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Food allergen labeling: compliance with the mandatory legislation in Brazil

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Abstract

Food allergies are reproducible adverse reactions mediated by specific immunological mechanisms that occur in sensitive individuals after consumption of a certain food. It is recommended that the allergic person excludes from the diet the food that triggers the allergic reactions. In Brazil, the Collegiate Board Resolution nº 26 of July 2, 2015, establishes the requirements for mandatory labeling of the main foods that cause food allergies, by implementing the use of alerts. The objective of this work was to verify if food labels in Brazil comply with this resolution. This is a cross-sectional descriptive study carried out at the Ezequiel Dias Foundation from July/2018 to September/2018. The compliance of food labels was investigated according to the requirements for mandatory labeling of the main foods that cause allergies, regulated by CBR 26/2015. The results showed that 12.13% of the analyzed foods did not contain the allergy alert. In addition, 31% of the samples used precautionary allergen labeling, due to possible cross-contamination by an allergenic food. People who have food allergies benefit from advances in food labeling. However, much still needs to be done to ensure that legislation is duly complied, in order to improve the quality of life of allergic people.

Keywords: Food allergy; food labeling; allergens; legislation

Practical Application: As allergic must avoid the intake of the substance that causes allergy, food label should be clear and more explicit with all the present and possible food allergen information. Brazilian legislation on allergens is recent and there is scarce data about its compliance. Nonconformities regarding allergen legislation were found in 31.4% of 379 food labels analyzed. Of the products analyzed, 12.1% of the labels should contain but did not print the mandatory alert for allergics.

1 Introduction

Food allergies are reproducible adverse reactions mediated by specific immunological mechanisms that occur in sensitive individuals after consumption of a certain food (Brasil, 2015). They affect up to 10% of the population (Sicherer, 2011), being about 5% of adults and 8% of children with increasing evidence of increased prevalence (Gupta et al., 2011; Sicherer & Sampson, 2014). Foods that are most often implicated in food allergies are nuts, crustaceans, milk, eggs, fish, soybeans, and wheat (Sánchez & Sánchez, 2015). Consumption of foods containing fragments typically proteins, but sometimes also chemical haptens causing allergies (e.gallergens) by susceptible (e.g allergic) people can cause several signs and symptoms (Boyce et al., 2011). Some symptoms are: abdominal pain or cramps, abnormal breathing sounds, anxiety, confusion, coughing, diarrhea, difficulty breathing, hives, itching, nausea, vomiting, redness of the skin, nasal congestion, wheezing and slurred speech. Some signs are: cardiac arrhythmia, pulmonary edema, low blood pressure, rapid pulse, mental confusion, angioedema in the throat that can cause blockage of the airways, lack of oxygen, pale skin and anaphylaxis, which is the most serious manifestation that can lead to death (Chafen et al. 2010).Currently there are no effective treatments for food allergies, so to ensure the non-manifestation of signs and symptoms the allergic must avoid the intake of the substance that causes allergy (Sicherer & Sampson, 2014).

The identification of the possible allergens present in each food is a challenge for the consumer, especially in relation to the derivatives. The presence of the term "vegetable oil", for example, often does not make clear the origin of the product which can be soy, peanut, sunflower, cotton, among others (Taylor & Hefle, 2001). On the other hand, some people with peanut allergy are not aware that arachis oil is another way to describe peanut oil (Kwon et al., 2020).The same difficulty can arise in the interpretation of labels containing lecithin, gelatin and hydrolyzed proteins (Taylor & Hefle, 2001). Furthermore, in the case of cross-contamination, this information was not available to Brazilian consumers. The solution to this problem was to provide clear and more explicit information on a label, with all the present and possible food allergen information. Considering all these difficulties, mothers of Brazilian allergic children came together in 2014, creating a movement called "Put it on the Label" that aimed to raise awareness among the non-allergic population about the need to label foods that are known to be more allergenic. The mobilization of this group, mainly through social networks, pressured the legislatures in Brazil to discuss a project to standardize the labeling of food allergens (Põe no Rótulo, 2013). Thus, after consultations and public hearings to make food labels clearer for people with food allergies, the Collegiate Board of the National Sanitary Surveillance Agency,

