Undeclared allergens in imported packaged food for retail in Australia

Michael John Sheridan[a], Martina Koeberl[b], Claire Elizabeth Hedges[b], Erik Biros[c], Thimo Ruethers[a], Dean Clarke[b], Saman Buddhadasa[b], Sandip Kamath[a,d] & Andreas Ludwig Lopata[a,d] *.

[a] *Molecular Allergy Research Laboratory, College of Public Health, Medical and Veterinary Sciences, James Cook University, 1 James Cook Drive, QLD 4811b*

[b] *Food Allergen Laboratory, Analytical Services Branch, Department of Industry, Innovation and Science, National Measurement Institute, Port Melbourne, VIC 3207*

[c] *College of Medicine and Dentistry, James Cook University, Townsville, Australia*

[d] *Australian Institute for Tropical Health and Medicine, James Cook University, 1 James Cook Drive, QLD 4811*

*Corresponding author. Email: andreas.lopata@jcu.edu.au

Abstract

The *Australia New Zealand Food Standards Code* (the Code) requires a declaration of the presence of 11 different allergens made through the label on a food product. Most food recalls in Australia are now due to undeclared allergens . This survey determined the extent of undeclared allergens in imported food products on the Asian retail market in Australia. A total of 50 imported packaged foods were selectively purchased from local Asian grocery retail stores in Melbourne and the presence of undeclared gluten, milk, peanut and egg determined. Analysis was performed using commercial enzyme-linked immunosorbent assay (ELISA) (R-Biopharm). Thirtyseven undeclared allergens (gluten n = 12, milk n = 12, peanut n = 6, and egg n = 7) were detected in 23 of the 50 products analysed (46%), with 18% containing multiple undeclared allergens. The high number of undeclared allergens is alarming and in line with the increasing number of food recalls and anaphylaxis recorded in Australia.

Keywords

Food labelling; undeclared allergen; food allergy; food recalls.

Introduction

The prevalence of food allergy is increasing globally with Australia having one of the highest incidences of confirmed food allergy among children (Osborne et al. 2011). Results conducted by the HealthNuts study (Osborne et al. 2011) confirm challenge-proven IgE-mediated food allergy reaction to egg, peanut, sesame, shellfish, and cow's milk in 10% of children and constitute the majority of undeclared food allergens in processed food products (Osborne et al. 2011; Prescott et al. 2011).

Food-induced anaphylaxis hospital admissions rose in Australia by approximately 350% between 1997 and 2005 (Liew et al. 2009). Mullins et al found hospital admission food anaphylaxis rates increasing 1.5-fold over 7 years (2005/6 to 2011/12) (Mullins et al. 2015). In addition, Mullins et al revealed a 10% per year increase in food anaphylaxis admissions in Australia from 1997-2013 (Mullins et al. 2016). Also, hospital fatal food anaphylaxis rates increased by 9.7% per year over the same period (Mullins et al. 2016).

There is no cure for food allergy, so management relies on strict food avoidance. Undeclared allergens in packaged food present a serious health risk to allergic consumers. Despite mandatory food-labelling laws, accidental ingestion of undeclared allergens in food products is common, causing frequent life-threatening and sometimes fatal reactions globally (Burks et al. 2012).

All food products sold in Australia must comply with the *Australia New Zealand Food Standards Code*, set by Food Standards Australia and New Zealand (FSANZ). According to *the Code* all mandatory allergens must be labelled on food products. Accurate and complete food label information is a primary risk management control to assist allergic consumers in avoiding potentially contaminated foods (Gendel 2013). Consumer interpretation of label information has been associated with perceived level of risk and consumer behaviour (Hefle et al. 2007; Zurzolo et al. 2012). A study from Canada on 1,454 peanut allergic respondents demonstrated that 47% attributed accidental exposure to inappropriate labelling (Sheth et al. 2010). Similarly, a survey of food allergic consumers performed by the German Allergy and Asthma Association found more than 40% of reactive respondents reported allergen presence which was not declared on the label of food products (Schnadt & Pfaff 2016). A European Union

prospective cohort study reported that 37% of patients attributing accidental allergic reactions to mandatory allergens not declared on the product label, including peanut, milk and sesame (Blom et al. 2018). In line with these findings, a recent Australian survey of allergy clinicians over a three-month period reported 14 incidents of anaphylaxis due to suspected consumption of packaged food containing undeclared allergens (Zurzolo et al. 2018).

