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LABELING ASSESSMENT OF LACTOSE-FREE DAIRY PRODUCTS

ROTULAGEM DE PRODUTOS LÁCTEOS ISENTOS DE LACTOSE: AVALIAÇÃO DA CONFORMIDADE

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Abstract. The reliability of information contained in labels is crucial, especially for individuals with lactose intolerance. This study investigated the reasonableness of information on 70 labels of lactose-free milk and dairy products sold in supermarkets in the Metropolitan Region of Grande Vitória, Espírito Santo. The products were categorized into 15 groups and featured the phrases "lactose-free", "zero lactose,""0% lactose," "without lactose," or "does not contain lactose" adjacent to the product nomination. A checklist was developed containing 76 items from RDCs n° 429/2020 and IN nº 75/2020, 64 items from n° 727/2022, and 3 from n° 715/2022, from Anvisa. The items were classified as "compliant", "non-compliant", or "not applicable", and the data obtained were tabulated in Microsoft Excel® and analyzed through frequency estimation (%) and by groups. For RDC N° 429/2020, an adequacy rate of 63.1% was observed for all evaluated items, with non-compliance primarily related to the new model of nutritional information table and its constituents. Among the groups, 6 (40.0%) had a higher percentage of non-compliance regarding RDC N° 727/2022. It was also noted that none of the products complied with the requirements of this legislation. One label (1.4%) in the cheese group did not comply with RDC N° 715/2022 as it was not lactose-free despite the claim on its label. The information on labels presented some inadequacies concerning current legislation, which could compromise consumers' health and quality of life.

Keywords: food labeling; legislation; lactose intolerance.

Resumo. A fidedignidade das informações dos rótulos é imprescindível, especialmente para aqueles indivíduos intolerantes à lactose. Esse estudo investigou a adequação das informações de 70 rótulos de produtos leite e derivados isentos de lactose, comercializados em supermercados da Região Metropolitana da Grande Vitória, Espírito Santo. Os produtos foram categorizados em 15 grupos e apresentavam os dizeres “isento de lactose”, “zero lactose”, “0% lactose”, “sem lactose” ou “não contém lactose”, próximo à denominação de venda. Elaborou-se checklist contendo 76 itens avaliados para a RDC n° 429/2020 e IN n° 75/2020, 64 itens para a n° 727/2022 e 3 para a n° 715/2022 da Anvisa. Os itens foram classificados em "conforme", "não conforme”, “não se aplica" e os dados obtidos tabulados no Microsoft Excel®, analisados por meio de estimativa de frequência (%) e conforme os grupos. Para a RDC n° 429/2020, verificou-se 63,1 % de adequação para todos os itens avaliados, destacando-se as não conformidades relativas ao novo modelo de tabela de informação nutricional e seus constituintes. Dos 15 grupos de produtos avaliados, 6 (40,0 %) apresentaram maior percentual de inadequações quanto a RDC n° 727/2022. Notou-se que todos os produtos não atenderam completamente ao exigido pela legislação. Um rótulo (1,4 %) do grupo dos queijos estava inconforme com a RDC n° 715/2022 em função de seu produto não ser isento em lactose, mas apresentar essa afirmação no seu rótulo. As informações presentes nos rótulos apresentaram alguma inadequação frente à legislação vigente, podendo comprometer a saúde e qualidade de vida dos consumidores.

Palavras-chave: rotulagem de alimentos; legislação; intolerância à lactose.

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INTRODUCTION

Lactose is a disaccharide found in milk, formed from the union of two monosaccharides – galactose and glucose. Lactase, a membrane glycoprotein of intestinal microvilli, hydrolyzes this sugar and allows its absorption. Lactose intolerance (LI), or hypolactasia, is characterized by partial or total reduction in lactase activity and can be classified as congenital, primary or secondary[1].

In the absence or deficiency of the enzyme, there is an increase in bacterial fermentation, due to undigested lactose in the lumen, which can cause nausea, colic, flatulence, diarrhea, abdominal pain and distension, headache, heart rhythm disturbances[2,3].