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ANVISA, sanctioned theCollegiate Board Resolution n° 26 of July 2, 2015, which came into force twelve months after publication. This Resolution advocates the presentation of foods, ingredients, food additives and technology adjuvants that contain or are derived from or have been contaminated with potentially allergenic foods in warnings about their content in an alert "**ALLERGICS: CONTAIN (common names of foods that cause food allergies)", "CONTAINS DERIVATIVES OF (common names of foods that cause food allergies)"** or **"MAY CONTAIN (common names of foods that cause food allergies)"** (Brasil, 2015). The main foods / substances causing food allergies described in the Annex to the legislation and which may appear on the warnings are: 1. Wheat, rye, barley, oats and their hybridised strains; 2. Crustaceans; 3. Eggs; 4. Fish; 5. Peanut; 6. Soybean; 7. Milk of all species of mammalian animals; 8. Almond (*Prunus dulcis*, sin.: *Prunus amygdalus*, *Amygdalus communis* L.); 9. Hazelnuts (*Corylus* spp.); 10. Cashew nuts (*Anacardiumoccidentale*); 11. Brazil nut (*Bertholletiaexcelsa*); 12. Macadamias (*Macadamia* spp.); 13. Nuts (*Juglans* spp.); 14. Pecan nut (*Carya* spp.); 15. Pistachio nut (*Pistacia* spp.); 16. Pine nut (*Pinus* spp.); 17. Chestnut (*Castanea* spp.); 18. Natural latex. Although recent, the legislation has been in place for more than three years and works to verify whether food labels conform to this resolution has so far been unknown. The purpose of this study was to verify the compliance of food labels according to the requirements for mandatory labeling of the main foods that causes allergies.

2 Materials and methods

The samples used in this study were collected by health authorities through a quality monitoring program established in the state. These samples were analyzed bythe technical staff of the Labeling Analysis Service of the Ezequiel Dias Foundation (FUNED), an important Brazilian public health agency, in partnership with the Federal University of Minas Gerais (UFMG). Information on the food labels analyzed was tabulated according to the requirements established in the Collegiate Board Resolution (CBR) n° 26 of July 2, 2015 (Brasil, 2015). The analyzed items in each label were: report number, product (sales denomination), date of manufacture (if any), expiration date brand, and allergen alert warning. If food product had the alert, it was analyzed the presence of legible characters, if it was grouped immediately after or below the list of ingredients, if the letters were in the upper case and bold with a contrasting color with the bottom of the label, with a minimum height of 2 mm and not less than the height of the list of ingredients, as advocated by legislation. Also were counted if the warnings were in a covert place, removable by sealing, or difficult to visualize were counted, as well as whether the food contained an allergenic ingredient in the CBR 26/2015 list and did not make the corresponding alert. It was also noticed if there was alert about some ingredient without it (or derivative) was in the list of ingredients of the food. Alerts were also evaluated for the absence of the word "ALLERGICS". It was also verified the presence of the expression "may contain", which is allowed by the regulations. The word "traces" which is not permitted by legislation but has also been assessed, since if the manufacturer makes use of that term, it will be a non-conformity. Other evaluated items were also the incorrect spelling and the claim about absence of allergens.

Data collection was performed in 2018 with foods manufactured after the date that the legislation entered into force (from 2016 until September 2018), available in the Harpya Database program version of the system: 2.1.2518. From the collection gathered, the data were collected from food categories that are known to have some allergenic ingredient in their composition or list of ingredients and excluding other allergen-free foods.

The sample data were tabulated in Microsoft Excel Software and were evaluated in the form of absolute numbers and frequency.

