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Concerns arise: wheat allergy risk in pre-packaged food products from China

Wenfeng Liu[a,b,c,d], Jian Wang[a,b,c,d], Zhongliang Wang[a,b,c,d], Fangfang Min[a,b,c,d], Yong Wu[a,c,d], Juanli Yuan[a,d,e], Jinyan Gao[b,d], Hongbing Chen[a,c,d,*]

[a] State Key Laboratory of Food Science and Resources, Nanchang University, Nanchang 330047, China
[b] School of Food Science and Technology, Nanchang University, Nanchang 330031, China
[c] Sino-German Joint Research Institute, Nanchang University, Nanchang 330047, China
[d] Jiangxi Province Key Laboratory of Food Allergy, Nanchang University, Nanchang 330047, China
[e] School of Pharmaceutical Sciences, Nanchang University, Nanchang 330036, China

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ABSTRACT

Understanding and monitoring the cross-contamination of food allergens is crucial for safeguarding public health and ensuring food safety. Food allergen risk assessment, derived from classical toxicological principles, can identify and quantify the risk of allergies. This study aimed to investigate the risk of wheat allergic reactions to prepackaged foods from China through the utilization of food allergen risk assessment. A total of 575 products have been surveyed, wheat/gluten, milk and egg were major allergens labelled on products. According to voluntary incidental trace allergen labelling 3.0 (VITAL® 3.0) program, the number of products belonged to Action Level 2 were 303. Integration of precautionary allergen labeling (PAL) analysis indicated that 9.57% products would pose a potential risk to wheat allergic individuals. The probabilistic risk assessment results suggest that 7 984 allergic reactions may arise among wheat-allergic consumers during 10 000 eating occasions due to the consumption of pre-packaged food products with incorrect wheat-related allergen labelling. This study demonstrated that a risk assessment-based approach can support the guidance of allergen labelling and management of food allergen for pre-packaged food products, providing protection for allergic individuals in food consumption and for food manufacturers in food production and trade.

1. Introduction

Food allergy is defined as a kind of public health issue due to its high prevalence and life-threatening, which impose heavy burden to health and medical system[1]. Similarly, food allergy is considered as a food safety issue from the viewpoints of food allergic consumers and their caretakers, food enterprises and regulatory authorities[2]. Even with the promising outcome of immunotherapy, individuals with food allergies are still advised to avoid specific foods.

Over 160 foods have been identified as allergenic food[3]. However, for pre-packaged foods which provided to consumers or for catering purpose, the Codex Alimentarius Commission have released the *General Standard for the Labelling of Prepackaged Foods* (*CXS 1-1985*), which stipulates the following foods or ingredients shall always be declared on the label:

· Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of theses;
· Crustacea and products of these;
· Eggs and egg products;
· Fish and fish products;
· Peanuts, soybeans and products of these;
· Milk and milk products (lactose included);
· Tree nuts and nut products;
· And sulphite in concentrations of 10 mg/kg or more.

* Corresponding author at: State Key Laboratory of Food Science and Resources, Nanchang University, Nanchang 330047, China.
E-mail address: chenhongbing@ncu.edu.cn (H.B. Chen)
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Reviewed by the Ad hoc Joint Food and Agriculture Organization/ World Health Organization (FAO/WHO) Expert Consultation on Risk Assessment of Food Allergens in 2022, cereals containing gluten and its products is defined as one of the global priority allergens, as well as crustacean, egg, fish, peanut, milk, tree nuts and sesame, from the perspective of prevalence, potency and severity[4]. Recent report has shown that about 0.97% of global population was affected by wheat allergy[5], the prevalence of wheat allergy was 6.5% in Europe[6] and 1% in China[7]. A population-based study has revealed that the prevalence of wheat allergy in Saudi Arabia was 9%[8]. A retrospective study indicated that 6.5% nursery children in Kawasaki city experience wheat allergy[9]. In Brazil, the prevalence of self-reported wheat allergy was 0.79%[10]. Moreover, based on an analysis of a total of 1 952 episodes of anaphylaxis in 907 patients in China, wheat allergens have a significant impact on the onset of food-induced anaphylaxis[11]. Wheat-related adverse reactions would threaten wheat allergic individuals' lives (e.g., wheat-dependent exercise-induced anaphylaxis), the wheat related allergens labelling on the packaging of pre-packaged foods can be beneficial for wheat-allergic consumers to implement strict wheat proteins avoidance diet.

Most of jurisdictions refer to this standard (*CXS 1-1985*) to regulate the allergen labelling of pre-packaged foods[12]. Several countries have enacted national regulations on allergen management through surveys of the risk of food allergens (prevalence, severity and potency) and allergen labelling of pre-packaged foods. For the allergen labelling of pre-packaged food regulated by FDA, *Food Allergen Labeling and Consumer Protection Act of 2004* (FALCPA) identified eight major allergens that should be declared on the label[13]. In Canada, the *Food and Drug Regulations* (C.R.C., c.870) lists 11 priority allergens that should be declared on the label (https://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf). In Australia and New Zealand, there are 11 major allergenic food[14]. And the *Food Standards Code* has stipulated that food manufactures are required to declare the presence of major allergens when they are present in ingredients, food additives or processing aids[14]. To rationally enact regulations or formulate management strategies related to allergen labelling, the potential presence of allergens and the risk posed to consumers are required to be investigated.

In China, a nation-wide epidemiology survey has not been carried out, resulting in lack of knowledge about major allergens among Chinese allergic population. However, a study of meta-analysis has revealed that the prevalence of food allergy for self-reported was 11.5%, 11.6% for SPT positive and 6.2% for oral food challenge positive (OFC-positive)[15]. At present, eight major food allergens are required to be declared on the packages and the requirements of the allergen labelling were voluntary according to *China National Standard GB 7718-2011*[16]. In 2014, National Health Commission of the People's Republic of China released the draft to consider to mandate allergen labelling[16]. Given that China is the world's most populous country and there are no mandatory requirements for allergen labelling in China, it is imperative to investigate the present status of allergen labelling and evaluate the allergy risk in pre-packaged foods.

