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Gluten Contamination of Labelled Gluten-Free Food Products Marketed in China

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Abstract: Gluten plays a central role in the development of several gluten-related disorders, with coeliac disease being one of the most well-known. A strict gluten-free diet is currently recognised as the only safe and effective treatment for coeliac disease. This study aimed to determine the degree of gluten contamination in labelled gluten-free food products available on the Chinese market. In 2024, 119 prepackaged products labelled as gluten-free were purchased from internet suppliers, 33 of which were imported. Each product was analysed in duplicate, using the cocktail solution (patented) to extract gluten and the RIDASCREEN® Gliadin sandwich R5 ELISA to determine the gluten content. The results showed that among the 119 products, 86 (72.3%) contained gluten less than 5 mg/kg, 12 (10.1%) between 5 and 10 mg/kg, 5 (4.2%) between 10 and 20 mg/kg and 16 (13.4%) above 20 mg/kg. None of the products imported contained gluten above 20 mg/kg, while 16 out of 86 (18.6%) Chinese-made products did. There was a significant difference in the prevalence of gluten contamination between imported and domestically made products ($p < 0.01$). These findings highlight the need for Chinese food regulatory agencies to impose requirements of production that lead to prevent gluten contamination, confirmed by possible monitoring of such compliance through routine sampling and testing.

Keywords: coeliac disease; food contamination; gluten; gluten-free diet; gluten-related disorders; labelled gluten-free; gluten quantification; R5 ELISA

1. Introduction

Gluten is the major structural protein found in grains such as wheat, barley, rye, oats, and it plays a central role in the development of several gluten-related disorders (GRDs), including coeliac disease (CD), dermatitis herpetiformis, gluten ataxia, IgE-mediated wheat allergy and non-coeliac gluten sensitivity [1,2]. CD is one of the most well-known GRDs, affecting approximately 1% of the global population [3]. A strict gluten-free diet (GFD) is currently recognised as the only safe and effective treatment for CD [4,5].

For most patients with CD, extremely low doses are tolerable. Evidence exists suggesting that exposure to less than 10 mg per day is unlikely to cause histological changes to the intestinal mucosa while exposure to 50 mg per day is likely to do so [6–8]. These levels contributed to establish that it is safe to consume gluten-free foods with a gluten content below 20 mg/kg [9]. This threshold has been adopted by major food regulatory agencies, including the Codex Alimentarius Commission [10], the United States Food and Drug Administration [11] and the European Food Safety Authority [12]. However, some organizations, such as the Gluten-Free Certification Organization (GFCO) in North America and the Celiac Sprue Association (CSA)/United States of America, Inc., recommend even stricter gluten limits of ≤ 10 mg/kg and ≤ 5 mg/kg, respectively [13,14]. There is currently mandatory

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national food safety standard for gluten-free foods in China. Based on the dietary habits of the Chinese population, if gluten levels not exceeding a maximum threshold of 20 mg/kg, even if a patient with CD consumes a large amount of gluten-free food it would be very difficult to exceed the safe threshold of 10-50 mg of gluten per day [15].

Despite the increasing availability of naturally gluten-free and commercially produced gluten-free foods, completely eliminating gluten from the diet remains highly challenging. Gluten is one of the most widely used food ingredients in the food industry. Contamination of gluten-free foods with gluten-containing foods can occur at multiple stages of food production, from farms and factories to restaurants and homes [16,17]. Prolonged intake of gluten-contaminated foods may cause persistent intestinal damage and symptoms in patients with CD on a GFD [18]. Consumers rely on labels to choose gluten-free foods. However, reports from multiple countries indicate that gluten contamination is common in gluten-free foods [17]. Such data is not available in the case of China. Therefore, this study aimed to determine the degree of gluten contamination in labelled gluten-free food products available on the Chinese market, using the R5 ELISA recommended by Codex Alimentarius.

2. Materials and Methods

2.1. Food Products

In March 2024, 119 prepackaged food products labelled as gluten-free were purchased from Chinese internet suppliers. All products were assigned a unique laboratory code, and their detailed information (including brand, production location, basic ingredient, food category, etc.) were documented on an Excel spreadsheet. According to the basic ingredients of the food, products were classified as rice, mixed grains, legumes and potatoes, mixed food, oats, millet, corn, buckwheat and quinoa. Mixed grains refer to foods with two or more grains as main ingredients. Mixed food refers to food that contains two or more different categories of ingredients, such as rice and soya. According to the food category, products were classified as flour, noodles, seasoning, biscuit and bread, snacks and breakfast porridge. This study protocol is exempt from approval by the ethics committee of the China National Center for Food Safety Risk Assessment.