3 Results

3.1. Samples

We evaluated 457 food labels that were included in the reports available in the database. Of these, 78 samples were excluded because they did not meet one or more established inclusion criteria, as shown in Figure 1. The 78 excluded samples had a manufacturing date within the twelve-month adjustment period by the manufacturers as established in the CBR 26/2015. Of the 379 samples that were included in the study, 46 of them (12.1%) did not have the alert for allergic, thus, the alerts presented in the other samples were analyzed. A total of 219 nonconformities were found in 119 samples (31.4%).

3.2. Categories

The analyzed foods were divided into 35 categories, which are described in Figure 2. Among all the samples, the six most analyzed categories were milk (53 samples), followed by cheese bread (33 samples), flour (30 samples), cookie (26 samples), frozen fish and cheese (22 samples).

3.3. Reported allergens

Of the reported allergens, four of these were identified in most samples (Figure 3). Milk was the most frequent allergen (58%), followed by soybean (45%), wheat, rye, barley, oats and their hybridized strains (39%) and eggs (24%).

3.4. Evaluated items

Of the 333 labels that presented the alerts, the most frequent nonconformities were the absence of the word "ALERGIC" at the beginning of the alert (15.0% of the samples) and the fact that it contains an ingredient that is present in the list of 18 allergens in CBR 26 / 2015 and did not alert the consumer to 7.9% of the samples (Table 1).

3.5 Precautionary allergen labeling (PAL) with the expression "may contain"

The study showed that of the 379 samples analyzed 31% (117 samples) made use of this precautionary allergen labeling. Among these samples, the categories of foods in which the expression "may contain" appeared most frequently (Figure 4) were flour (29 samples), followed by bread (16 samples) and biscuit (15 samples). The most frequent allergens in precautionary allergen labeling (Figure 5) were barley (117 samples), followed by rye (69 samples) and oats (69 samples).

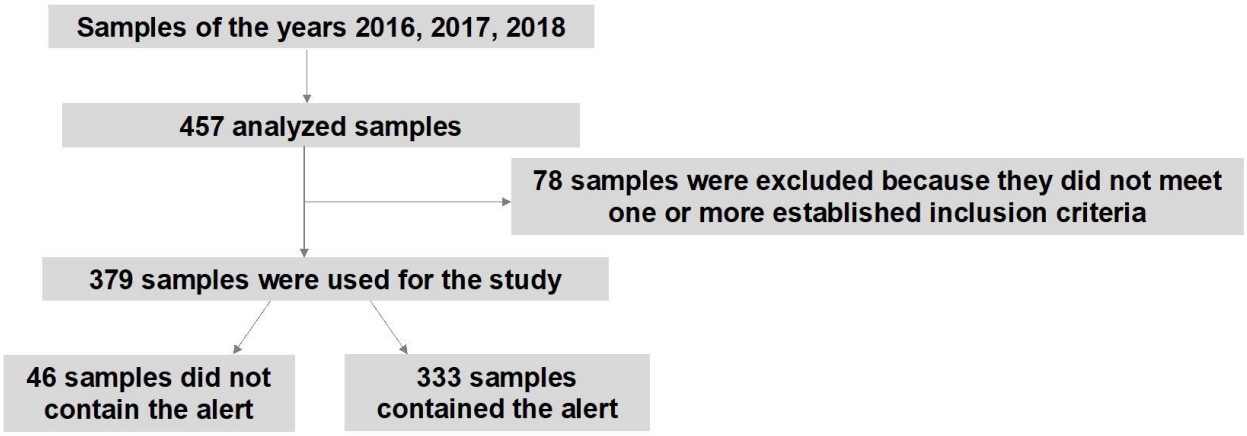

Figure 1. Sample flowchart.