Worldwide, LI prevalence stands at 65%, varying depending on race, ethnicity and gender [2]. According to the Brazilian Society of Pediatrics, it is estimated that 40% of the Brazilian population has primary LI, starting after 3 years of age[4].

The growing number of individuals diagnosed with lactose intolerance and the search for a better quality of life through greater demand for lactose-free products have sparked the interest of the food industry, especially the dairy one, in developing products low in or without lactose. This is possible by adding exogenous lactase or through other lactose hydrolysis processes[5,6].

In Brazil, the National Health Surveillance Agency (Anvisa) is one of the bodies that regulates food labeling, including products that are low in or free of lactose [7]. Collegiate Board Resolution (RDC) No. 429/2020 [8] provides for the nutritional labeling of packaged foods, containing information such as nutritional information table, front-of-pack nutrition labeling, and nutritional claims (NCs). Normative Instruction (IN) No. 75/20207 establishes the technical requirements for the statement of nutritional labeling on packaged foods through annexes that complement RDC No. 429/20208, such as models for the statement of the nutritional information table, specific requirements for formatting the nutritional information table, authorized terms for NC statement, the composition criteria for a product to present the information "does not contain".

RDC No. 727/20229 also provides for the labeling of packaged foods in addition to warnings about lactose, stipulating minimum values that foods must contain for the information "contains lactose" to appear. And RDC No. 715/202210 addresses the health requirements for hyposodium salt, foods for weight control, foods for nutrient-restricted diets and foods for diets with controlled sugar intake. Because these products serve a specific group of the population with special dietary needs, the reliability of the information on their labels becomes even more relevant.

However, even though labeling is mandatory and subjected to regulations, the standards are not always followed appropriately by food industries, which can lead to nutritional risks for the population, especially for those individuals who have some type of food restriction and/or intolerance.

In light of the foregoing, this study aims to assess the adequacy of label information, taking into account RDC No. 429/2020[8], IN No. 75/2020[7], RDC No. 727/2022[9] and RDC No. 715/2022[10], concerning lactose-free products sold in supermarkets in Greater Vitória, ES, Brazil, as well as to present their possible effects for consumers.

METHODS

This is an observational and descriptive study assessing the information contained on the labels of lactose-free products. The products were categorized into fifteen groups, defined in accordance with the Identity and Quality Technical Regulations (RTIQs) for milk and its derivatives by the Department of Agriculture, Livestock and Food Supply (MAPA), which had the terms "lactose-free", "zero lactose", "0% lactose", "no lactose" or "does not contain lactose" adjacent to their sales denomination7. The identity of the products' manufacturers was not disclosed (MAPA, 2023)[11].

According to the RTIQs, the products were categorized as yogurt (15), cheese (13), UHT milk (10), Brazilian cream cheese (8), dairy drink (6), heavy cream (4), condensed milk (3), curd (2), ricotta cream (2), butter (2), traditional cream cheese (1), milk jam (1), powdered milk (1), fermented milk (1) and pasteurized milk (1). A total of 70 labels of 24 processed food products were analyzed, from the milk and dairy products group (Figure 1), available in supermarkets in the Metropolitan Area of Greater Vitória (RMGV - Vitória, Serra, Fundão, Vila

Velha, Cariacica, Guarapari and Viana), Espírito Santo, considering the location in neighborhoods of different socioeconomic classes. The collection of label information, together with the capture of images, was carried out between March and May 2023 in the supermarkets' physical stores. The conduction of the research was authorized by the supermarkets, upon prior request.

The information on the labels was assessed by comparison with what is required by ANVISA's RDCs No. 429/2020; IN No. 75/2020; RDC No. 727/2022; RDC No. 715/2022[8,7,9,10], with the aid of a checklist prepared by the researchers via Google Forms. The checklist was divided into 4 blocks, with the first consisting of two items intended to describe the product's sales denomination and brand name. The other three blocks were divided as follows: 76 items from RDC No. 429/2020[8] and IN No. 75/2020[7]; 64 items from RDC No. 727/2022[9] and 3 items from RDC No. 715/202210, which were classified as "compliant", "non-compliant" and "not applicable".