2.2. Determination of Gluten

Experiments were conducted centrally at the China National Center for Food Safety Risk Assessment. All food products were analysed in duplicate, using the cocktail solution (patented) (R7006) from R-Biopharm (Darmstadt, Germany) to extract gluten and RIDASCREEN® Gliadin sandwich R5 ELISA (R7001) from R-Biopharm to determine the gluten content. The sandwich ELISA is suitable for testing products where the proteins are not hydrolyzed. The RIDASCREEN® Gliadin competitive R5 ELISA (R7021) from R-Biopharm was used to review for products known to have been subjected to hydrolysis and therefore where smaller gluten peptide fragments may escape the detection of the sandwich ELISA. Every 10 products, the gluten contamination on environmental surfaces was determined using RIDA®QUICK Gliadin immunochromatographic strips (R7003) from R-Biopharm. The manufacturer's instructions were strictly adhered to for each analysis.

The gluten quantification range of sandwich ELISA is 5 mg/kg to 80 mg/kg, while the competitive ELISA range is 10 mg/kg to 270 mg/kg.

2.2.1. Sample Extraction and Preparation

Homogenised well 50 g or 50 mL of each food sample to ensure taking a representative test portion, and stored the homogenised sample in centrifuge tubes, with at least 5 g of processed sample in each tube. To avoid any potential cross-contamination, samples were homogenised in different rooms and at different time intervals. For each sample processed, the blender and the environmental surfaces was rinsed with 60% ethanol.

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For sandwich ELISA, we weighted 0.25 g of processed sample (1 g for oat sample) in a new tube, in sample containing tannins and polyphenols an additional 0.25 g of skim milk powder was added. After this preparation, 2.5 mL of cocktail solution (10 mL for oat sample) was added to each tube, mixed thoroughly by vortexing, and then incubated in a water bath at 50 °C for 40 min. After the incubation, 7.5 mL of 80% ethanol (30 mL for oat sample) was added, and the tube was rotated at room temperature for 1 h. For competitive ELISA, we weighed 1 g of processed sample, added 10 mL of 60% ethanol (9 mL for liquid sample), and the tube was rotated at room temperature for 10 min. After the rotation, for both ELISA, the tube was centrifuged at 2500× *g* for 10 min and then the supernatant was transferred into a 1.5 mL Eppendorf tube as sample extract.

2.2.2. Gluten Quantification

For sandwich ELISA, the sample extract was diluted with 1× dilution buffer at a ratio of 1:12.5. Standard and diluted sample extract were added in duplicate into pre-defined ELISA wells and incubated for 30 min at room temperature, then the ELISA plates were washed with washing buffer. Enzyme conjugate was added into each well, incubated for 30 min at room temperature, and washed the ELISA plate with washing buffer. Added substrate and chromogen, incubated for 30 min at room temperature in the dark.

For competitive ELISA, the sample extract was diluted with 1× dilution buffer at a ratio of 1:50. Standard and diluted sample extract were added in duplicate into pre-defined ELISA wells, enzyme conjugate was added into each well, incubated for 30 min at room temperature, and washed the ELISA plate with washing buffer. Added substrate and chromogen, incubated for 10 min at room temperature in the dark.

All samples were stopped the reaction with stop solution, and the absorbance was read on an automated microplate reader RIDA®ABSORBANCE 96 (ZRA96FF, R-Biopharm). The data were generated using the RIDASOFT® Win.NET (Z9996FF, R-Biopharm) software programme, which created a calibration curve based on the standards; the samples were analyzed according to this standard curve to determine the gluten content.

As two domestically made products (one rice flour and one corn flour) had strong water absorption and poor solubility, to guarantee gluten extraction efficiency, the dilution factor was doubled, accordingly the limit of quantification (LOQ) for sandwich ELISA was adjusted to 10 mg/kg of gluten, and the gluten level of these two products was assumed to be 5 mg/kg, half of the LOQ.

2.3. Statistical Analysis

The results are expressed as proportions, medians and range, as appropriate. The chi-square test was used to compare the proportion of contaminated (>20 mg/kg) and uncontaminated (≤20 mg/kg) products in each group. The level of significance was $p < 0.05$. Statistical analyses were performed using SPSS for Windows Release 16.0 programme (SPSS Inc., Chicago, IL, USA).