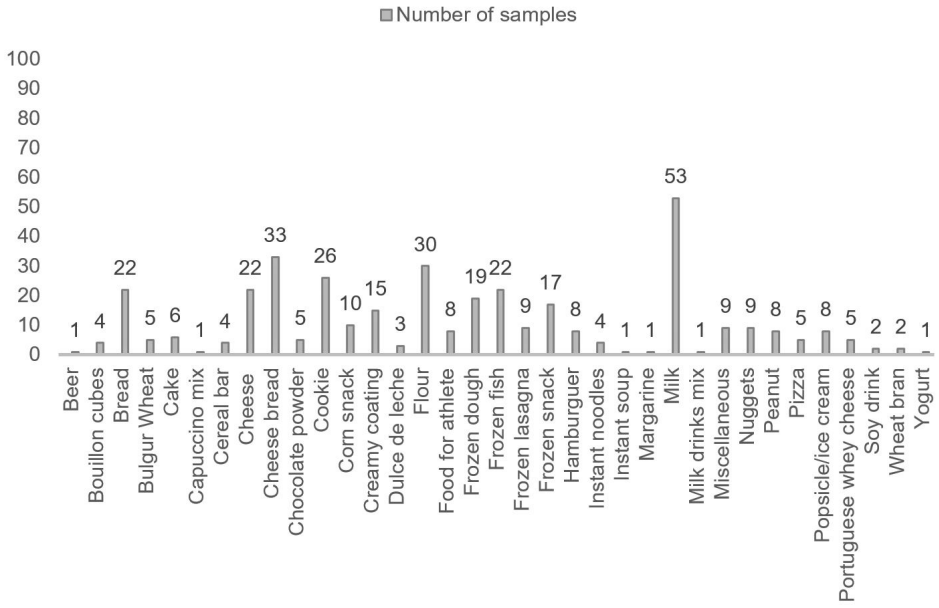

Figure 2. Samples analyzed and their respective categories.

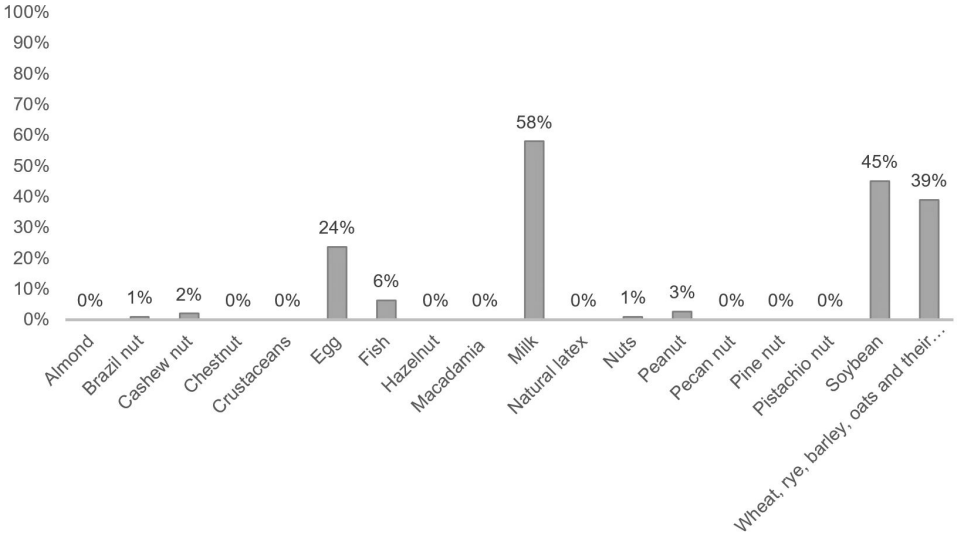

Figure 3. Allergens declared.

Table 1. Items of RDC 26/2015 (Brasil, 2015)and established in the study that were evaluated.

