



# Precautionary Allergen Labelling in Serbia: Market Audit and Consumers' Perception

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## Abstract

**Background:** Precautionary allergen labels (PAL) should be used to indicate the possibility of allergen presence in the food. This study aimed to determine the prevalence and types of precautionary labeling statements on different pre-packaged food products in retail stores in Belgrade, Serbia, as well as to assess consumers' attitudes and behavior towards PAL statements.

**Methods:** This was a descriptive study. The following characteristics of 1404 pre-packaged foods were analyzed: prevalence of PAL, listed food allergens on PAL, and the types of the advisory terminology. In the group of 275 participants (94 with food allergies, and 181 persons who purchasing food for a household member with food allergy) reading practice of PAL, purchasing practice based on PAL, and the opinion about PAL statements credibility were evaluated.

**Results:** Overall, 33.9% of products had precautionary statements for one or more allergens. "Tree nuts" were the most common allergens listed in the PAL. The most common type of PAL was "May contain traces of x [allergen]" (52.7%). The PAL was always read by half of the participants. Less than half (43.3%) of the participants incorrectly believed that PAL is regulated by national law. A quarter of participants thought that the PAL statements are trustworthy.

**Conclusion:** PAL statements frequently are not user-friendly and are not providing sufficient protection for food allergic patients. To gain buyers' confidence, protect health and provide security, the necessity for the strategies that would regulate PAL by the law exists.

**Keywords:** Allergen labeling; Precautionary allergen labeling; Consumer attitudes; Food safety

## Introduction

Food allergy is a serious health issue, affecting approximately 10% of the population. The prevalence of food allergy has increased in the last dec-

ades around the world (1). Despite the impact on physical health, food allergies represent a significant psychosocial, (2) and economic burden (3).



Due to the lack of adequate preventive and curative strategies, food allergies can be defined as a global health issue (4). The management of food allergies relies primarily on the avoidance of foods that trigger an allergic reaction. To avoid negative effects, patients, which are allergic to food, are dependent on the accurate information of the allergen declaration from the list of ingredients. Successful avoidance is a complex issue, which not only involves patients and their families, but also involves the food industry, government agencies and public health authorities (5). Mandatory allergen labeling has improved the safety of food for consumers with food allergies. In order to help these consumers, legislation on food labeling is implemented in most countries in the world. European Union (EU) Regulation 1169/2011 demands the listing of 14 ingredients that can cause allergies and/or intolerances labeled on the pre-packaged foods (6). Nevertheless, food-allergic consumers also may find other labels on food packages, called precautionary allergen labels (PAL), also known as “may contain” labels. By definition, precautionary statements are related to the allergens, which might be present in the product due to unintentional cross-contamination during food production (7). In most countries, PAL are optional and currently unregulated by the law (8). The current use (or miss-use) of PAL is not clear due to a lack of legislation i.e. when and how to apply them (9). Despite all of the above mentioned, PAL statements are present on the products more often in recent years (10). Some manufacturers are declaring PAL on most of their products. PAL may be present on products that do not contain any allergen residues whatsoever (11). This practice may have undesirable consequences. Due to the elimination of certain groups of products, food-allergic consumers can be at risk from malnutrition (12). On the contrary, some studies report that products without PAL statements contained undeclared allergens (13). Concentrations of allergens in unlabeled products could potentially reach levels that can present a threat to public health (14). Nonstandardized terminology, variety of different phrases on the warning statements

are additional problem (11, 15). In these situations, allergic patients and their families are confused, they misinterpret PAL statements and eventually, PAL loses its credibility (16, 17). Furthermore, health care professionals are confused too, and they are unable to provide adequate advice to their patients (18).

Studies on PAL statements (11, 19, 20) and consumers' attitudes towards it (9, 17) have been conducted in many developed countries. Recently, similar studies are conducted in developing countries (15, 21). Given the large differences in food labeling between the developed and developing countries in the legislations and implementation of it, market studies across the world are of prime importance (8).

The studies on PAL statements do not exist in Serbia, a country that is approaching European Union. The present research study aimed to determine the prevalence and types of precautionary labeling statements on different pre-packaged food products in retail stores in Belgrade, Serbia, as well as to assess the consumers' attitudes about PAL statements.

## Methods

### *Assessment of precautionary allergen labels (PAL) on the pre-packaged foods*

The study was performed in Belgrade, Serbia from Feb to Apr 2016. In order to obtain information on as many products as possible, the three different supermarket chains were visited: the largest international grocery store, the largest national grocery store and one economy store.