In Australia, FSANZ also coordinates and monitors food recalls due to contamination (FSANZ 2017). Indications from recent Australian food recalls, often associated with high-risk food categories, continues to show that now 46% of food recalls are due to undeclared allergens and are the most frequent cause for recalls (FSANZ 2017). Categorisation of food groups enables regulatory bodies, including FSANZ, to partition food recalls for better monitoring and reporting (Bucchini et al. 2016).

Koeberl et al points out that Australian regulatory agencies take a 'lightly regulated rather than strictly regulated approach', as a balance between the costs of regulatory burden and system efficiency (Koeberl et al. 2018). While food labelling appears well regulated in Australia and largely adopted by industry, this is less common in some Asian countries. Australian food imports continually increase, with the total share from the Association of Southeast Asian Nations (ASEAN) increasing from 18% to 23% from 2002 to 2012 (DAWR 2014). The aim of the current study was to determine the extent of compliant food products sold in Australia according to the *Australia New Zealand Food Standards Code*. This pilot study selectively purchased imported packaged food products, from a number of Asian countries, for sale in Asian retail grocery stores in Melbourne, Australia.

Materials and methods

Food selection

Fifty packaged food samples were purchased from six Asian retail grocery stores across Melbourne, Australia. Food products were selected according to the following criteria: (1) Products lacking evidence of labelling for the four allergens to be analysed and (2) packaged foods were selected based on the publicly available FSANZ guidance list of food recall categories: 'Mixed and/or Processed Foods' (n=17), 'Bread and Bakery' (n=14), 'Confectionery' (n=13) and 'Non-Alcoholic Beverages' (n=6). A detailed description of the selected food types per category is listed in Table 1.

Food samples that could be identified by name on the label were designated into one of these four categories. Food samples lacking label identification were given generic names based upon visual interpretation, if not evident from product label and/or contents. Grocery stores and food products (brands and identifying product names) have been de-identified for this study. All packaged food products were dry and shelf stable and transported and stored at ambient temperature in original packaging.

Sample analysis

Sample preparation and analysis was performed at the Food Allergens Laboratory of the National Measurement Institute (NMI), Analytical Services Branch, Port Melbourne, Australia. The ELISA test kits from R-Biopharm, utilised in this study, are validated and certified in many studies and the test for gliadin is a Codex Alimantarius Type I method, approved by the AACC and the AOAC. The aim of this study is not to compare the actual values of these allergens, but the simple detection of allergen in each of the analysed extracts (R-Biopharm AG, Darmstadt, Germany; RIDASCREEN® FAST Peanut R6202, RIDASCREEN® FAST Ei/Egg 6402, RIDASCREEN® FAST Milk R4652, RIDASCREEN® Gliadin R7001, Immer et al. 2004, Weiss et al. 2014, Weiss et al. 2016).

Refer to Table 2. For R-Biopharm RIDASCREEN® LOD and LOQ.

Sample preparation and sample analysis was conducted according to the manufacturer's protocols. Each sample was analysed once, using duplicate wells for standards and samples. Tested samples with detected allergen were retested. Samples that resulted in a concentration higher that the standard curve were retested with dilutions to fall within the standard range of the respective ELISA kit. The result was multiplied by the dilution factor for final concentration of the sample. For conversion

of whole peanut and egg results to equivalent protein (multiplication by 0.22 and 0.49, respectively) in accordance with manufacturer instructions. ELISA systems are the most utilized technique for the detection of food allergens in various food matrices (Koeberl M et al. 2018). However, ELISA kits have some disadvantages, as analytical tool because values calculated by one ELISA kit cannot be considered as absolute values. Nevertheless, one can still compare if a food sample is regarded positive by different ELISA kits (Senyuva et al. 2019).

Label verification

The information provided on the food packaging label in the English language, including ingredient list, allergen warnings, manufacture and distributor information was recorded. Here, we define 'country of origin' as country of export, and assume significant ingredients originated and/or substantial manufacturing occurred in that country. Native speaking staff of the NMI translated label declarations and/or ingredient lists (in a language other than English) into English. Information provided in English and other languages were compared. This was performed to determine if the declaration was made in the original language and if any variation exists between labels. Detected analytical results for each product sample were compared against each product food label for assessment of compliance with *the Code,* Standard 1.2.1-8(1)(d) for information required on a food label, including Standard 1.2.3-4 Mandatory Declaration Statements. In addition, assessment of English legibility requirements, Standard 1.2.1-24 (Australia New Zealand Food Standards Code 2017; Australia New Zealand Food Standards Code 2018) and for 'hidden allergens', *the Code*, Standard 1.2.4-4 (Australia New Zealand Food Standards Code 1.2.4 2015) were conducted.

