adequacies in relation to the requirements established in the current legislation. Therefore, it is worth highlighting the relevance of this research to public health.

In the international scope, studies have also been carried out to investigate the declaration of allergens on product labels. The Argentine study conducted by López et al.<sup>23</sup> verified the declaration of food allergens in 21 food labels commonly consumed by children in 2012 and 2014, in order to observe how companies have declared allergens in these labels and the observed changes in two years. The authors noted that several allergens were added in the warning declarations, as well as the presence of a declaration in products that have not stated them previously. However, in both evaluated years, inconsistencies were found, such as the omission of the declaration "it contains soybean derivatives" in foods that contained soy lecithin in their composition, and the declaration "it contains" in allergens that were not present in the list of ingredients. It is worth mentioning that, in this country, the labeling of allergenic foods was not mandatory during the period in which the study was carried out.

The preventive labeling, responsible for informing the presence of allergens in cases of cross-contamination, was investigated by Zurzolo et al.<sup>24</sup> in the packaging of 1,355 products. The Australian authors observed that 65% of the products presented a precautionary declaration for one or more allergens and that the most listed ingredients in preventive labeling were walnuts (36.2%) and peanuts (34.1%), followed by sesame seeds (27.5%) and eggs (22.6%). The American study conducted by Pieretti et al.<sup>25</sup> determined the frequency and the preventive language used on the labels and identified ambiguities for food allergic consumers. Of the 20,241 evaluated products, only 17% contained preventive information on the labels. It is worth noting that in these countries, preventive labeling is still optional, and that in the current Brazilian resolution, such information stands out as a mandatory requirement.

In this context, allergen labeling accuracy is a means of preventing food hypersensitivity reactions, since it transmits information extremely important to allergic consumers who rely on the integrity and clarity of the declaration of allergenic ingredients in food packaging.<sup>6</sup> The inadequacies presented in this study may lead to serious harm to the health of allergic consumers, which may contribute to an increase of expenses in public health services. In addition, monitoring by regulatory bodies is indispensable for meeting the requirements of allergen labeling in order to prevent possible adverse reactions in allergic individuals.

# Conclusion

The present investigation showed that a part of food companies still do not meet the requirements of Resolution No. 26, July 2015, since inadequacies were detected on the labels of the evaluated allergenic foods. It is worth stressing the relevance of this context for public health, since allergic consumers require greater care and attention before consuming any product in order to avoid undesirable reactions. The mission of continuous and effective supervision of compliance with the requirements could be an issue to be re-evaluated by ANVISA and other responsible bodies, with the purpose of ensuring that the consumer has access to safe reports about products.

# **Contributors**

Miranda CCS participated in the conception and planning of the study, in the obtaining, analysis and interpretation of the data and in the writing of the article; Gama LLA participated in the conception and planning of the study, in the analysis and interpretation of the data, in the writing and in the critical review of the final version of the article.

Conflict of interest: The authors declare that there are no conflicts of interest.

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