3. Results

A total of 119 food products were collected, all of which were investigated for gluten contamination using sandwich ELISA. Based on the mean gluten level of two extractions, 86 (72.3%) out of the 119 products contained gluten less than 5 mg/kg, 12 (10.1%) between 5 and 10 mg/kg, 5 (4.2%) between 10 and 20 mg/kg and 16 (13.4%) above 20 mg/kg (Table 1). Six out of 16 gluten-contaminated products (37.5%) had levels above 100 mg/kg.

Table 1. Level of gluten contamination in the 119 analysed products labelled as gluten-free.

Gluten content (mg/kg)	Number of products	Median (Range) (mg/kg)
5–10	12	6.1 (5.0–9.8)
10–20	5	12.1 (10.3–17.3)
>20	16	75.2 (28.4–2737.4)

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Thirty-three (27.7%) out of the 119 products were produced outside China, especially in Thailand (11), the United States (5), Germany, Australia (4 each), the United Kingdom (3), Spain (2), as well as Philippines, Sri Lanka, New Zealand and Italy (1 each). Among the 33 imported products, 28 (84.8%) contained gluten less than 5 mg/kg, 4 (12.1%) between 5 and 10 mg/kg, 1 (3.0%) between 10 and 20 mg/kg and none above 20 mg/kg. Among the 86 domestically made products, 58 (67.4%) contained gluten less than 5 mg/kg, 8 (9.3%) between 5 and 10 mg/kg, 4 (4.7%) between 10 and 20 mg/kg and 16 (18.6%) above 20 mg/kg. There was a significant difference in the prevalence of gluten contamination between imported and domestically made gluten-free products ($p < 0.01$).

The gluten contamination in labelled gluten-free products according to the basic ingredient and to the food category was showed in Table 2 and Table 3, respectively. Significant differences ($p < 0.05$) were found in the proportion of gluten contamination in food products with different basic ingredients, with significantly higher proportions of contamination in buckwheat (50.0%), quinoa (50.0%), millet (33.3%), mixed grain (25.0%) and corn (20%) products, whereas gluten was not detected in oats and mixed foods (Table 2). By food category, flour (23.1%), biscuits and bread (18.8%) had a higher proportion of contamination than seasonings (4.5%), but the difference was not statistically significant ($p > 0.05$) (Table 3).

Table 2. Incidence and range of gluten contamination in products labelled as gluten-free, by basic ingredient [1].

Basic ingredient	No. of products	Incidence (%) of <5 mg/kg gluten	5–10 mg/kg		10–20 mg/kg		>20 mg/kg	
			Incidence (%)	Range (mg/kg)	Incidence (%)	Range (mg/kg)	Incidence (%)	Range (mg/kg)
Rice	36	26 (72.2)	5 (13.9)	5.0–8.0	3 (8.3)	10.3–17.3	2 (5.6)	35.9–390.1
Mixed grains	20	14 (70.0)	1 (5.0)	9.8	– [2]	–	5 (25.0)	45.5–2737.4
Legumes and potatoes	17	14 (82.4)	2 (11.8)	7.1–7.7	–	–	1 (5.9)	47.8
Mixed food	10	7 (70.0)	3 (30.0)	5.0–6.6	–	–	–	–
Oats	7	7 (100.0)		–	–	–	–	–
Millet	6	4 (66.7)		–	–	–	2 (33.3)	75.2–1381.3
Corn	5	3 (60.0)	1 (20.0)	5.0	–	–	1 (20.0)	28.4
Buckwheat	4	1 (25.0)		–	1 (25.0)	11.5	2 (50.0)	331.1–335.3
Quinoa	2	1 (50.0)		–	–	–	1 (50.0)	64.9
Others	12	9 (75.0)		–	1 (8.3)	12.1	2 (16.7)	56.7–75.2
Total	119	86 (72.3)	12 (10.1)	5.0–9.8	5 (4.2)	10.3–17.3	16 (13.4)	35.9–2737.4

[1] The incidence is the number of products containing the specified concentration of gluten. [2] None of the products contained the specified concentration of gluten.

Table 3. Incidence and range of gluten contamination in products labelled as gluten-free, by food category [1].