Statistical analysis

The risk of detecting undeclared allergens in food products was determined using the generalized linear models (GLM) for binomial family. A country of origin was also included in models as a covariate. The results are presented as risk ratio (RR) with 95% confidence interval. Statistical significance was defined at the conventional 5% level. All computations were performed using the Stata/MP 13.1 statistical package (StataCorp LP, USA).

Results and Discussion

The present study reveals a high percentage of imported packaged foods with undeclared allergen (46% for sale in Asian stores in Melbourne, Australia). The analytical detected allergens and their distribution amongst the four food product categories is shown in Figure 1. The highest number of allergens was detected in the 'Bread and Bakery' category with 26 allergens in 14 products. This was followed by 'Confectionery' (8 in 13) and 'Mixed and/or Processed Foods' (3 in 17). No undeclared allergen was detected in 6 coconut drinks ('Non-alcoholic Beverages') analysed, which may reflect increased regulatory scrutiny due to a large number of recent food recalls from this category (FSANZ 2015). A total of 37 allergens detected in all, with 18 percent of all products contained multiple undeclared allergens.

The Code 1.2.3-4 does not allow for the presence of any foods or substances included in the mandatory declaration requirements, excluding exemptions (Australia New Zealand Food Standards Code 1.2.3 2017). In Australia, Voluntary Incidental Trace Allergen Labelling (VITAL), an industry initiative to formalise Precautionary Allergen Labelling (PAL), performed dose-distribution modelling for PAL recommendations and proposed threshold reactions in 1% of the representative population (ED_{01}) (Allergen Bureau 2011). These recommendations include 0.2 mg for peanut protein, 0.03 mg for egg protein and 0.1 mg cow's milk protein (Allen et al. 2014). The "Summary of the VITAL Scientific Expert Panel Recommendations" includes a wheat protein threshold of 1.0 mg (Allergen Bureau 2011). It was noted that for wheat-allergic consumers, foods containing <20 mg/kg, would be largely protective (Allergen Bureau 2011). In this current study, none of the samples with detectable peanut, egg or milk, was below the VITAL recommended threshold values. For this comparison, the results for whole peanut and whole egg were converted to equivalent protein. The concentration of some allergens, in particular milk, peanut and gluten was over 8,000 mg/kg. Figure 2 reveals some of the allergens were present in very high concentrations, with 75% of gluten containing products above 8,000 mg/kg and also 33.33% of milk containing products. The low levels of detected allergens can occur due to cross-contamination or sharing same processing equipment. The high values detected represent percentage of the food product analysed, which is more likely to be intentionally added to the food product.

The highest number of undeclared allergens was in the category 'Bread and Bakery' products for gluten and milk (Figure 2), followed by egg and peanut. The overall risk of detecting undeclared allergens is shown in Table 3, with the highest risk for gluten with 2.19, followed by milk (1.95), peanut (1.35) and egg (1.22). However, the risk was the highest for undeclared gluten in this category with 4.3, followed by milk (3.44) and interestingly the lowest risk was for peanut (0.7) (Table 4).

These findings appear to somewhat contrast FSANZ food recall statistics (1 January 2007 and 31 December 2016) showing 'Mixed and/or Processed Foods' category with the highest number of recalls, more than double than in the category 'Bread and Bakery' (FSANZ 2017). Nevertheless, FSANZ statistics include all food recalls for the period, not only undeclared allergen recalls, thus not corresponding to our methodology and findings.

Studies of undeclared food allergens in Europe and the USA are numerous in contrast to Australian studies, yet each study differs in food category, labelling, allergen selection and methodology. In 2015 authorities in Denmark, Norway, Sweden and Finland performed a survey of undeclared milk, egg, peanut, hazelnut and gluten allergens. This extensive study on 351 imported packaged foods determined that 10% of products where not correctly labelled with the detected allergen (Bolin & Lindenberg 2016). A study by Pele et al of 569 cookies and chocolates, for undeclared peanut and hazelnut, found that chocolates where more likely to contain undeclared allergens than cookies (Pele et al. 2007).