The 76 items of RDC No. 429/2020[8], together with IN No. 75/2020[7], were related to the adequacy of the nutritional information table, front-of-pack nutrition labeling, NC, statement templates for the nutritional information table, specific requirements for formatting the nutritional information table; authorized terms for the declaration of nutritional claims, the composition criteria for a product to present the information "does not contain". As for RDC No. 727/2022[9], the 64 items included general requirements, sales denomination, list of ingredients, warnings about the main foods that cause food allergies, warning about lactose, warnings related to the use of food additives, nutritional labeling, net content, identification of origin, identification of the batch, and instructions for conservation, preparation and use. The information required in the annexes was investigated on the product labels: concerning dietary reference values; rules for rounding and expressing quantities in the nutritional information table (NIT); non-significant amounts of energy value, nutrients and their form of expression; serving size/number of food servings, rounding rules; statement of household measurements; templates for NITs; requirements for formatting the simplified statement of nutritional information; names of constituents or their alternative names and their respective abbreviations, order, indentation and units of measurement; limits on added sugars, saturated fats and sodium for statement of front-of-pack nutritional labeling, list of foods in which it is prohibited and their templates; terms, composition and labeling criteria for NC statements.

And, finally, the 3 items on the checklist relating to RDC No. 715/2022[10] were: composition, quality, safety and labeling requirements, and essential composition requirements of foods for nutrient-restricted diets and foods for controlled nutrient intake diets.

The results obtained were tabulated in Microsoft Excel®, constituting the database; they were analyzed by means of frequency estimates (%) and according to group categories, in accordance with the RTIQs, mentioned previously.

RESULTS

Figure 1 shows a flowchart for the labels of the assessed lactose-free products, grouped according to food groups and the RTIQs.

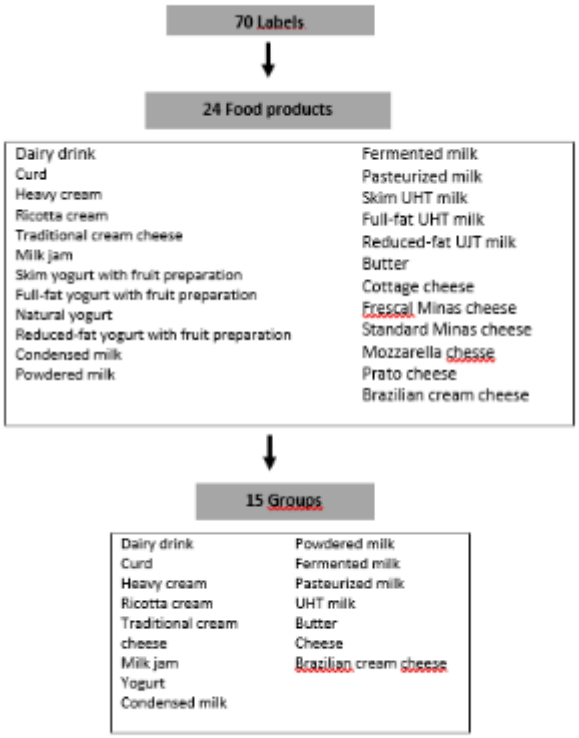

FIGURE 1 - Flowchart for the labels of the assessed products, grouped according to food groups and the RTIQs.

The yogurt, UHT milk and cheese groups were found more frequently and with a greater diversity of brands. Table 1 shows the percentage of labels that were in full compliance with the items contained in the legislation (RDC No. 429/2020, IN No. 75/2020, RDC No. 727/2022, RDC No. 715/2022).

TABLE 1 - Percentage of labels that fully complied with legislation related to lactose-free milk products and dairy products, sold in supermarkets in the Metropolitan Area of Greater Vitória, ES, 2023.

Legislation	n	%
RDC Nº 429/2020	1	1,4
RDC Nº 727/2022	0	0
RDC Nº 715/2022	62	88,6

n = 70

It was observed that 98.6% of the product labels analyzed had at least one non-conformity as to RDC No. 429/20208. Of the 76 items checked, 63.1% were compliant, for all labels assessed (Table 1).
Table 2 presents the items most frequently found in disagreement with RDC No. 429/2020.