Seven categories of pre-packaged products were included in the survey: biscuits, bread and toast, breakfast cereals, chocolate and candies, instant soups, meat products, and ready meals. These food groups were selected because they contain multiple ingredients of which some are common allergens that must be declared on the food labels according to the EU 1169/2011 regulation (6). The survey included all pre-packaged foods within the seven listed categories, which were at the

time of the survey available on the shelves in each store.

The presence of PAL was checked on all food products. The following was noted on the products that contained PAL: listed food allergens and the types of the advisory terminology (may contain, may contain traces, etc.). Labels were further checked for ambiguous statements. The ambiguous statements were defined as: the statements in which the allergen was not declared adequately (for example the type do tree nuts was not discovered, the terminology such as “flour” instead of “wheat” was used), and the statements, which used the scientific terminology instead of the regular names (for example: “whey”, “casein” instead of “milk”). PAL was analyzed in situ, notes were taken upon which the database was created.

### *Attitudes towards precautionary allergen labels (PAL)*

A cross-sectional study aiming to assess consumers' perception and attitudes toward PAL statements was conducted in the Dietetic Unit of the Institute of Hygiene and Medical Ecology at the Faculty of Medicine, University of Belgrade, Serbia. The initial sample consisted of 1300 participants who came to the Dietetic Unit for nutritional counseling. The participants were asked the following questions: Do You have or suspect You have any food allergy?; Are You buying food for a household member who has or suspects he/she has any food allergy at the time of the investigation? In total, 275 participants responded positively to either of these questions, and were thus included in the study sample.

The questionnaire consisted of two sections: (i) demographic characteristics: age, gender, marital status (coded as: single (including those who are divorced, widowed, or without partner) vs. married (including those with partners)); education level (coded as: less than or more than 12 years), smoking habits (coded as current smoker vs. non-smoker); regular physical activity (coded as: yes vs. no) and (ii) PAL statements section. In the PAL statements section the participants answered the following questions:

- How often were you reading PAL in the past 6 months? (always, sometimes, never)
  - How often would you buy the product which contained the following PAL statement:
    - “May contain x [allergen]”
    - “May contain traces of x [allergen]”
    - “Manufactured in a facility that also processes... x [allergen]”? (always, sometimes, never)
- During the previous survey in the shops, these three PAL statements were noticed the most often and this was the reason why we used them in our questionnaire.
- Do you think that the PAL statements are defined by the laws and regulations in Serbia? (yes vs no)
  - Do you consider PAL statements credible? (yes vs no)

The study was conducted according to the guidelines given in the Declaration of Helsinki and all procedures were approved by the ethical board of the Faculty of Medicine, University of Belgrade, Serbia. Written informed consent was obtained from each participant.

### *Statistical analysis*

The authors used SPSS 20.0 statistical software (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, ver. 20.0. Armonk, NY: IBM Corp.) for data analysis. Descriptive statistics was presented as mean values  $\pm$  standard deviation (SD) for numeric variables, or as percent (relative numbers) for categorical variables. Differences between groups were tested using Pearson's  $\chi^2$  test. All *P*-values less than 0.05 were considered significant.

## **Results**

### *Assessment of precautionary allergen labels on the pre-packaged foods*

The survey included 1404 pre-packaged food products from seven categories. Overall, on 33.9% (476/1404) products PAL statements were noted. PAL statements were most commonly recorded in the following food categories: “biscuits” (67.8% of the surveyed pre-packaged bis-

cuits), “chocolate and candies” (64.3%), “instant soups” (61.3%) and “breakfast cereals” (59.5%) (Fig. 1). Less frequently (<5%) PAL statements were noted on “meat products” and “ready meals”. PAL statements were not recorded among “bread and toast” food products. Per-

forming more detailed PAL observations, the most common allergens listed in the advisory labels were “tree nuts” (62.1%). “Peanuts” and “sesame” were noted on about 40% of products (Fig. 2).