A USA study of dark chocolate bars detected peanut at concentrations of 9 to 170 mg/kg^{-1}. 17% of these chocolates did not bear a label statement for peanut, while 33% contained milk at between 60 to 3,400 mg/kg^{-1} (Bedford et al. 2017) Similarly, Ford et al found peanut more likely in products bearing a PAL statement (Ford et al. 2010). In addition, this study found egg, analysing 401 food products, in 1.8% of products with egg PAL statement and 2.6% without PAL. Furthermore, milk in 10.2% of products

with milk PAL statement and 3% without, and peanut in 4.5% with PAL and nil without (Ford et al. 2010). A different study by Crotty and Taylor detected milk in 14 of 18 dark chocolate candy products bearing PAL statements, ranging in allergen levels from 3.7 to 15,000 mg/kg^{-1} (Crotty & Taylor 2010). It is noteworthy that method comparison studies can yield different results and this disparity must be considered by regulatory agencies if placing allergen thresholds on packaged foods or where quantification is cited (Senyuva et al 2019).

In Australia there are very limited studies investigating high-risk food categories for mandatory undeclared allergens. In 2004-5 the Western Australia (W.A.) Department of Health, Food Monitoring Program, surveyed tree nuts in 76 packaged foods for retail sale including biscuits, cakes, chocolates, convenience meals and ice cream, and found 55% (n=76) of products with detectable allergens and 50% of these lacked label declarations (WAFMP 2006). In contrast a study by the Department of Primary Industries (DPI) Food Authority, New South Wales (N.S.W.) analysed various food categories for dairy, egg, gluten, peanuts, sesame, soy and tree nuts, and found only approximately 15% of products (n=448) with detectable undeclared allergen not identified in the ingredient list (DPI 2018). Nevertheless, these studies differ considerably in the type of allergens and food categories analysed. This is expected because there is no single global list of mandated substances that must be declared on packaged food products. The World Health Organisation Codex Standard (STAN 1-1985) for food labelling prescribes nine foods and ingredients that are to be declared (WHO 2007). Australia's mandatory declared substances are inclusive of all nine including gluten, peanut, egg, and milk analysed in this study and in addition incorporate sesame and lupin (FSANZ 2018; Australia New Zealand Food Standards Code 1.2.3 2017).

Mandatory declarations

In Australia, food for sale is required to adhere to labelling provisions for substances that must be declared in accordance with *the Code* (Australia New Zealand Food Standards Code 1.2.3 2017). In this study all samples were purchased selectively as

described in the material and method section. Hence, all 23 products with detectable allergens did not display mandatory declaration(s) on the package labelling, non-compliant with *the Code*. *The Code* does not specify the format for displaying mandatory allergens on the product label, other than legibility requirements (Australia New Zealand Food Standards Code 1.2.1 2018; AFGC 2007). Therefore, mandatory substance(s) listed in the ingredient list fulfil *the Code* requirement regarding mandatory substance declarations.

This present study examined package labelling to determine whether products found to contain detectable allergen(s), declared these allergen(s) on the package label, in either English or in a language other than English. The language labelling for all products is summarised in Figure 3A, while labelling for products found to contain detectable allergens are summarized in Figure 3B. It is notable that a comparison between total products analysed and those found to contain detectable allergen showed the majority of products that did not possess a label in English were also found to contain detectable undeclared allergen. 35% of products did not possess a label in English and are thereby non-compliant with *the Code* mandate for a package label to be in English. Of the 8 products with no English label, only one product failed to declare detectable peanut, yet declared detected milk, egg and gluten in the original language. This outcome may suggest that the manufacturers of these products may have attempted to comply with legislation requirements. However, the importer, wholesaler or supplier may have failed to ensure entire label translation to English was applied to the package. Nevertheless, this product is still not compliant with *the Code*.

The Code also requires a food label statement of ingredients to identify each ingredient in accordance with Standard 1.2.4-4, which includes: “a name by which the ingredient is commonly known; or a name that describes the true nature of the ingredient; or a generic name for the ingredient that is specified…” (Australia New Zealand Food Standards Code 1.2.4 2015). Three products used subjective terminology. One contained detectable milk and declared “butter” in both languages and one product contained detectable gluten, declared as “flour” in both languages. In addition, one product contained detectable milk declared as “sodium caseinate” in both languages. Consumers may be unaware that this scientific term refers to a dairy derivative.