Food category	No. of products	Incidence (%) of <5 mg/kg gluten	5–10 mg/kg		10–20 mg/kg		>20 mg/kg	
			Incidence (%)	Range (mg/kg)	Incidence (%)	Range (mg/kg)	Incidence (%)	Range (mg/kg)
Flour	26	15 (57.7)	5 (19.2)	5.0–9.8	– [2]	–	6 (23.1)	56.7–1381.3
Noodles	27	21 (77.8)	2 (7.4)	6.3–7.1	1 (3.7)	11.5	3 (11.1)	45.5–2737.4
Seasoning	22	20 (90.9)			1 (4.5)	12.1	1 (4.5)	75.2
Biscuit and bread	16	10 (62.5)	2 (12.5)	5.9–6.6	2 (12.5)	10.3–17.3	2 (12.5)	28.4–35.9
Snacks	16	9 (56.3)	3 (18.8)	5.0–8.0	1 (6.3)	12.8	3 (18.8)	61.4–76.2
Breakfast porridge	12	11 (91.7)		–	–	–	1 (8.3)	47.8
Total	119	86 (72.3)	12 (10.1)	5.0–9.8	5 (4.2)	10.3–17.3	16 (13.4)	35.9–2737.4

[1] The incidence is the number of products containing the specified concentration of gluten. [2] None of the products contained the specified concentration of gluten.

A total of 22 seasoning products were tested: 19 liquids and 3 solids. All liquid products contained gluten less than 5 mg/kg. Among 3 solid seasoning products, 1 (33.3%) contained gluten less than 5 mg/kg, 1 (33.3%) between 10 and 20 mg/kg and 1 (33.3%) above 20 mg/kg.

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Eighteen products are known to have undergone a hydrolysis treatment, including 17 liquid seasoning products and one bread product, all of which contained gluten below the LOQ (5 mg/kg) as determined by sandwich ELISA. These products were retested using competitive ELISA, and the gluten content of all products was below the LOQ of the method (10 mg/kg), which means that after confirmation, all product results are still negative.

4. Discussion

In this study, we utilized the RIDASCREEN® Gliadin sandwich R5 ELISA, which detects intact gliadins and related prolamins from rye and barley, high-molecular-weight glutenin subunits from wheat, high-molecular-weight secalins from rye, and low-molecular-weight glutenin subunits from wheat. However, this method does not detect D-hordeins from barley [19]. It has been endorsed as a Codex Alimentarius Type I method for the analysis of gluten [20] and has been adopted by AOAC INTERNATIONAL as Final Action Official Method℠ 2012.01 with an "in foods" claim [21]. Most of the recent studies on gluten contamination have been conducted using the same R5 ELISA, which helps to compare findings obtained from different studies [22].

To our knowledge, this is the first report on gluten contamination in foods labelled as gluten-free in China. Our findings indicate gluten contamination in gluten-free products sold through Chinese internet suppliers is common, as reflected by both the proportion (13.4%) and the gluten level (37.5% of the contaminated products had a gluten level above 100 mg/kg) of the contaminated food products.

The findings of the present study are consistent with the global trends when compared to contamination studies of labelled gluten-free foods conducted in other countries [17,22]. In a meta-analysis that included 40 articles, the results showed that in the labelled gluten-free foods analysed, the prevalence of gluten contamination was estimated at 9.5% (95% CI 4.8%, 15.7%) [22]. Gluten levels above 20 mg/kg were detected in 2.2% (2/98) of the products labelled as gluten-free in Italy [23]. In a study conducted in Canada, gluten levels above 20 mg/kg were determined in 7 (9.1%) out of the 77 cereal foods labelled as gluten-free [24]. In a study conducted in southern India, 5 (9.8%) out of 51 grain products labelled as gluten-free showed gluten contamination above 20 mg/kg although the levels fell within low gluten range (32.5±5.8) [25]. Gluten contamination was found in 11.5% labelled gluten-free foods on the Turkish market [26]. In the United States, 16 (20.5%) out of the 78 products labelled as gluten-free foods were found to contain ≥ 20 mg/kg of gluten, with levels ranging from 20.3 to 60.3 mg/kg [27]. According to Valdés et al., 1071 out of 3088 (34.7%) gluten-free foods in Europe had gluten contamination above 20 mg/kg [28].

It is worth noting that none of the products imported contained gluten above 20 mg/kg, while 16 out of 86 (18.6%) Chinese-made products did. The current situation suggests that there is less attention to attaining a safe level of gluten in products meant to be destined for patients with CD and labelled as gluten-free when produced domestically. This represents a significant risk to the food safety of patients with CD, as unintentional gluten exposure can have serious health consequences.