TABLE 2 - Percentage of labels of lactose-free milk products and dairy products, sold in supermarkets in the Metropolitan Area of Greater Vitória, ES, 2023, that presented non-conformities as to Anvisa's RDC No. 429/2020.

Item	Rótulos com inadequações
I. Presence of "added sugars"	94,3 %
II. Footnote statement: "*Percentage of daily values provided by serving"	92,9 %
III. Correct use of the names of the constituents and the respective order of statement, indentation and units of measurement.	92,9 %
IV. Presence of front-of-pack nutrition labeling	92,3 %
V. Presence of "total sugars"	91,4 %
VI. Nutritional information table statement in accordance with one of the templates defined by IN No. 75/2020	88,6 %
VII. Use of 100% black characters and lines applied to a white background in the nutritional information table	84,3 %
VIII. Use of protective borders, bars, separation lines and symbols, and internal margins in accordance with the selected nutritional information table template.	82,9 %
IX. Statement of the number of servings per package	74,3 %

n = 70

Correct writing of the names of the constituents and the respective order of statement, indentation and units of measurement in the nutritional tables were in accordance with the regulation in only 5 (7.1%) labels (Table 2). The main errors found concerned the writing of dietary fibers as "dietary fiber", incorrect indentation of glucose, galactose, lactose, saturated fats, trans fats and the unit of measurement of energy value expressed in kJ (kilojoules), which is no longer provided for.

With respect to front-of-pack nutrition labeling (FOPNL), thirteen labels (18.6%) had amounts of added sugars and/or saturated fats and/or sodium above the limits defined in Annex XV of IN No. 75/2020[7], but they did not contain the record of this statement, which is mandatory. These labels were for traditional cream cheese, ricotta cream, yogurt, butter and Brazilian cream cheese. Only one product label (7.7%) from the yogurt group had FOPNL and was recorded correctly.

As for NCs, also mentioned in this resolution8, eight items were assessed as to the products listed on their labels. Among the labels analyzed, seventeen had NCs, of which six (35.3%) presented non-compliance with the pre-established requirements for this type of statement, according to Annex XX of IN No. 75/2020[7]. On the product labels, there was a claim that they were "rich" or "source" as to a certain nutrient; however, when the product's composition was analyzed, it was found that, for the former claim, the correct terminology would be "source". As for the latter, the claim should not be stated, since the products had percentages of daily values (% DV) lower than those established. The labels also presented NCs based on characteristics inherent to all foods of the same type. This misleading information was found in dairy drinks, UHT milk and powdered milk products.

Regarding the product groups defined through the RTIQs, it was found that the percentage of non-conformities for all items assessed in RDC No. 429/2020[8] was considerably high, mainly for these groups: traditional cream cheese (54.0%), butter (51.5%), Brazilian cream cheese (49.5%), heavy cream (41.5%), ricotta cream (40.5%), fermented milk (40.0%), dairy drink (38.3%) and cheese (37.6%).

As for RDC No. 727/2022, when the 65 items/pieces of information relating to it were assessed, it was noted that 92.8% of them were compliant for all labels, such as presence of the sales denomination, list of ingredients, nutritional table, identification of origin, batch and expiration date. However, for the item referring to the statement of the country of origin, which must be included as mandatory information, only 4 (5.7%) labels were compliant. The identification of origin through pre-established expressions such as "Made in...", "Product..." or "Industry..." was non-compliant on 24.3% of the labels analyzed, although this item is a complementary part of product identification.

Regarding net content, 61.4% of the 70 labels were conforming. Although all labels stated the quantity of product contained in the package in the correct measurement units, they did not present the quantitative indication expressions determined by Inmetro Ordinance No. 249/202112.

During the analysis of the information contained in the labels, the following sentences were found:

"Specialized daily nutrition (...)"
"25 g of proteins to help you go further."
"With nutrients that help with recovery and gain of muscle mass, energy and feeling of satiety"
"[BRAND] is your perfect partner for everyday"
"Add [BRAND] to your diet and feel the difference of live probiotics."

Which is in disagreement with the law[10].
In addition to these sayings, a yogurt label claimed to have no flavorings; however, the presence of this type of food additive was found in the list of ingredients.