Terminology used to describe mandatory allergen can be ambiguous leading to consumer confusion. In an attempt to mitigate this, the Australian food industry has produced guidance documents such as *The Food Industry Guide to Allergen Management and Labelling* to assist manufacturers in providing food labelling clarity (AFGC 2007) and *Unexpected Allergens in Food* to assist with identifying 'hidden allergens' (Allergen Bureau UAIF 2011; Baker et al. 2018; Zurzolo et al. 2012; Steinman 1996). Use of subjective terminology is regulated in Australia to prevent 'hidden allergens'. Packaged food containing allergenic substances that are not declared on the label, or are not legible, or provided in ambiguous or subjective terms, or in a language other than English, pose a significant health risk to allergic consumers. In this study subjective terminology to describe a mandatory substance was discovered on both English labels and the corresponding translated labels, as well as with products that displayed a label in the original language only. This study shows that Asian packaged foods sold in Asian grocery stores in Australia possess often non-uniform presentation of labelling, resulting in products containing undeclared food allergens.

Precautionary Allergen Labelling (PAL)

Mandatory allergen labelling has improved the safety of food for allergic consumers. However, an additional form of voluntary labelling (termed Precautionary Allergen Labelling; PAL) has evolved to minimise the risk to consumers. The majority of studies in the literature focus on analysis of priority allergens in PAL packaged foods from high-risk categories. Surveys of non-specialty supermarket packaged foods indicate that PAL statements are frequently encountered. In Australia several studies have examined PAL products for sale, with one survey identifying that over 70% possessed PAL statements (Koplin et al. 2010). Another survey of 1,355 food products identified that 65% had a PAL advisory statement (Zurzolo et al. 2013). In total 128 PAL food samples from high-risk food categories, including muesli bars, sweet biscuits (cookies), savoury biscuits, chocolates and breakfast cereals were analysed for six allergens including peanut, hazelnut, milk, egg, soy and lupin. The authors found that only 7% contained detectable peanut. Since no other allergens were detected in PAL foods tested, the authors suggested that PAL packaged foods for retail sale in Australia pose a low risk to allergic consumers (Zurzolo et al. 2013). Their findings were determined from packaged foods sampled at major supermarkets only (Woolworths, Coles, Aldi),

therefore predominantly reflecting Australian products with a higher likelihood of scrutiny by the supermarket chains.

In contrast, our current study focused on imported foods from Asian countries for sale in Asian grocery stores in Melbourne, Australia. A very high proportion (46%) of analysed packaged foods from these stores were found to contain undeclared allergens. This study determined the number of PAL statements on product labels, although, not necessarily related to the allergen of study. PAL in the original language was not displayed on any product label in English and therefore, none of the 50 products sampled possessed a PAL statement in English. However, 22% possessed a PAL statement in a language other than English, indicating a very low level of PAL for packaged Asian food products. In comparison, of the 23 positive products 9 possessed PAL in a language other than English. Given the correlation between samples, found to contain undeclared allergen and those with PAL, this finding may suggest manufacturers suspected cross-contamination. Low level PAL of Asian products suggests that food purchases from these stores pose a higher risk to allergic consumers than packaged foods purchased from major Australian supermarket chains. This is of particular importance as the food trade from Asian into Australia continues to increase by about 2.5% per annum (DAWR 2014).

Country of Origin

The highest representation of food products analysed in this study came from China and Thailand followed by South Korea (Figure 4): 28% China, 26% Thailand, 14% South Korea, 10% India, Taiwan and Sri Lanka 8% respectively, 2% each for Malaysia, Japan and Vietnam. Likewise, products with the highest number of detectable undeclared allergens were imported from China (50%), followed by Thailand (39%) and South Korea (71%). However, there was no statistically significant association between country of origin and number of undeclared allergens in imported products.

Conclusion

In conclusion, this study confirms that undeclared allergens can be frequently detected in imported packaged foods from Asia for retail sale in Melbourne, Australia. In addition, these foods often contain multiple undeclared allergens, with gluten the most frequent allergen. Those products containing undeclared allergen failed to provide mandatory allergen declarations on the label in English or in terminology consistent with regulations. Inconsistent and variable label terminology may be due to allowances

in *the Code*. The difference between native language labelling in the 'country of origin' and applied English labelling should be further investigated and may require greater governance.