Consistent to previous studies, we found a higher risk of gluten contamination in buckwheat (2/4) and quinoa (1/2) products labelled as gluten-free on the Chinese market [23,27,29]. However, unlike studies conducted in other countries, we did not detect gluten contamination in oat products [22]. Previous research has shown that cross-contamination is particularly prevalent in oats that are not specifically produced and labelled as gluten-free. This difference may be explained that the oats tested in this study were all marked or identified as gluten-free and therefore must have followed stricter controls to prevent the introduction of foreign gluten-containing grains. Several studies have shown that patients with CD can safely consume moderate amounts of oats that are not contaminated with gluten [30,31]. However, commercial oat supplies are frequently contaminated with wheat. For instance, a study in Canada found that 88% of 133 oat products contained more than 20 mg/kg of gluten [32]. Cross-contamination of naturally gluten-free foods can occur at various points in the food chain, including at planting, harvesting, and/or processing. If naturally gluten-free grains are rotated with wheat, barley, rye or oats, mixing of grains in the field can occur [17]. Additionally, gluten-

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containing seeds can persist in the soil, leading to the unintentional collection of gluten-containing grains during harvest. Further contamination may occur when storage facilities and transport systems are shared. Moreover, food manufacturers often use the same equipment and facilities for producing both gluten-free and gluten-containing products, further increasing the risk of cross-contamination.

The proportion of contaminated flour-based products in this study exceeded 20%. One of the specimens was rye flour with a gluten contamination concentration of 56.7 mg/kg. The product claims to be gluten-free and has pasted a report on its website stating that no gluten was detected and not indicating whether gluten was removed during the product processing. Rye itself contains gluten, and retailers only judge products as gluten-free based on test results, indicating an urgent need for standardization of gluten testing methods by third-party testing companies.

Currently, there is a lack of education about gluten-free foods throughout the Chinese society, and the concept of gluten is extremely vague to consumers [33]. A meta-analysis revealed that the prevalence of gluten contamination in labelled products offered by food services was 41.5% (95% CI 16.6%, 66.4%), and the probability of getting gluten-contaminated gluten-free food in food services is higher than home [34]. Due to the lack of a national standard for gluten-free foods, Chinese restaurant workers receive insufficient systematic training, and training and education policies regarding gluten-free dietary requirements should be actively pursued for food service employees. Patients with CD or other GRDs must be vigilant when reading labels and asking questions about food preparation when eating out. Such measures will no doubt contribute to protecting and improving the health of patients with CD and other GRDs.

The results highlight the complexity of maintaining a GFD. However, due to issues related to labelling, cross-contamination, and trace amounts of gluten, patients with CD face unique challenges. Strict adherence to a GFD is crucial for these individuals, but the aforementioned issues can impede proper compliance. Inaccurate labelling or inadequate standards may result in unintentional gluten exposure, while cross-contamination and trace amounts of gluten present ongoing risks. Therefore, it is essential to explore additional measures needed to ensure food safety for this group, including stricter regulations and clearer labelling practices to minimize contamination risks and ensure that gluten-free products meet the required standards.

To ensure the long-term health and food safety of patients with CD and other GRDs, it is essential for Chinese food regulatory agencies to establish comprehensive national standards for gluten-free foods. A certification foundation could be established for companies, similar to organizations in other countries, through laboratories accredited by recognized bodies and authorized to detect and quantify gluten. Certification bodies accredited under relevant standards for the agro-food industry would also be essential to ensure food safety. Additionally, an annual review of Hazard Analysis and Critical Control Points (HACCP) systems in the food industry should be conducted to ensure ongoing compliance and further minimize the risk of gluten contamination.

5. Conclusions

This study provides important insights into the status of gluten contamination in food products labelled as gluten-free on the Chinese market. The results suggest that gluten contamination in domestically made products is common, with some products containing relatively higher levels of gluten. These findings highlight the need for Chinese food regulatory agencies to impose requirements of production that lead to prevent gluten contamination, confirmed by possible monitoring of such compliance through routine sampling and testing. Manufacturers of gluten-free foods need to ensure that ingredients are gluten-free and eliminate cross-contamination at the production stage. This can be remedied by establishing standards and stricter controls on future labelling of gluten-free foods in China to ensure that the risk of gluten contamination is reduced for patients with CD and other GRDs. Our recommendations for improving gluten-free food regulation in China can also provide references for countries lacking regulatory measures for gluten-free foods.

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Abbreviations

The following abbreviations are used in this manuscript:

CD	Coeliac disease
GFD	Gluten-free diet
GRDs	Gluten-related disorders
LOQ	Limit of quantification

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