The inclusion of allergen labelling on pre-packaged food products is crucial in safeguarding individuals with allergies who follow the avoidance diet. However, the voluntary requirement of allergen labelling and the presence of confusing allergen information can result in considerable frustration for individuals with food allergies[17]. Moreover, almost 60% of Chinese adults consume pre-packaged food products which is steadily rising[18]. The majority of allergic consumers may face unintended risk since they lack an adequate understanding of allergen labelling and are unaware of the accurate composition of allergens in pre-packaged food products.

Food allergen risk assessment can determine the likelihood of allergic individuals experiencing adverse reactions when exposed to specific food allergens during consumption[19]. Quantitative risk assessment is widely acknowledged as a highly effective approach for population risk management. This approach requires the quantification of parameters related to allergic individuals in order to accurately assess the risk posed to allergic population, including individual threshold, consumption and allergen concentration[17]. The ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens assembled experts, comprised of scientists, regulators, physicians, clinicians and risk managers, to review the scientific evidence, discuss methodologies and develop guidelines for the food allergen risk assessment. The consultation provided recommendations on the priority allergens list[4], allergen threshold[20], the establishment of precautionary allergen labeling (PAL)[21] and allergen labelling exemption[22]. To address risk assessment strategies for allergenic foods, a collaborative effort between the European project EuroPrevall, the UK Food Standards Agency, and ILSI convened a workshop for deliberation. The workshop concluded that quantitative risk assessment utilizing probabilistic modeling stands out as the most promising methodology for population risk assessment[23]. In the United States, a food ingredient is required to adhere to FALCPA requirements if it triggers an allergic reaction that poses a health risk to individuals health. Moreover, the FDA Threshold Working Group advocates for a risk assessment-based approach as the most comprehensive and transparent scientific method for establishing allergen thresholds[24], which serves as a valuable tool for allergen labelling and risk management practices. However, the access for these quantitative parameters, which are necessary for quantitative risk assessment, is quite challenging for food enterprises or authorities. Based on the methodology of allergen risk assessment, the Allergen Bureau designed the Voluntary Incidental Trace Allergen Labelling (VITAL), which is a tool for standardized approach to PAL[25]. This risk management tool, now advanced to VITAL 3.0, can contribute to mitigating allergy risk for allergic individuals by determining allergen residue levels in pre-packaged food products.

Considering the requirement of allergen labelling for food manufacturers in China is voluntary as stipulated in GB 7718 in China, this study investigated the present condition of allergen labelling on pre-packaged foods. Moreover, specific to wheat allergy, we analyzed the accuracy of wheat related allergens labelling, and quantified the risk utilizing the VITAL 3.0 program and quantitative risk assessment.

2. Materials and methods

2.1 Materials

Quantitative enzyme linked immunosorbent assay (ELISA) test kits for determine the gluten and the cocktail (patented) for protein extraction were purchased from R-Biopharm, Darmstadt, Germany

(RIDASCREEN® Gliadin, Art. No: R7001, and The Cocktail (patented), Art. No: R7006). The ethanol (99.5%) was purchased from Aladdin (Shanghai, China) (Art. No: E118433-5L). The further microtiter low binding plate were purchased from Greiner bio-one (Art. No: 655901).

Sample collection was conducted using stratified random sampling. Specifically, 5 administrative districts in Nanchang, Jiangxi Province, China were first randomly selected based on the administrative division of Nanchang. Subsequently, according to the scales of pre-packaged food outlets, the outlets were categorized to supermarkets and retail stores. Lastly, for each of the 5 randomly selected administrative districts, one large supermarket chain and one retail store were randomly selected, with a total of 5 large supermarket chains and 5 retail stores. Prepackaged foods were randomly collected from the previously identified outlets.

By using Excel, the product name, information of allergen labelling (including summary allergen labelling and PAL), net weight and food category were recorded for further analysis. The summary allergen labelling means the statement that the product contains food allergens. And the PAL means the statements like the product may contain food allergens or the products was made on equipment that also produces products containing food allergens.

2.2 Sample preparation

All collected commercial products have been completely homogenized to achieve a fine powder or homogenized mixture using sterile equipment. All homogenized samples were preserved in sealed container and stored at room temperature in a dry environment. The extraction of gliadin was carried out as soon as possible according to the instruction of ELISA test kit.

2.3 Quantitative ELISA test to gluten

The quantification of gluten in pre-packaged foods was conducted by using the ELISA test kit certificated by the Association of Official Analytical Chemists (AOAC). The mechanism of the assay is based on the specific binding of the R5 monoclonal antibody to the gliadin. The gluten content was determined by doubling the quantification result of gliadin.

The determination of gluten content for extracted food samples was performed by following the protocol of manufacture provided in the kit. Briefly, the extracted food samples were diluted to the appropriate magnification. And the wash buffer and conjugate were also diluted as required and set aside. The diluted samples and standards were added in duplicate into to low-binding plate, and transferred the samples to pre-defined ELISA well by using multi-channel pipettes. After 30 min incubated, discarded the liquid in the wells and washed twice. The enzyme conjugate was added and incubated at room temperature for 30 min. Subsequently, washed twice and added the substrate and chromogen into each well. The reaction was stopped after 30 min incubation by adding stop solution provided by the kit. The absorbance at 450 nm was obtained.

The limit of detection (LOD) is 0.5 mg/kg gliadin or to 1 mg/kg gluten, and the limit of quantification (LOQ) is 2.5 mg/kg gliadin or to 5 mg/kg gluten. The quantitative gluten results were calculated by RIDASOFT® software according to the ELISA test results.

2.4 The determination of VITAL 3.0 Action Level and allergen labelling assessment

Using the net weight of each pre-packaged food product to mimic the reference amount or serving size that consumers typically consume. The calculation of Action Level was based on the VITAL 3.0 calculator to assess the potential risk of pre-packaged food products to allergic individuals[16]. The equation was as following:

$$\text{Action Level} = \frac{\text{Reference dose (mg)}}{\text{Reference amount or serving size (kg)}} \quad (1)$$

where reference dose of wheat was set as 0.7 mg[26].