Evaluated items	n	% of non conformities (n = 379)	% of non conformities (n = 333)[1]
Alert with wrong spelling	17	4.5	5.1
Alert with the word "traces"	9	2.4	2.7
Alerts are not grouped immediately after or below the list of ingredients	14	3.7	4.2
Alert is in places concealed, removable by the opening of the seal or difficult to see	0	0	0
Alert on any food without it (or derivative) listed in the food ingredient list	6	1.6	1.8
Claim of absence of allergens	9	2.4	2.7
Alert with letter size smaller than the height of the ingredient list	3	0.8	0.9
No uppercase letter	8	2.1	2.4
Absence of bold letter	4	1.1	1.2
Illegible characters	0	0	0
Contains ingredient from RDC 26/2015list and does not make the alert	30	7.9	9.0
This product does not contain the allergy alert	46	12.1	-
Do not contain the word "ALLERGIC"	57	15.0	17.2
Does not have a minimum height of 2 mm	16	4.2	4.8
No contrasting color with the bottom of the label	0	0	0

[1]Referring only to the products that made the alert (379 – 12.13% = 333).

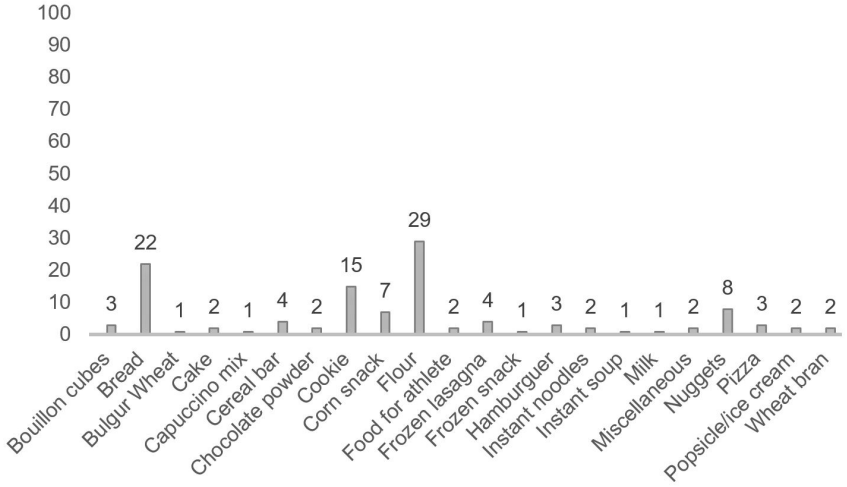

Figure 4. Food categories that made use of precautionary allergen labeling.

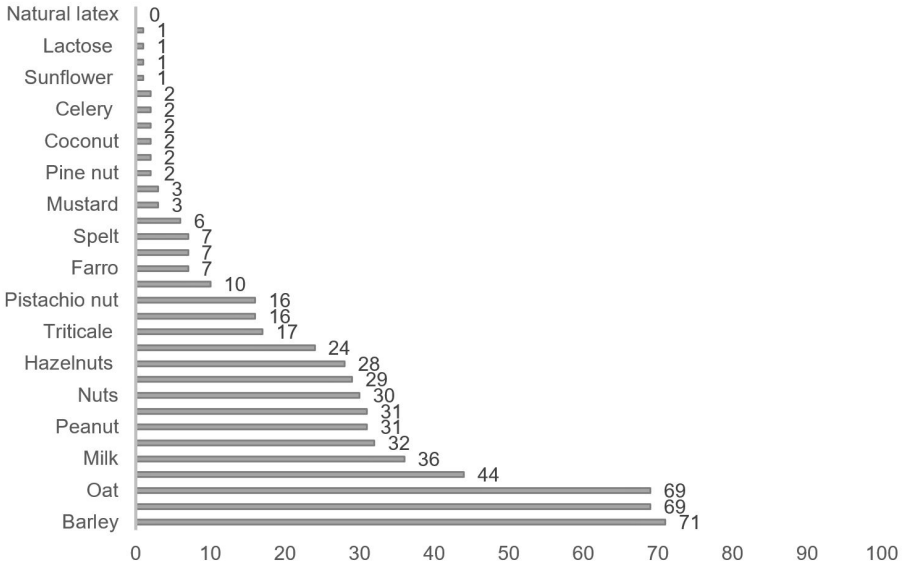

Figure 5. Allergens present in the expression "may contain".