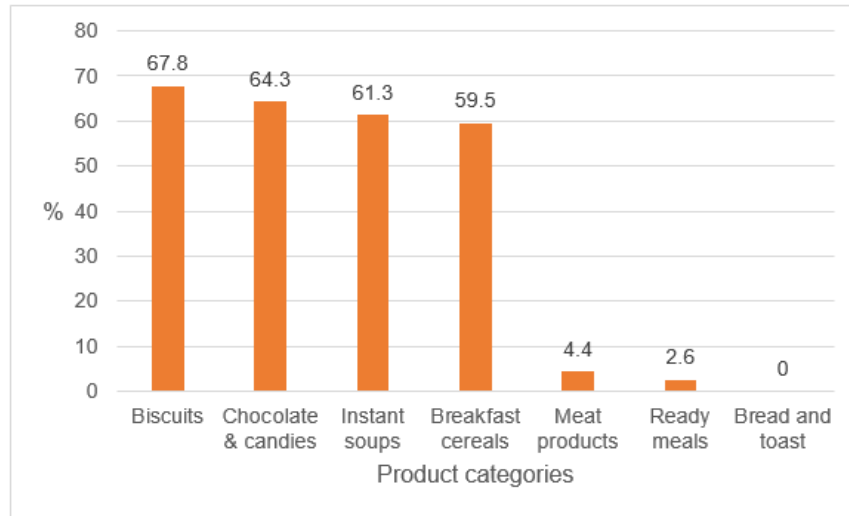


Fig. 1: Frequency of Precautionary Allergen Labels (PAL) of the seven food categories (out of 1404 assessed products)

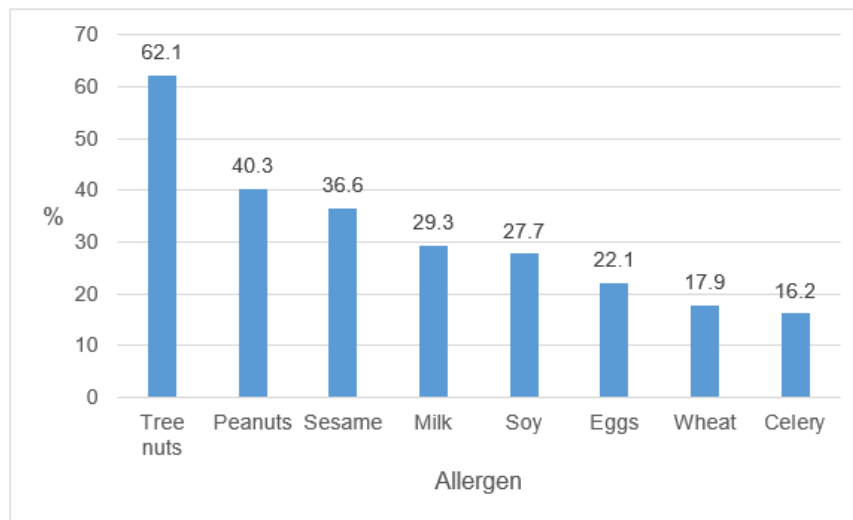


Fig. 2: The percentage of allergens listed in the PAL (on 476 out of 1404 assessed products)

On the observed samples of food products, it was noted that seven different types of PAL statements were used (Table 1). The most commonly used PAL-related phrase was “May contain traces of x [allergen]” recorded on more than

one-half of all inspected pre-packaged food products containing PAL. The second most frequent PAL-related advisory phrase was “May contain x [allergen]” (38.3%). Other phrases were noted less frequently (<3%).

**Table 1:** Prevalence of different types of precautionary labeling (on 476 out of 1404 assessed products)

<i>Type of advisory terminology</i>	<i>N (%)</i>
May contain traces of x [allergen]	251 (52.7)
May contain x [allergen]	182 (38.3)
Manufactured in a facility that also processes x [allergen]	14 (2.9)
Manufactured on shared equipment/line with products containing x [allergen]	11 (2.3)
The production process may cause cross contamination of product with x [allergen]	9 (1.9)
Packaged in the proximity of x [allergen]	6 (1.3)
May contain x [allergen] because of the production process which is nearby	3 (0.6)

Variety of ambiguous statements was noted on the analyzed PALs. The most extreme examples of ambiguities were referring to tree nuts, milk and wheat. For example, the PAL statements for tree nuts were not precise in defining the type of nuts (walnut, hazelnut, etc.) present in the product; the type of tree nut was not disclosed on 57% (165/290) PAL. Instead of using the term “wheat”, on 16 products terminology such as “gluten”, “flour” and “noodles” was used. More precisely, seven products listed “flour” and two listed “traces of noodles” but did not identify the source (e.g. wheat, rice, corn). On 12 products, instead of the term “milk” the terms “milk pro-

teins”, “milk protein isolate” and “ whey proteins” have been noted.