Notably, gluten protein constitutes 80%−85% of the total wheat proteins[27]. The presence of wheat proteins in pre-packaged were calculated based on the results of ELISA test, assuming 80% gluten protein content in the total protein composition for a conservative purpose. According to VITAL 3.0[28], the Action Level 1 was that the wheat proteins concentration of food products lower than Action Level, and the Action Level 2 was that the wheat proteins concentration of food products higher than or equal to Action Level, indicating the requirement of wheat related PAL.

According to the ingredient list and the wheat proteins concentration, we checked the information of summary allergen labelling and PAL, some relevant definitions are as follows:

Correct labelling 1 (CL-1): a summary allergen labelling or PAL while the wheat proteins concentration over Action Level or there was no labelling while the wheat proteins concentration less than Action Level;

Correct labelling 2 (CL-2): a summary allergen labelling or PAL while the ingredient contained wheat or there was no labelling while the ingredient did not contain wheat;

Incorrect labelling 1 (ICL-1): a summary allergen labelling or PAL while the wheat proteins concentration less than Action Level or there was no labelling while the wheat proteins concentration over Action Level;

Incorrect labelling 2 (ICL-2): no labelling while the ingredient contained wheat or there was a summary allergen labelling or PAL while the ingredient did not contain wheat.

2.5 Quantitative wheat allergy risk assessment

In order to evaluated the risk of pre-packaged foods, the products with incorrect wheat allergen labelling were screened firstly. Subsequently, the products with wheat/gluten in ingredient list and with wheat summary allergen labelling were excluded. And the remained pre-packaged food products were included for quantitative risk assessment. A previous study indicated that the level of food intake in general population could be used to represent those in allergic population[29]. Consequently, an assumption was made to utilize the net weight of pre-packaged food products as a representation of consumption data of individuals since there was no nation-wide survey for allergen consumption during single eating occasion in China. The weight of the minimum individual package of each pre-packaged food product was recorded during the sampling practice and was used to establish the distribution of food consumption.

The R program was employed to perform the establishment of distributions and the Second-Order simulation. The *fitdistrplus* package in RStudio was employed to fit the distributions and

ggplot2 package was employed to plot the curves. In establishing the distribution of total wheat proteins exposure, the analysis was based on parameters involving gluten protein concentration, pre-packaged food consumption, and a conservative multiplier of 1.25 (assuming 80% gluten protein content in the total protein composition). The wheat proteins threshold distribution was established by employing the discrete population elicit dose (ED) values reported by Remington et al.[30] in 2020. The exponential distribution model was applied to fit the wheat proteins concentration data, consumption data and the population ED values. The risk characterization was evaluated using the second-order Monte Carlo simulations. The parameter of simulation was set as 100 runs of 10 000 iterations.

In this study, the mathematical formula for estimating mean risk referred to Spanjersberg et al.[31], which is shown as follow:

$$R_{\text{mean}} = \sum_{k=1}^{k} \frac{\text{Allergic reactions in run } k}{\frac{n}{k}} \quad (2)$$

In this formula, R_{mean} means the mean risk of allergic reactions, k means the runs, and n means the iterations.

3. Results

3.1 The characteristics of collected products

3.1.1 The category of collected food products

A total of 575 pre-packaged food products were collected from 5 supermarkets chain and 5 food retail stores. According to the *Classification Catalogue of Food Production License* issued by the State Administration for Market Regulation[32], all collected products were categorized into 16 common categories and 35 specific categories (Fig. 1). The majority of collected products were bakery (n = 129), potato and expanded food (n = 119), biscuits (n = 80), confectionery products (n = 70), and nuts (n = 46) when considered the common categories (Fig. 1A). More specifically, the expanded food (n = 118), heat-processing bakery (n = 104), biscuits (n = 80), nuts (n = 46), confectionery (n = 40) consist of the majority of collected pre-packaged food (Fig. 1B).

3.1.2 General analysis of allergen labelling information

According to the information recorded, the allergen labelling of all 575 pre-packaged food products were classified into summary allergen labelling only (n = 274), PAL only (n = 20), summary allergen labelling and PAL (n = 125) and no allergen labelling (n = 156) (Fig. 2A). As is shown in Fig. 2B, from the perspective of the common categories, the higher rate of summary allergen labelling and PAL was seen in biscuits (n = 46), bakery (n = 25), potato and expanded food (n = 24) and confectionery products (n = 17). As for the summary allergen labelling only, the bakery (n = 79), potato and expanded food (n = 67), nuts (n = 30) and biscuits (n = 24) got higher rate. Only 6 kinds common categories of food had the PAL, that were confectionary products (n = 10), potato and expanded food (n = 4), bakery (n = 2), nuts (n = 2) and aquatic products (n = 1), beverage (n = 1).

3.1.3 The analysis of food allergens labelled on collected pre-packaged foods

Since the report by ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens recommended cereals containing gluten and its products, crustacean, egg, fish, peanut, milk, tree nuts and sesame as global priority allergens[4], the analysis of the labelling of this group of allergens on pre-packaged foods was performed. As for the pre-packaged food products with summary allergen labelling and PAL (n = 125), allergens that were labelled more frequently were milk and its products (n = 112), wheat/cereals containing gluten (n = 111), and egg and its products (n = 87). And