4 Discussion

The approval of Collegiate Board Resolution n° 26 of July 2, 2015, driven by the population, brought a victory to the Brazilians. However, this achievement demonstrates how the country and its consumers were deprived of clearer and more explicit information about the existence of allergens in food labels. This study showed that although the resolution was in force for more than two years, 31.4% of the products had some type of nonconformitiesand 12.1% of the products analyzed did not present any kind of consumer warning about the presence of allergens, which may cause a public health problem, given the vulnerability of the allergic population. A study carried out in Malawi with 105 products, including 100 cookies and 5 baby food, showed that none of the locally produced products had the allergen declaration, but 73% of the products imported from South Africa, Zambia, Zimbabwe, India, China and Europe presented the declaration, which indicates that food entering the country contains more information for the consumer (Mfueni et al., 2018). In Poland, there was observed a high level of conformity in 58,3% of evaluated facilities regard to declared allergen information to consumers on the labeling of food products, as a consequence of the obligatory nature of this action in European Union (Dzwolak, 2017).It has been noted that there is a dearth of published data on the effective enforcement of allergen legislation worldwide. Although several countries have legislation for the labeling of allergenic foods, their suitability is not always checked, which may lead to a weakness in compliance with the proposed regulations.

In general, a related compliance with formatting data was observed, such as the warning in bold with uppercase letter and contrasting color with the bottom of the label. However, 3.7% non-compliance was observed related the need for the alerts to be grouped immediately after or below the list of ingredients and 4.2% in relation to the minimum height required. Such nonconformities can discourage the consumer and make it difficult to locate and view the warning. The regulations between countries vary greatly in the way the alert should be carried out and, in a study, performed by Soon (2018) 33.9% of the samples analyzed contained bold alerts and 8.7% contained the uppercase letter. In the present study, about 2% of the samples presented such nonconformities. A research conducted in the United States showed that some of the participants didn't have knowlegde about the food allergy legislation in the country (Kwon et al., 2020). They believed that all food allergens were reported on the food labels when the Food Allergen Labeling and Consumer Protection Act (FALCPA) demand merely the eight major food allergens (Kwon et al., 2020). Alert visibility is the main point of any allergen labelling legislation, since consumers may find it not readable or sufficient, as in the study of Soogali & Soon (2018), who interviewed 113 consumers andmore than 80% felt that allergens in the ingredient list should be emphasized using a bold or capitalized font or highlighted with suitable background color in Mauritius.Another way to help people with food allergies isusing the word "contains" andmaking labels clearer by specifying the allergen with a parentheses (Kwon et al., 2020).

The Brazilian legislation recommends the use of the term "ALLERGIC: MAY CONTAIN" if the manufacturer can not guarantee the absence of cross-contamination of food, ingredients, food additives or technological adjuvants by food allergens. The appearance of the expression "may contain" was evidenced in 31% of the samples, especially in the flour category, which demonstrated that some producers prefer to be legally aware of the possible presence of allergens in their products, perhaps even due to the difficulty of complete removal of the allergenic ingredient from the production line, which in certain situations is very complex. Recently, a study conducted in Malaysia that analyzed 505 foods, also showed a similar percentage of labels that used the term "may contain" (Soon, 2018), which indicates that this difficulty is evident in other countries. However, in that study the precautionary alert was carried out in 22 different ways, due to the lack of guidance on the legislation of this country. In this present study, it was observed nonconformity in the standardization of the words "may contain", for example, in 9 labels the alert appeared with the expression "traces", which is not recommended by Brazilian legislation.