Overall, 275 participants (238 women and 37 men) were interviewed concerning their attitudes to PAL. Among them, 94 were persons with food allergies, and 181 were persons who had no allergies themselves but were purchasing food for a household member with food allergy. These groups shared similar characteristics according to their age, marital status, education level, smoking habits, regular physical activity.

Reading practices of PAL statements are presented in Table 2.

**Table 2:** Reading practices of PAL statements according to demographic characteristics (275 participants)

<i>Variable</i>	<i>Always</i>	<i>Sometimes</i>	<i>Never</i>	<i>P-value*</i>
Age (yr)				
18-30	25 (44.6 %)	19 (33.9)	12 (21.5)	0.721
31-50	88 (51.8 %)	42 (24.7)	40 (23.5)	
51-60	23 (46.9 %)	15 (30.7)	11 (22.4)	
Gender (%)				
Male	18 (48.6)	9 (24.4)	10 (27.0)	0.782
Female	118 (49.5)	67 (28.2)	53 (22.3)	
Marital status				
Married	66 (47.1)	39 (27.9)	35 (25.0)	0.651
Single	70 (51.9)	37 (27.4)	28 (20.7)	
Education (years)				
≤ 12	54 (39.7)	45 (33.1)	37 (27.2)	0.006
> 12	82 (59.0)	31 (22.3)	26 (18.7)	
Smoking habits				
No	98 (50.0)	51 (26.0)	47 (24.0)	0.598
Yes	38 (48.1)	25 (31.6)	16 (20.3)	
Physical activity				
No	93 (46.3)	60 (29.9)	48 (23.8)	0.205
Yes	43 (58.1)	16 (21.6)	15 (20.3)	

\* $\chi^2$  test

In general, in the past six months, this information was always read by 49.5% of the participants. Subjects with higher education read this information more often than less educated subjects. The frequency of reading was independent of participants' age, gender, marital status, smoking habits and physical activity.

Purchasing practices, based on precautionary statements, are presented in Table 3. Between

22.9% and 37.8%, participants reported that they would always or sometimes buy the product that contains PAL, depending on the particular phrase used in the PAL. The least number of participants would buy food with a label "May contain x [allergen]". Thus, 77.1% would never buy food with this type of PAL. The noted difference was statistically highly significant ( $P < 0.001$ ).

**Table 3:** Purchasing practices for PAL statements (275 participants)

<i>Would You buy product with the following label:</i>	<i>Always N (%)</i>	<i>Sometimes N (%)</i>	<i>Never N (%)</i>
"May contain x [allergen]"	8 (2.9)	55 (20.0)	212 (77.1)
"May contain traces of x [allergen]"	11 (4.0)	63 (22.9)	201 (73.1)
"Manufactured in a facility that also processes x [allergen]"	22 (8.0)	82 (29.8)	171 (62.2)

Less than half (43.3%) of the participants incorrectly believed that PAL is regulated by national law. Our participants did not have much confidence in PAL and only a quarter (25.1%) of them sincerely believe that the PAL statements are trustworthy.

## Discussion

To the authors' knowledge, this is the first comprehensive study about PAL statements on pre-packaged foods in Serbia. The strength of this study is the thorough approach, which covers the two different perspectives: the realistic situation surveyed in the retail stores and subjective consumers attitudes.

33.9% of the examined products contained these advisory labels. Certain categories of products, such as "biscuits", "chocolate and candies", "instant soups", and "breakfast cereals" were the categories with the highest usage of PAL. About 60% of these products contain PAL. It would be impractical to compare the overall presence of PAL statements among different studies. Observations were different because studies included different categories of food. Usage of PAL was noticeably different between the categories (19).

It is practical to compare some categories, for example, those where PAL statements were most frequently noticed. Research in the USA found that in categories of chocolate candy and cookies more than 50% products contained PAL (20). French study included 26 categories, were the most frequently noted PAL statements in the groups "cereals bars", "chocolate products", "ice creams", "breakfast cereals", "cakes and biscuits" (70-90%) (19). In Malaysia, 29.3% of food products had "May contain" statements, but in the group "powder and paste" all products had PAL, and in the groups' snacks and confectionary more than 40% (15). In Malawi, on the contrary, there was no use of PAL on any of the locally manufactured products, but 38.7% of imported biscuits had precautionary statements (21).