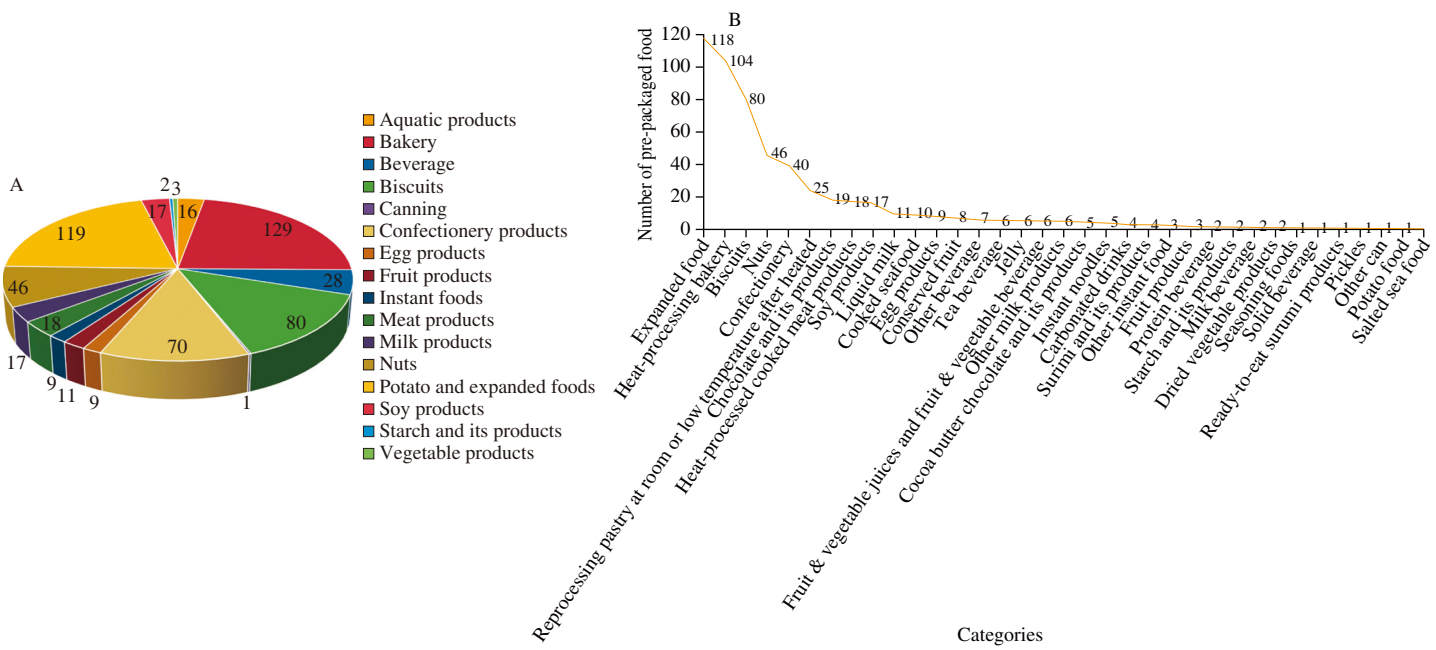
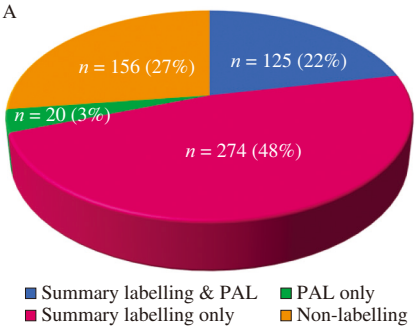


Fig. 1 Categories of all collected pre-packaged products. (A) The common categories of all collected products. (B) The specific categories of all collected products.

A



B

Summary labelling & PAL	Summary labelling only	PAL only	Non-labelling	
0 (0%)	1 (33.33%)	0 (0%)	2 (66.67%)	Vegetable products
0 (0%)	2 (100%)	0 (0%)	0 (0%)	Starch and its products
0 (0%)	15 (88.24%)	0 (0%)	2 (11.76%)	Soy products
24 (20.17%)	67 (56.30%)	4 (3.36%)	24 (20.17%)	Potato and expanded foods
2 (4.35%)	30 (65.22%)	2 (4.35%)	12 (26.08%)	Nuts
0 (0%)	8 (47.06%)	0 (0%)	9 (52.94%)	Milk products
0 (0%)	8 (44.44%)	0 (0%)	10 (55.56%)	Meat products
5 (55.56%)	4 (44.44%)	0 (0%)	0 (0%)	Instant foods
0 (0%)	0 (0%)	0 (0%)	11 (100%)	Fruit products
0 (0%)	6 (66.67%)	0 (0%)	3 (33.33%)	Egg products
17 (24.29%)	20 (28.57%)	10 (14.29%)	23 (32.85%)	Confectionery products
0 (0%)	0 (0%)	0 (0%)	1 (100%)	Canning
46 (57.50%)	24 (30.00%)	0 (0%)	10 (12.50%)	Biscuits
2 (7.14%)	4 (14.29%)	1 (3.57%)	21 (75.00%)	Beverage
25 (19.38%)	79 (61.24%)	2 (1.55%)	23 (17.83%)	Bakery
4 (25.00%)	6 (37.50%)	1 (6.25%)	5 (31.25%)	Aquatic products

Fig. 2 General information of allergen labelling. (A) The number of different types of allergen labelling in all collected pre-packaged foods. (B) The number of different types of allergens labelling for every common category of food.

those pre-packaged food products with PAL only, wheat/cereals containing gluten (n = 17), milk and its products (n = 12), and egg and its products (n = 7) labelled more commonly. Similarly, wheat/cereals containing gluten (n = 179), milk and its products (n = 130), egg and its products (n = 98) were more prevalent as seen in the pre-packaged food products with summary allergen labelling only (Fig. 3).

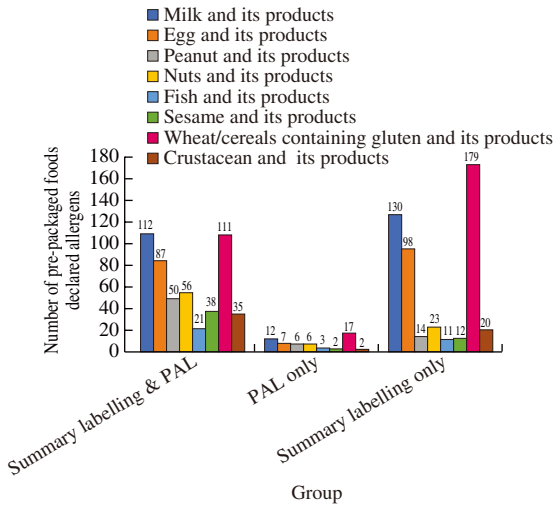


Fig. 3 Declaration of global priority allergens in collected food products with different type of allergen labelling.