The presence of milk (58%), soy (45%), wheat (39%) and eggs (24%) reveal products available on the market that are possible causes of allergic reactions, which may limit food choices of the allergic population (Sánchez & Sánchez, 2015).It should be noted that 28.5% of the evaluated labels were milk, cheese and cheese bread, which influenced the large number of samples containing milk and / or derivatives in its composition. However, it is known that in the case of soy, for example, many ultraprocessed foods make use of the emulsifying additive lecithin in its formulation, which further increases the restriction of food consumption for allergic people, due to the use of a derivative from the soybean and not specifically of the soybean grain itself (Soon, 2018). Another study carried out in France with 17.309 foods showed that soy was present in 20% of food ingredient lists, however, only 12% of foods warned about this allergenic component (Battisti et al., 2017).This demonstrates the lack of product options for this group of people with restrictions on certain components or ingredients. Other studies also demonstrates the high frequency of these same allergens. In one of the 505 analyzed products, the soybean was the most declared allergen (approximately 52%) followed by wheat and milk (Soon, 2018).In another study wheat appeared in the statement of 95% of the 105 biscuits and baby food, milk in 64% and soy in 55% of the samples (Mfueni et al., 2018).It can be concluded that the results presented in this study and others results agree with the high frequency of soy and / or food derivatives.

Although the initial words format in the warning, such as "ALLERGICS" is not widely adopted in all countries, like in the European Union (Food and Drug Administration, 2004; European Union, 2011), in Brazil, the use of the initial word is mandatory and certainly has the function of directing the information to allergic persons. However, a study indicated that 15.04% of the samples did not present the initial word, which may go unnoticed for the population that has hypersensitivity and represents a senseless alert for non-allergic individuals.

Also, 7.9% (n = 30) of the labels contained ingredient from the RDC 26/2015 list and did not alert. A one-year cohort conducted with 157 adults diagnosed as allergic showed that 73 patients had 151 allergic reactions due to the accidental consumption

of a wide variety of foods. Among these allergic reactions, 41% were caused by packaged foods(Blom et al., 2018). The severity of the symptoms was assessed by the Müller Grading System, and 7 of the 14 foods represented a serious public health concern with a predicted risk greater than 10% for the respective allergic populations, and this was caused by the presence of milk, egg, peanut or sesame (Blom et al., 2018).This demonstrates the lack of adequacy in the communication of the allergens by many manufacturers, which can directly impact the life of allergic people. Another problem perceived in the present study was written alert with incorrect spelling in 4% of the samples, such as the use of the word "ALLERGIC" in the singular. As a result, the consumer may have difficulty understanding the allergens or possible allergens present in the product.

The limitations of this study are related to the absence of date of manufacture in a large number of samples. For this reason, samples were eventually excluded because of the lack of knowledge of whether or not that product had been produced after the one-year adjustment period established after the publication date of RDC 26/2015. Another limitation of this study is related to the compound ingredients in function of the diversity of aggregate food in this, which do not necessarily have to be declared according to the norm. An allergenspecific alert can be declared, even thought it is not described in the ingredients list. Also, it can be highlighted the poor verification of the effective presence of the allergens described in the legislation.

5 Conclusion

The food sample analyzes results demonstrate that despite the implementation of legislation regulating the labeling of allergenic foods, progress is still needed. This is due to the fact that 12.1% of the products still did not present any type of consumer alert and 31.4% had some nonconformities. Most of the samples were in accordance with the terms recommended by the legislation, grouped in the correct place, in legible and standardized letters according to the format stipulated by the resolution. However, non-compliance with the legislation was observed in some samples, especially in the related issue absence of the word "allergenic", absence of allergen declaration when the food or derived ingredient was in the list of ingredients and incorrect spelling. It is highly necessary that all allergens in the ingredient list be alerted. This is because it is difficult to identify them in the middle of a long list, or consumers may not know that one of the ingredients is derived from an allergenic food.

The practice of precautionary allergen labeling seen in 31% of the samples is positive by itself. However, the excessive use of it can accuse the lack of interest of the manufacturers in modifying their lines of production, limiting the choices of allergic population. With this study, we can conclude that Brazil and the many other countries of the world are gradually becoming aware of the impact of food allergies and possible ways to reduce negative outcomes by improving labeling. People who have food allergies benefit from advances in food labeling, but much still needs to be done to ensure a better quality of life for these people.

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