Regarding the groups defined according to the RTIQs, for RDC No. 727/2022[9], it was found that 6 of them (40.0%) had a higher percentage of non-conformities in relation to the assessed items (Table 3).

TABLE 3 - Percentage of items with non-conformities, assessed for RDC No. 727/2022, on the labels of the groups with lactose-free milk and dairy products, sold in supermarkets in the Metropolitan Area of Greater Vitória, ES, 2023

Groups	Non-conforming items
Butter	12,5 %
Fermented milk	12 %
Dairy drink	9,8 %
Powdered milk	9 %
UHT milk	8,3 %
Yogurt	7,9 %

n = 64

Despite the reduced frequency estimate values, for the items with inadequacies on the labels of the groups shown in Table 3, some stood out, such as the statement of sales denomination, the statement of flavoring food additives and of the batch in a visible, legible and indelible way, the allergen warnings in capital letters, bolded and in a color contrasting with the background of the label.

As for the three items assessed on the basis of what is required by RDC No. 715/2022[10], 95.2% were adequate. However, despite the high percentage of adequacy, 8 (11.4%) labels were not complying with the standards. The 8 labels that were not in full compliance were those that belonged to the butter, Brazilian cream cheese and cheese groups, with 33%, 16.5% and 10.2% of non-conformities, respectively.

For the butter group, the two labels collected did not present the mandatory warning "Diabetics: contains...", regarding the presence of mono- or disaccharides.

In the Brazilian cream cheese group, 3 (37.5%) labels did not contain the warning described above, and another label also did not include lactose in the nutritional information table. One of the cheese labels did not add the amount of glucose to its nutritional information table, but mentioned its presence in the warning for diabetics. Furthermore, in the cheese group, one of the labels of standard Minas cheese, supposedly lactose-free, stated in its nutritional information table that the amount of lactose present was "less than 0.15 g" for a 30 g serving.

DISCUSSION

The 2017-2018 Family Budget Survey (POF), by IBGE, shows that Brazilians consume, on average, 32.2 kg of dairy products per year. The most consumed are fluid milk (20.1 kg/per capita/year), cheeses (2.2 kg/per capita/year) and yogurts (1.56 kg/per capita/year)[13]. This data may explain the more frequent presence of the yogurt, UHT milk and cheese groups on supermarket shelves that was found in this study.

The results reinforce the relevance of studies that assess the veracity of label information, as they provide consumers with knowledge about the composition, nutritional characteristics of the food and its possible health benefits[14, 15].

Regarding the representative percentage of labels that have not yet adapted to the formats required for the nutritional information table and the FOPNL (Table 2), it may be related to the deadline for adequacy, set by Anvisa, and the data collection period of our study. For products intended for direct sale to the consumer, such as those included here, and which are already being sold, this deadline was October 8, 2023, with the final deadline for packaging to be exhausted being April 22, 2024 (via a public civil action).

The presence of FOPNLs helps the consumer during the purchase and is a health promotion tool by allowing the identification of nutrients present in that food and by encouraging healthier food choices. This is because the consumption of products with high levels of added sugars, saturated fats and sodium, found mainly in ultra-processed foods, is associated with a possible development of chronic diseases, such as high blood pressure, obesity, dyslipidemia and type 2 diabetes mellitus[16].

Bandeira et al.[17] carried out a cross-sectional study with 2400 Brazilian consumers to evaluate the performance of five FOPNL models (octagon, magnifying glass, circle, triangle and nutritional traffic light). The study showed that the models positively influenced the understanding of nutritional content, the perception of healthiness and the consumer's purchase intention.

NCs increase the consumer's intention to purchase certain products, as maintaining health is an important point and these claims contribute to a positive impact when choosing the product[18]. However, in this study, 35.3% of the products analyzed showed non-compliance with regard to this aspect.

The presence of phrases, information and/or sayings that highlight the possible superiority of these products in relation to others and that cannot be proven simply by reading the labels, is considered fraud[19]. When labeling packaged foods, one must not highlight, attribute, convey, emphasize, indicate or advise when it comes to any information, words, effects, presence or absence, qualities or properties of the food that could lead the consumer to error, misunderstanding or confusion about the true attributes of the food9. Labeling legislations are designed to prevent the presence of this misleading information. However, our study and other ones show that the requirements are not being met[17, 20, 21].