Subsequently, the wheat-related labelling has been further analysis by integrating the type of allergen labelling with food categories for analysis. For the food products with summary allergen labelling and PAL, the biscuits (n = 46) presented the highest number of products that informed wheat/cereals containing gluten, following by the bakery (n = 25), potato and expanded foods (n = 18), confectionery products (n = 4), nuts (n = 1) and beverage (n = 1) (Table 1). As for the products with summary allergen labelling only, the majority products that labelled the wheat/cereals containing gluten were composed of bakery (n = 78), potato and expanded foods (n = 51), and biscuits (n = 24) (Table 2). In 20 pre-packaged food products with PAL only, 7 confectionery products, 4 potato and expanded foods, 2 nut products, 2 bakery products and 1 aquatic product, 1 beverage product claimed the wheat/cereals containing gluten on the label (Table 3).

3.2 The VITAL Action Level and the accuracy of wheat related allergen labelling

According to the formula, the Action Level of each pre-package food was calculated. The results showed that 272 of 575 products were categorized into Action Level 1, and 303 products were Action Level 2 (Table 4). A further analysis indicated that 56 (9.74%) pre-packaged food products lacked the wheat related PAL which could present a potential risk to wheat-allergic individuals.

Specifically, all the meat products, beverage at Action Level 2 lacked the PAL, and 50% (4 of 8) for the soy products, 33.33% for the nuts (5 of 15) and aquatic products (1 of 3), 18.18% (10 of 55) for the potato and expanded foods, 17.36% (21 of 121) for the bakery, 14.29% (1 of 7) for the instant foods, 11.54% (9 of 78) for the biscuit and 8.33% (1 of 12) for the confectionery products. All these results indicated that a certain portion of products at Action Level 2 in each food categories present a potential risk of allergic reaction to allergic consumers.

According to the Action Level and the ingredients list of pre-packaged foods, the accuracy of wheat related allergen labelling was evaluated. As shown in Fig. 4, the proportion of correct labelling was 80.35% (CL-1, n = 462) and 82.43% (CL-2, n = 474), respectively. And the proportion of incorrect labelling was 19.65% (ICL-1, n = 113) and 17.57% (ICL-2, n = 101), respectively. For those products with incorrect labelling, a further analysis related to common categories

Table 1
Analysis of 8 food allergens in pre-packaged foods with summary allergen labelling and PAL.

Categories	Milk and its products	Egg and its products	Peanut and its products	Nuts and its products	Fish and its products	Sesame and its products	Wheat/cereals containing gluten and its products	Crustacean and its products
Biscuits	46	40	27	23	2	21	46	9
Nuts	1	1	2	0	1	0	1	2
Egg products	0	0	0	0	0	0	0	0
Starch and its products	0	0	0	0	0	0	0	0
Soy products	0	0	0	0	0	0	0	0
Instant foods	4	4	3	1	3	2	4	4
Bakery	23	22	9	13	2	6	25	1
Canning	0	0	0	0	0	0	0	0
Meat products	0	0	0	0	0	0	0	0
Milk products	0	0	0	0	0	0	0	0
Vegetable products	0	0	0	0	0	0	0	0
Potato and expanded foods	19	13	3	4	10	3	18	17
Aquatic products	2	2	0	2	3	1	3	2
Fruit products	0	0	0	0	0	0	0	0
Confectionery products	15	5	5	12	0	4	13	0
Beverage	2	0	1	1	0	1	1	0

Table 2
Analysis of 8 food allergens in pre-packaged foods with summary allergen labelling only.

Categories	Milk and its products	Egg and its products	Peanut and its products	Nuts and its products	Fish and its products	Sesame and its products	Wheat/cereals containing gluten and its products	Crustacean and its products
Biscuits	15	12	2	2	0	2	24	0
Nuts	1	1	7	16	0	0	9	2
Egg products	0	2	0	0	0	0	0	0
Starch and its products	0	0	0	0	0	0	1	0
Soy products	1	0	1	0	0	0	5	0
Instant foods	0	1	0	1	0	0	3	0
Bakery	50	70	0	1	0	4	78	3
Canning	0	0	0	0	0	0	0	0
Meat products	0	2	1	0	1	3	2	1
Milk products	8	0	1	0	0	0	0	0
Vegetable products	0	0	0	0	0	0	1	0
Potato and expanded foods	33	5	2	1	6	3	51	13
Aquatic products	2	5	0	0	4	0	2	1
Fruit products	0	0	0	0	0	0	0	0
Confectionery products	16	0	0	2	0	0	3	0
Beverage	4	0	0	0	0	0	0	0

Table 3
Analysis of 8 food allergens in pre-packaged foods with PAL only.

Categories	Milk and its products	Egg and its products	Peanut and its products	Nuts and its products	Fish and its products	Sesame and its products	Wheat/cereals containing gluten and its products	Crustacean and its products
Biscuits	0	0	0	0	0	0	0	0
Nuts	1	1	2	2	0	0	2	0
Egg products	0	0	0	0	0	0	0	0
Starch and its products	0	0	0	0	0	0	0	0
Soy products	0	0	0	0	0	0	0	0
Instant foods	0	0	0	0	0	0	0	0
Bakery	0	1	1	0	0	2	2	0
Canning	0	0	0	0	0	0	0	0
Meat products	0	0	0	0	0	0	0	0
Milk products	0	0	0	0	0	0	0	0
Vegetable products	0	0	0	0	0	0	0	0
Potato and expanded foods	3	0	0	0	1	0	4	1
Aquatic products	0	1	0	0	1	0	1	1
Fruit products	0	0	0	0	0	0	0	0
Confectionery products	7	3	3	4	1	0	7	0
Beverage	1	1	0	0	0	0	1	0

was conducted (Table 5). The surveyed products of the egg products, milk products and fruit products had absolutely correct information about wheat related allergen labelling according to both the content of ingredient and the wheat protein concentration (100% for CL-1 and CL-2). Upon analysis, it was discovered that the Canning surveyed did not have any labelling indicating the presence of food allergens, and there were no wheat or cereals products listed in ingredient (CL-2), while the results from the ELISA test revealed wheat proteins concentrations exceeding Action Level (ICL-1).

Table 4
Analysis of VITAL Action Level for different categories of food products.