Packaged food products lacking regulatory labelling compliance can be readily obtained from Asian grocery stores in Melbourne, Australia. Further targeted food category and alternate method studies are necessary to validate these findings, providing important information for regulatory compliance agencies to protect allergic consumers.

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Disclosure Statement

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Food Categories	Examples of food types
Mixed And/Or Processed Foods	Custard mix, custard powder and blanc mange powder, jelly, dairy and fat based desserts, dips and snacks, sauces and toppings (including mayonnaises and salad dressings), soup bases, snack food including chips and crackers, frozen meals, canned products including spaghetti and baked beans.
Bread and Bakery	Breads and related products, including fancy breads, biscuits, cakes and pastries.
Confectionery	Lollies, jubes, gelatin based candies.
Non-Alcoholic Beverages	Water including carbonated, mineralised and soda waters, water based flavoured drinks including fruit drink and soft drink, fruit and vegetable juices, coffee, coffee substitutes, tea, herbal infusions and similar products.

Table 1. Food product categories.[a]

[a] FSANZ Guidance List - These definitions were obtained from FSANZ and are referred to on the Food Recall Statistics web page under the heading 'food categories associated with food recalls' (FSANZ 2017).

Table 2. Undeclared Allergen risk profile.

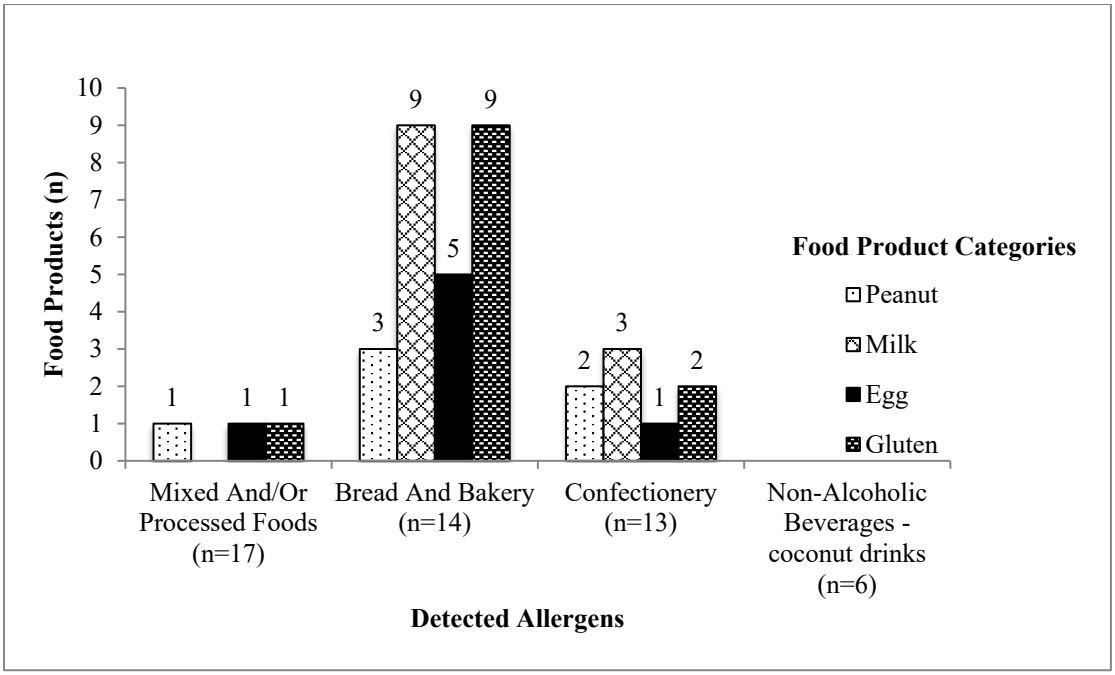
Allergen	Risk Ratio	P-value	95% Confidence Interval	
Peanut	1.35249	0.000	1.352168	1.352817
Gluten	2.19374	0.001	1.400028	3.437428
Milk	1.95228	0.001	1.337709	2.849213
Egg	1.21596	0.000	1.215677	1.216261
Cons	0.28947	0.000	0.187831	0.446135

Note: The highest risk of detecting undeclared allergen is for gluten > milk > peanut > egg, as determined using generalized linear models for binomial family.

Table 3. 'Bread & Bakery' undeclared allergen risk profile.