In the study by Leonel de Lima, Macêdo and Neves[5], of the twelve UHT zero lactose milk labels sold in Natal, RN, seven contained information that misled the consumer and encouraged the purchase of the product. Sousa et al.[20] showed that there is a lack of trust in nutritional information on labels among students at a public university in the city of Curitiba, PR. Distrust was associated with disbelief in the food industry, due to the marketing strategies used and the presentation of imprecise and incorrect nutritional information on the labels, corroborating what was found in this study.

In the study by Melo et al.[22], sixteen labels of dairy products sold in a municipality of Batalha, AL, were assessed. Of these labels, only 1 (one) was fully in accordance with the provisions of RDC No. 360/2003 (revoked by RDC No. 429/2020) – a Brazilian cream cheese label.

According to Martínez-Pineda and Yagüe-Ruiz[23], failure to state the presence of an allergen is the main labeling error when analyzing the risks of ingesting milk and dairy products, cereals, oilseeds, eggs and crustaceans for pediatric patients in the European Union. Soon and Wahab[24], in their turn, identified that, in addition to undeclared allergen, other types of labeling errors are found, such as incorrect information, missing information and illegible printing. These findings are in line with what was verified in this study.

The role of labeling legislation is also fundamental for the management of diseases, including diabetes. This is because it helps consumers make better choices when purchasing food, based on its composition documented on the label[25]. Therefore, the mandatory warning "Diabetics: contains..." and the amount of mono and disaccharides on the labels is fundamental for food choices and disease control in this population. In this study, some products showed non-compliance, just as Batista et al.[26] found that only 3.1% of processed foods sold in a hypermarket in the city of Uberlândia, MG, stated the amount of this sugar in the nutritional table.

According to RDC No. 715/2022[10], for food to be considered lactose-free, "the amount of lactose must be equal to or less than 100 milligrams per 100 grams or 100 milliliters of ready-to-eat food". Therefore, the cheese label found in the study could not be considered a lactose-free food, as it contains 500 mg of lactose/100 g of food. The correct nomenclature to be used, in this case, would be "low lactose content", as is the case with products such as fermented dairy products, hard (aged) cheeses and butter.

When products that are claimed to be lactose-free are mistakenly purchased, they can cause various consequences for the consumer. Firstly, it violates the Consumer Protection Code, which states in its Art. 6th, item III, that one basic right is access to "clear, proper information about the different products and services, with correct specification of quantity, characteristics, composition, quality and price, as well as the risks they present"[27].

Furthermore, and of greater importance, it can have negative consequences on the health of the consumer, since the ingestion of lactose by intolerant individuals promotes symptoms of varying severity, such as abdominal pain, diarrhea, nausea, flatulence and borborygmus.

It is known that the initial approach taken by professionals such as nutritionists for individuals with LI is the temporary restriction of the consumption of milk and dairy products, in order to stop the symptoms. In this way, lactose-free products become part of the patient/client's diet. Bueno et al.[28] also highlighted the importance of standards related to labeling, considering labels as means of information about the composition of the purchased product. In this sense, the absence or inaccuracy of nutritional information can lead consumers to make mistakes when choosing products, which can pose risks to their health and compromise their quality of life.

CONCLUSION

Given the information found in this study, it is possible to state that the legislation regarding the labeling of milk and its lactose-free derivatives were not being complied with in 2023. There were inadequacies regarding sayings that could mislead the consumer, absence of front nutritional labeling and untrue claims about the product being lactose free. Thus, the health and quality of life of consumers can be compromised, especially those who are lactose intolerant.

However, the presence of labeling alone does not guarantee that the information will be well understood by the consumer, as said information must be clear and accurate as to the characteristics of the product. Actions such as nutritional education aimed at consumers, with measures that encourage reading labels, become imperative, as they promote knowledge and enable healthier choices. Health professionals, especially nutritionists, must advocate that labeling includes correct and unequivocal nutritional information.

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