Categories	VITAL Action Level 1	VITAL Action Level 2	Products at VITAL Action Level 2 without wheat related PAL (proportion (%))
Biscuits	1	78	9 (11.54)
Nuts	31	15	5 (33.33)
Egg products	9	0	0
Starch and its products	2	0	0
Soy products	9	8	4 (50)
Instant foods	2	7	1 (14.29)
Bakery	8	121	21 (17.36)
Canning	0	1	0
Meat products	17	1	1 (100)
Milk products	17	0	0
Vegetable products	3	0	0
Potato and expanded foods	64	55	10 (18.18)
Aquatic products	13	3	1 (33.33)
Fruit products	11	0	0
Confectionery products	59	12	1 (8.33)
Beverage	25	3	3 (100)
Total	272	303	

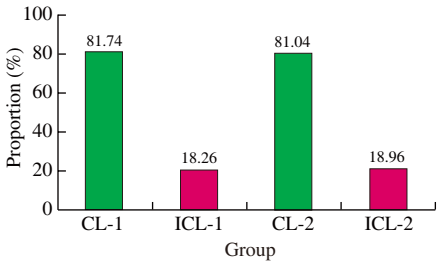


Fig. 4 Proportion of correct labelling and incorrect labelling out of all collected food products.

3.3 The risk characterization of collected pre-packaged food products

According to the screening process, 54 samples were finally used to assess the risk of wheat allergic reactions. The exponential model has properly fitted the wheat proteins concentration data and simulated consumption data (Fig. 5). The Monte Carlo simulation was performed in the RStudio. Based on the gluten concentration distribution and consumption distribution, the gluten intake distribution was also established. The parameters of the distributions have been shown in Table 6. The risk was evaluated using a further Monte Carlo simulation based on the wheat proteins intake distribution and threshold distribution. The average number of allergic reactions out of 10 000 simulations of single eating occasion were estimated to be 7 984 allergic reactions within wheat allergic population when consuming the products with incorrect wheat related allergen labelling.

4. Discussion

In China, wheat is the primary and most important crop that serves as a staple food for the majority of the population. Moreover, China has been forecast to be one of leading producer and importer of wheat, with nearly 18% wheat was foreseen to be produced in China[33]. According to statistical data, the consumption of wheat flour among Chinese residents has exhibited a consistent annual increase[34]. Whether utilized as a dietary staple or as an ingredient in

Table 5
Analysis for the food products with incorrect labelling.

Categories	CL-1		ICL-1		CL-2		ICL-2		Total
	Frequency	Proportion (%)	Frequency	Proportion (%)	Frequency	Proportion (%)	Frequency	Proportion (%)	
Biscuits	70	88.61	9	11.39	69	87.34	10	12.66	79
Nuts	39	84.78	7	15.22	38	82.61	8	17.39	46
Egg products	9	100	0	0	9	100	0	0	9
Starch and its products	1	50.00	1	50.00	1	50.00	1	50.00	2
Soy products	12	70.59	5	29.41	13	76.47	4	23.53	17
Instant foods	7	77.78	2	22.22	8	88.89	1	11.11	9
Bakery	103	79.84	26	20.16	105	81.40	24	18.60	129
Canning	0	0	1	100	1	100	0	0	1
Meat products	15	83.33	3	16.67	16	88.89	2	11.11	18
Milk products	17	100	0	0	17	100	0	0	17
Vegetable products	2	66.67	1	33.33	2	66.67	1	33.33	3
Potato and expanded foods	82	68.91	37	31.09	84	70.59	35	29.41	119
Aquatic products	12	75.00	4	25.00	14	87.50	2	12.50	16
Fruit products	11	100	0	0	11	100	0	0	11
Confectionery products	56	78.88	15	21.12	60	84.51	11	15.49	71
Beverage	26	92.86	2	7.14	26	92.86	2	7.14	28
Total	462		113		474		101		575

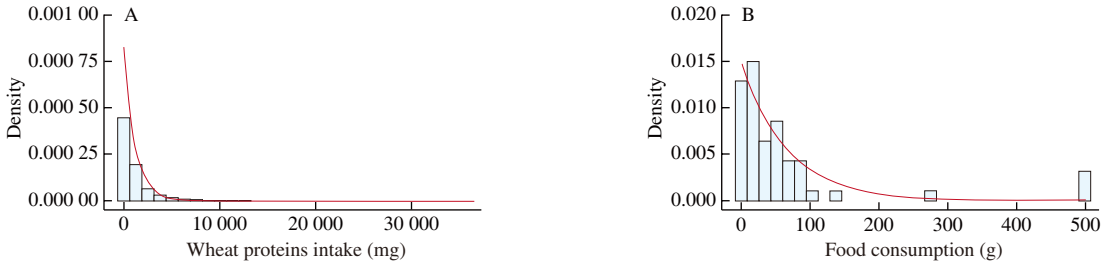


Fig. 5 Exponential model fit to the data of wheat proteins intake (A) and food consumption (B).

the manufacturing of prepackaged foods, wheat and its derivatives hold significant prominence[35]. Of individuals suffering from allergic anaphylaxis in China, 20% children and 40% adults were triggered by wheat[11]. The rise in the availability of pre-packaged food options in the market has led to an increased significance of pre-packaged foods in the daily consumption habits of residents in China[36]. Consequently, unintended allergic reactions to pre-packaged food occurred though the legislation of allergen labelling has been introduced and the use of PAL has been recommended[37]. Investigating the gluten residues in commercially available pre-packaged foods and the accuracy of allergen labelling on them, especially with current regulations requiring voluntary labelling of allergens, would practically help wheat allergic consumers minimize the risk of accidental allergic reactions.

Table 6
Related parameters deriving from fitting an exponential model to different classes of data.