Allergen	Risk Ratio	P-value	95% Confidence Interval	
Peanut	0.705807	0.000	0.705638	0.705977
Gluten	4.311255	0.000	1.942099	9.570532
Milk	3.443748	0.002	1.568817	7.559455
Egg	1.378119	0.000	1.377788	0.222577
Cons	0.961495	0.000	0.415348	0.222577

Note: The highest risk that the undeclared allergen is present in bakery products is for gluten > milk > egg > peanut, as determined using generalized linear models for binomial family



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615 Figure 1. Distribution of detected allergens in food product categories.

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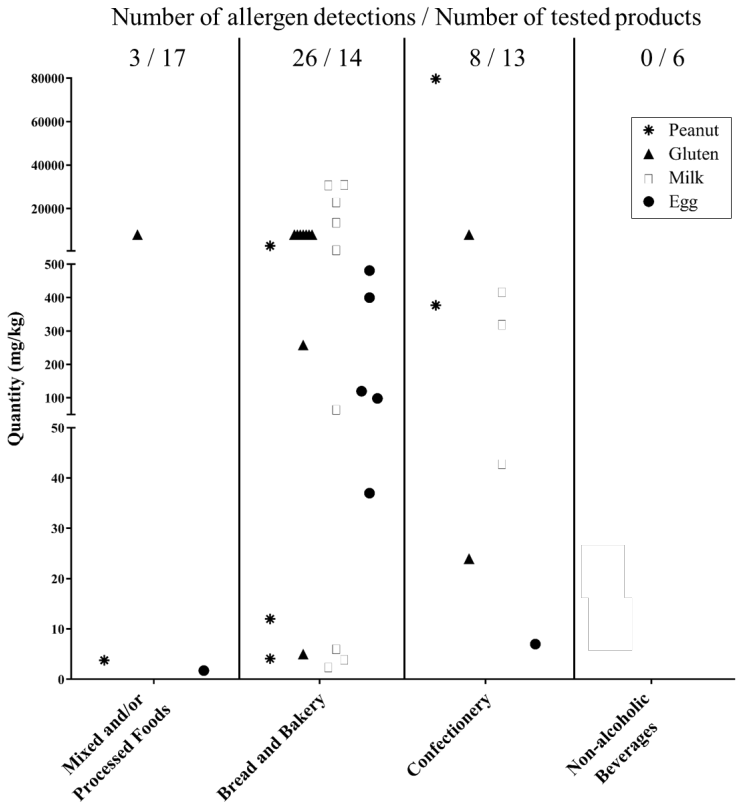

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618 Figure 2. Distribution of detected food allergens within the four food product
619 categories.

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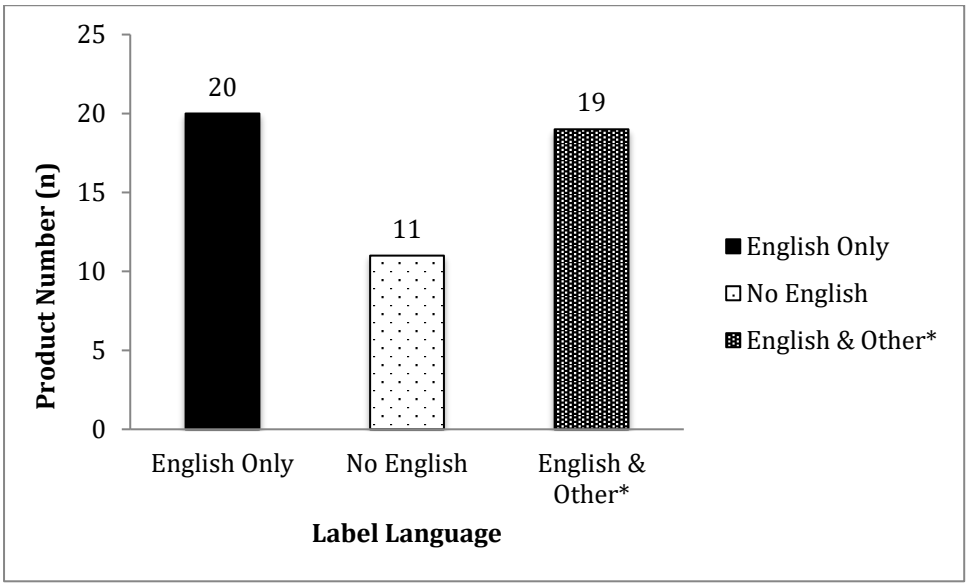

Figure 3A. Label language comparison for all samples (n=50). Note: English & Other refers to a combination of both labelling in English and in a language other than English.