In our research, the most commonly listed allergen in the advisory labels was "tree nut" which is in line with the results of previous studies (11, 20).

Despite all efforts, allergens can end up in food during the processing (cross-contamination, use of shared equipment or facilities, etc.), packaging, transportation, or even storage. Having in mind these risks, food manufacturers are using PAL (11). The question that imposes is whether they

should use PAL to such extent? Are food manufacturers asking for protection behind PAL from the potential lawsuits? Is this an alibi for disrespecting Good Manufacturing Practices (GMP)? Legislations around the world require that PAL should not be used as a substitute for GMP (6, 22).

The second part of the research was evaluating participants' attitudes. It is interesting to mention that the majority (86.5%) of the participants were women, which is in line with other studies (23, 24). One of the reasons may be the fact that women more often accept to participate in the research interviews. However, we consider that the main reason for this is the fact that in Serbia women are often taking care of the family food purchases and nutrition.

During food purchasing daily, consumers take into consideration several factors, such as the cost, the taste, and nutritive values of food (25). For food allergic individuals the situation is a little bit more complex. They are primarily looking for the allergens on the labels daily; dealing with both allergy labels as well as with PAL makes an additional burden. The participants who avoid food with PAL spend more time identifying suitable foods and pay on average more than their non-allergic counterparts (7).

22.9% of the participants were ignoring PAL statements when buying food. Some types of advisory statements are frequently avoided. For example, participants were the least likely to buy a product with the label „may contain x [allergen]” in comparison with other types of advisory terminology. Different forms of statements are perceived as different risk, which is in line with other research studies (17, 26, 27). This opinion of the patients is incorrect because most studies have shown that there are no correlations between the amount of allergen present in a product and the use of PAL statements, especially different terminologies (28, 29).

Significant number of our participants had the wrong understanding of the legislations, which refer to PAL. Thus, 43.3% incorrectly believe that PAL is regulated by law. Participants in the USA and Canada had a similar attitude; most of

them believed that such statements were mandatory (17). Unfortunately, the value of PAL has been depreciated through overuse and inconsistent application (9). Many participants in developed countries did not believe that the PAL statements were credible or desirable (30). Because of that, our observation shows that three-quarters of the participants in Serbia do not have trust in PAL.

Instead of helping food allergic consumers to obtain meaningful and useful information about the desired food product, PAL loses its roll and credibility. Without the legislation, PAL statements lead to confusion and anxiety and the question remains what is in the background of the use or non-use of PAL. On the other hand, the lack of trust in PAL leads to the risk of unwanted allergic reactions. According to the experts, the standardization of PAL is of utmost importance. A better approach is required, which will find adequate balance between health and risks for the allergic consumers (10, 17). This approach should be based on the communication of the food industry manufacturers and the recommendations of the public health authorities, which will define tolerable risk levels of allergens. The adoption of the risk-based approach to PAL should be global and should bring benefits to all food-allergic patients (10).

This study has its limitations, which need to be mentioned. Firstly, we did not manage to cover all categories of food. However, we did manage to survey a quite large number of products from the groups, which contained multiple ingredients of which some are common allergens. The strength of this study is also the choice of the three different types of superstores, which are present on the territory of the Republic of Serbia. Secondly, the study was conducted at the Dietetic Unit that may seem like a limitation. The study did not want a selected population, such as group of diagnosed allergic patients commonly included in these types of studies. We considered that in our general population greater number of people suffers from food hypersensitivity than the confirmed cases. Our goal was to include as many participants as possible motivated to use allergen

labels. In our Dietetic Unit, we are having patients with confirmed food allergies and patients with some form of hypersensitivity not confirmed.

## Conclusion

A large number of products contain PAL statements but then again, PAL statements are frequently not user-friendly and they are given in different phrases and are sometimes very ambiguous. These kinds of PAL statements are not providing sufficient protection for food-allergic patients. Allergic patients do not trust these PAL statements. This condition requires immediate attention towards the regulatory policy, having in mind that the avoidance of food, which can trigger an allergic reaction, is the only way to control the allergies to food. Clearly defined use of PAL statements through the legislations, based on the risk assessment, would restore the credibility of PAL among the consumers and would be of great benefit to public health.

## Ethical considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

## Conflict of interest

The authors declare that there is no conflict of interest.

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