Source of data	Rate	Akaike Information Criterion (AIC)	Bayesian Information Criterion (BIC)
Gluten concentration ($\times 10^{-6}$)	6.90×10^{-5}	1 144.86	1 146.85
Simulated consumption (kg)	0.015	562.78	564.77
Wheat proteins intake (mg)	8.33×10^{-4}	161 805.1	161 812.3

In this study, 419 of the 575 collected food products are presented with any kind of allergens statement. Moreover, the analysis revealed that only 48% of these products featured summary allergen labelling, while 3% presented PAL only. An investigation of allergen labelling of food products imported into Australia from China indicated that 73% of improted food products declared the summary allergen statement, while 8.9% declared the PAL statement[16]. In Thailand, a survey of the allergen labelling on pre-packaged food products shown that 30.2% of collected products had "may contain" labelling[12]. The employment of PALs is to alert consumers about the potential presence of unintended allergens. However, the use of PAL is voluntary, and there has been no legislation in place to regulate in most jurisdictions, leaving the potential risk to allergic consumers or stakeholders uncertain[38]. Regrettably, the excessive and inconsistent use of PAL without a global framework could dimish its credibility of PAL, and undermine the consumers' confidence, untimately impacting their quality of life. Our study also discovered that over 20% of the allergen labelling on products reviewed was not accurate. Specifically, 11.83% food products list cereal or wheat as ingredients without including proper allergen labelling. Therefore, wheat allergic consumers can avoid consuming such kind of food by reviewing ingredients lists. However, 7.13% food products do not list wheat or cereals in their ingredients, but have the allergen labelling attached to them. The allergic consumers would be confused when checking the labelling, fewer options for food cosumption would be accessible. In this case, the extensive use of allergen labelling, the wording vary widely would make consumers lost confidence in allergen labelling and result in increasingly neglect of allergen labelling. Moreover, in this study, after reviewing the allergen labelling, the ingredients and the ELISA results, it has found that some products without allergen labelling contained undeclared gluten at detectable level, which would be potential risk for wheat allergic population[39]. Currently, the application of allergen labelling on pre-packaged foods is not mandatory in China. Moreover, there are no specific guidelines for food manufacturers on how to use allergen labelling. Therefore, even when allergens have not been introduced into pre-packaged foods or the level of allergens do not pose a potential risk, the allergen labelling may be applied. Inappropriate use of allergen labelling indicates that reviewing the allergen labelling may not prevent allergic reaction, imposing a significant psychosocial and economic burden on allergic consumers[40]. The present study investigated prepackaged foods in Nanchang, recognizing inherent limitations in result application. Given potential regional variations in dietary habits and allergen prevalence, the study's focus on a single location may restrict generalizability to the broader Chinese population. To mitigate these constraints and enhance the robustness of subsequent investigations, advocating for a more expansive study becomes imperative. A pivotal stride in this direction involves adopting longitudinal methods to monitor allergen patterns and trends over extended durations. This approach promises a more nuanced and comprehensive knowledge of allergen risks in prepackaged foods across diverse Chinese regions, thereby contributing to the development of a universally applicable knowledge base. Moreover, the utilized detection kit in this study demonstrates efficacy in detecting gluten proteins; nonetheless, its limitation lies in the challenge of clearly identifying the specific source of these proteins, which may stem from either wheat or other grains. In the process of risk assessment, data from oral food challenges conducted with wheat-allergic populations were employed to establish threshold dose distributions. These distributions, when integrated with wheat proteins intake data, can facilitate the assessment of the risk associated with immunoglobulin-E (IgE)-mediated wheat allergic reactions.

Food recalls caused by food safety concerns can have a detrimental impact on the financial performance of listed companies, and a significant proportion of food products recalls are closely tied to negative consequences, encompassing a range of outcomes such as physical injuries, various forms of illness, and, in certain instances, even resulting in fatalities[41]. Food allergen risk assessment involves analyzing data on the characteristics of cross-contact to determine the probability of adverse reactions experienced by allergic

consumers when consuming specific allergenic food substances[19]. Employing a risk assessment approach to address and mitigate food safety issues, particularly those related to food allergies, would offer substantial benefits to stakeholders. The results of the quantitative risk assessment declared that the number of wheat allergic reactions was 7 984 out of 10 000 eating occasions regarding the consumption of pre-packaged food products with incorrect wheat allergen labelling. For individuals with food allergies, the discrepancy between food labelling and its actual contents poses a significant risk of triggering an allergic reaction[42]. Quantitative food allergen risk assessment ensures food safety for allergic consumers by identifying, evaluating and managing the risks associated with allergenic ingredients in foods. By accurately assessing the presence and levels of allergens in food products, manufacturers can provide clear labelling and information to help allergic individuals make safe food choices[43]. Moreover, utilizing scientific evidence through quantitative risk assessment to inform optimal intake for individuals with allergies can significantly contribute to the attainment of food safety objectives[44]. Most importantly, the implementation of scientific risk assessment serves as a fundamental process in determining tolerable food safety risk in the context of food allergy, which allows for the establishment of safe Reference Doses and Action Levels[45]. Currently, a few studies evaluated the wheat allergy risk. Remington et al.[46] conducted the quantitative risk assessment of wheat allergen in precautionary labeled and unlabeled products, and the results demonstrated that the wheat in a ready-made Indian meal predicted to cause reactions in up to 17% of the simulated eating occasions. However, the methodology of probablistic risk assessment has been widely utilized. Manny et al.[47] reported that a total of 15 881 allergic reactions could occur when milk allergic individuals consumed dark chocolate, while 3 802 for baked goods, 646 for cookies. The probabilistic risk assessment, based on the data from the French MIRABEL survey, indicated that the mean risk ranged from 38 to 5 500 allergic reactions for 1 000 000 eating occasions when the appetizers was consumed[48]. In the absence of consumption surveys for single eating occasion in China, this study relied on data regarding the net weight of pre-packaged foods as a proxy for population consumption patterns. However, it's important to acknowledge that this approach carried the potential for both overestimating and underestimating risk. All the risk evidence indicated that the presences of allergens in food products could be a significant factor contributing to global food recalls[49]. In the United States, the analysis of food recall cases from 2013 to 2019 showed that 2.3% of these recalls were attributed to gluten, while all other non-major allergens accounted for 1.6% of the food recalls[49]. In the United Kingdom, the food recalls from 2016 to 2021 were also analyzed, with a total of 597 foods related recalls reported, of which 16.9% were related to gluten[50]. The food recalls data registered in the Rapid Alert System for Food and Feed (RASFF) have been analyzed, and it was reported that gluten was one of the major allergens that caused the food recalls in Europe[38]. Generally, unintended presence allergens typically occurr as a result of cross-contamination throughout various stages within the food supply chain. Quantitative risk assessment of unintended allergenic proteins plays a pivotal role in providing the necessary information for determining the necessity of a food recall. Consequently, a critical imperative arises to accurately identify and characterize these risks while implementing suitable management strategies.