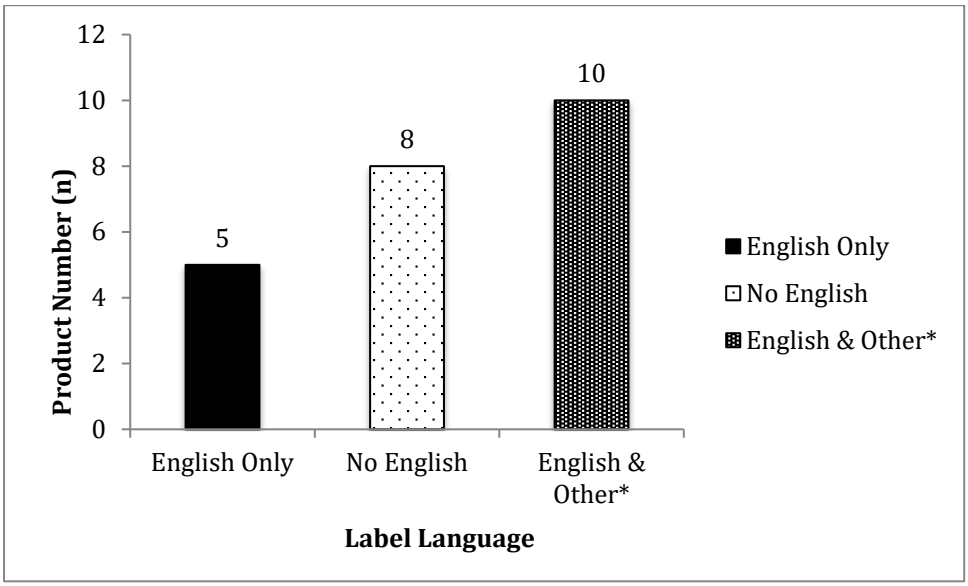

Figure 3B. Label language comparison for positive samples (n=23). Note: English & Other refers to a combination of both labelling in English and in a language other than English.

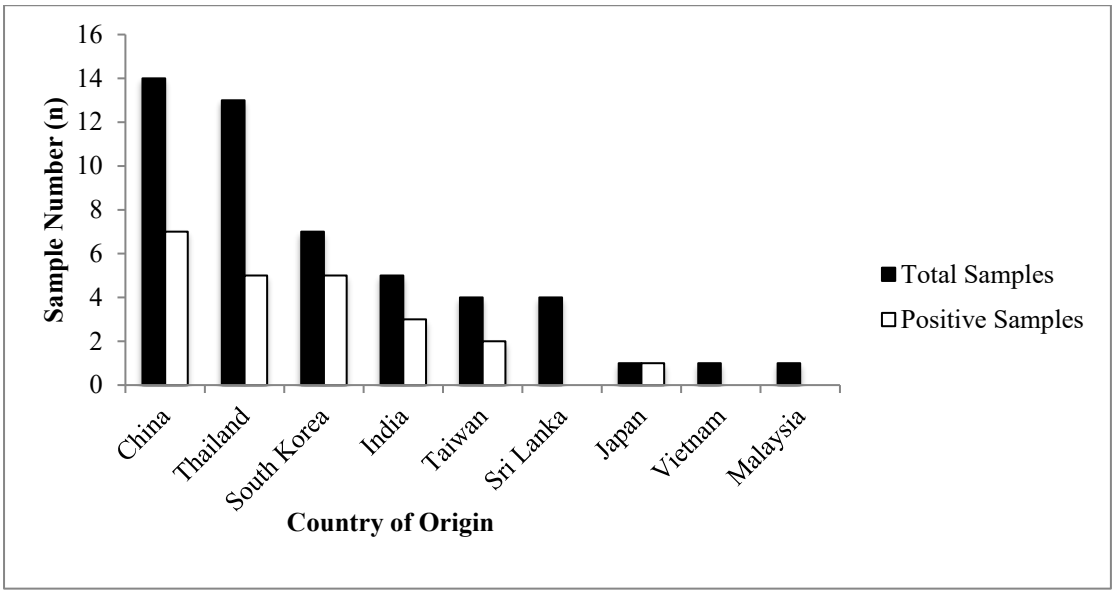

Figure 4. Comparison between total products sampled and products containing detectable allergens by country of origin.