Quantitative risk assessment involves the quantification of allergens, the establishment of allergen thresholds and the investigation of allergen exposure, et al. Out of the current available allergen detection technologies, ELSIA, polymerase chain reaction (PCR) and mass spectrometry (MS) methods exhibit potential for quantitative analysis and are more prominently used compared to other methods[51]. ELISA and MS methods typically detect the protein composition of foods by determining the epitopes or peptides of selected proteins, whereas PCR detects allergenic foods by determining the DNA sequence specific to the allergenic food[51]. These methods lack direct analysis of complete allergen proteins but rather derive them in other ways. Consequently, interpretations of their accuracy in measurements should be approached cautiously[51]. The establishment of allergen thresholds is prerequisite for quantitative risk assessment and the development of population risk management strategies[52]. A standard double-blind placebo-controlled food challenge (DBPCFC) serves as a credible method for determining individual threshold. With the growing awareness of allergen threshold, the importance of allergen thresholds in relation to public health and food safety is progressively strengthening. This trend underscores the transformation of the DBPCFC from a diagnostic tool to an informative resource capable of improving the management of food allergy both at individual and public health levels[53]. Recognized as a condition characterized by immediate onset, IgE-mediated food allergy prompts the measurement of food allergen exposure within a single meal or a relatively short period in the framework of quantitative risk assessment[54]. The allergen risk assessment primarily targets food allergic individuals while the pattern of consumptions may diverge from that of general population. Although Blom et al.[29] demonstrated, from a risk perspective, that no statistically significant difference in allergen exposure between allergic population and general population, leading to no different risk management decisions. However, the limited sample size and the demographic specificity of the survey population prompt consideration regarding the extent to which its conclusions can be extrapolated to other jurisdictions, indicating the need for further research. Furthermore, food allergen risk assessment furnishes a scientific foundation for risk management practices. Hazard identification in the context of risk assessment enables the scientific evidence for priority labelling of food allergens[4]. Managing allergen labelling based on the principle of risk assessment ensures the credibility of allergen labelling and facilitates effective risk communication with stakeholders, thereby mitigating risk uncertainty[43,55]. For food business operators, determining a safe level of risk through risk assessment contributes to evaluating the likelihood of allergen presence in food products, enabling the development of more robust strategies of risk control for protecting food safety[56]. For instance, conducting a quantitative risk assessment of the cleaning procedure within production line offers strengthened protection for risk management and harmonization of mitigation strategies such as PAL[57]. Moreover, employing quantitative risk assessment enables informed decisions regarding the utilization of PAL in a standardized and transparent manner[58]. The adoption of risk assessment methodologies for managing allergy risk within food supply chain will be the trend of the future[58].

The VITAL program has been developed to offer food manufacturers a risk-based approach for evaluating the potential of allergen cross-contact and considering the use of appropriate

PAL[28]. As a risk management tool, the VITAL program performs a critical role in reducing the abuse of PAL and facilitates efficient risk communication with allergic consumers. In this study, 9.57% of the products would pose a potential risk to wheat allergy consumers by determining the Action Level based on the VITAL program. While the survey of pre-packaged food products imported from Mainland China and Thailand to Australia deemed that 25.8% of the products from China and 10.8% of the products from Thailand posed the potential risks for allergic consumers[59]. In China, a study revealed that small-sized enterprises did not implement effective allergen control practices primarily due to the lack of knowledge regarding allergens[60]. Moreover, some companies have not actually engaged with the regulation and knowledge required to implement an effective allergen management system, even though they claimed to have carried out food allergen risk assessment and provided proper labelling. Existing practice in allergen assessment of pre-packaged food products implies that a risk assessment-based approach should be introduced to regulate the consistent and standardized use of allergen labelling globally. This manner would promote effective risk communication with allergic consumers. Additionally, a scientific risk assessment methodology would strengthen risk monitoring by authorities, protect the safety of food supply chain and facilitate self-risk management for allergic consumers.

5. Conclusion

This study provided an in-depth exploration of the gluten risk associated with pre-packaged food products available in China, encompassing the analysis of allergen labelling information, the determination of action levels, and the quantitative risk assessment. Wheat/gluten, milk and egg were major allergens labelled on surveyed pre-packaged food products when analyzing the allergen information. Moreover, the results of VITAL 3.0 program shown that 272 of 575 products (47.30%) were considered as VITAL Action Level 1, and 303 products (52.70%) were VITAL Action Level 2. The further analysis indicated that 55 (9.57%) pre-packaged food products lacked the PAL of wheat which could present a potential risk to wheat-allergic individuals. The results of the probabilistic risk assessment indicated that 7 984 allergic reactions could occur within 10 000 eating occasions regarding the consumption of re-packaged food products with incorrect wheat allergen labelling. Overall, this study preliminarily illustrates the risk of wheat allergy in pre-packaged food. However, the lack of consumption data and wheat allergen threshold data within Chinese wheat allergic population may result in an overestimation or underestimation of the wheat allergy risk. Notably, the findings in this study suggest that a risk assessment-based approach to guiding allergen labelling of pre-packaged food products will facilitate effective risk communication between food manufacturers and allergic consumers, providing protection for allergic individuals in food consumption and for food manufacturers in food production and trade. In the future, food allergen labelling could leverage emerging technologies such as blockchain and QR codes to provide clearer allergen information. Moreover, the collaborations between food manufacturers, regulators and healthcare professionals could contribute to creating personalized allergy control strategies.

Conflict of interest

Hongbin Chen is an editorial board member for *Food Science and Human Wellness* and was not involved in the editorial review or the decision to publish this article. All authors declare that there are no any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations within three years of beginning the submitted work that could inappropriately influence, or be perceived to influence, this work.

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