Current approaches in managing food allergy in Australian settings

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Statement of Sources

DECLARATION

I declare that this thesis is my own work and has not been submitted in any form for another degree or diploma at any university or other institution of tertiary education. Information derived from the published or unpublished work of others has been acknowledged in the text and list of references given.

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Declaration of Ethics

DECLARATION

The research presented and reported in this thesis was conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007) – updated 2018 and obtained approval from James Cook University Human Research Ethics Committee (HREC). In addition, Australian Privacy Principles under the *Privacy Act 1988* (*Privacy Act*) were adhered to ensure transparency for consent.

Ethics Approval & Disclosures:

HREC Approval Number #H7062 - Food Recall Innovation Tools

Human research ethics approval was sought for Low to Negligible Risk (LNR), de-identified retrospective data analysis and was granted by the JCU HREC.

Customer privacy protection was made publicly available on the www.FoodRecallAus.com.au website and app. This was necessary due to the nature of the de-identified data obtained and Government regulations mandating disclosure. Links to data storage platforms were embedded on consumer interfaces. The www.FoodRecallAus.com.au website and app 'About Us' page/tab displayed the following disclaimer: *No third party information is collected from users other than what is necessary for the app to function, except for de-identified app statistical user information, which may be used for research and in publications.*

Consumers who downloaded the application to mobile device(s) consented to data storage and usage requirements of the app store (Google Play™ and/or iTunes®). In addition, consumers enable or disable additional permissions once the app was downloaded to the mobile device(s). These consents and permissions are user directed and beyond the control of the investigators of this study.

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Food Recall Innovation Tools

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ABSTRACT

The literature review of **Chapter 1** defined food allergy and its mechanisms and informed on the current understanding of symptoms and diagnosis. Common diagnostics include RAST and Skin-Prick Test. Oral food challenge is considered the gold standard of diagnosis and Double-Blind Placebo-Controlled Food Challenge best practice for studies of food allergic individuals. Importantly, it was noted that avoidance is best practice for food allergic individuals and that there is currently no cure for food allergy. Government agencies have reversed previously held infant feeding guidelines to recommendations that parents not withhold common allergenic foods from infants.

Food allergy prevalence in Australia is examined, including the dramatic increases in morbidity and mortality over recent years, and is evidenced by hospitalisation and clinical presentation trends. A variety of theories have been proposed as to why food allergy is increasing, particularly in developed countries, prominent amongst these is the hygiene hypothesis.

Food Intolerance, Wheat Allergy, Gluten Intolerance & Coeliac Disease were also examined. The importance of food allergy cross-reactivity and thresholds was noted, especially in regard to aiding of a better understanding of the innate mechanisms of allergens. The industry-based organisation ‘Allergen Bureau’ has been actively researching in this space to assist food manufacturers with its precautionary food labelling system termed VITAL (Voluntary Incidental Trace Allergen Labelling).

Public perception was reviewed and found that people are turning to web-based information to inform regarding food allergy diagnosis and that public perception is an important consideration as food allergy risk management is dependent upon perceived risk assessment. This was particularly important for food allergic individuals when assessing food labelling. Food Allergy places significant Health Burden & Economic Impact upon Australia’s health system and both direct and indirect costs upon individuals and families.

Food allergy safety practices at Australian retail food services was examined. Cross-contamination of foods was of particular importance in the transmission of food allergens, along with the ability of food service staff to inform customers of ingredients and accurate food labelling. Of particular importance, is food services adherence to regulatory requirements including Food Safety Programs, Food Recall Procedures and Food Licencing for food safety inspections by regulatory enforcement officers such as Environmental Health Officers (EHO's). Legislative regulatory compliance initiatives such as mandatory Food Labelling, Food Recalls, and Food Safety Programs (FSP's) assist in reducing the risk of inadvertent allergic food reactions.

Mandatory substance declarations & labelling requirements including precautionary allergen labelling were examined. Importantly, the government agency Food Standards Australia & New Zealand administer the *Food Standards Code* and disseminate and coordinate food recalls for Australian Federal, State and Territory Government agencies to perform regulatory and compliance activities in relation to food recalls and food labelling compliance. **Chapter 2** researched undeclared food allergens in products for sale at Asian retail stores in Melbourne, Australia, finding a large proportion of undeclared allergens and non-compliant labelling, not previously published in this domain. The outcome of this included recommendations and consultation with Government agencies.

Government agencies and food allergy organisations have produced tools & resources, generally web-based. Government agencies also disseminate resources to aid in food safety compliance. It was noteworthy that there is a lack of mobile applications dedicated to informing food allergic sufferers. Most prominent organisations in Australia included the Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy & Anaphylaxis Australia (A&AA). These have developed and implemented important strategies and programs including, amongst others, the National Allergy Strategy and Food Allergy Week, respectively. **Chapter 3** adds to the body of food allergy resources with the development of the FoodRecallAus app, disseminated via Google Play™ and iTunes® stores, and an accompanying website. In addition, affiliation with strategic partners such as A&AA assisted in dissemination of this innovation. The backend customer download data was analysed finding an association between download rates and national media publicity of food recalls. **Chapter 4** summarises findings and research implications and provides insightful recommendations and directions for future studies within the scope of this field.

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Acronyms

α-Gal	Galactose-α-1,3-galactose
A&AA	Allergy & Anaphylaxis Australia
ABS	Australian Bureau of Statistics
AMA	Australian Medical Association
APT	Atopic Patch Test
ASCIA	Australasian Society of Clinical Immunology and Allergy
COI	Cost of Illness
CRD	Component-Resolved Diagnostics
DBPCFC	Double-Blind, Placebo-Controlled Food Challenge
DC	Dendritic Cell
DNA	Deoxyribonucleic Acid
DPI	New South Wales Department of Primary Industries
ECG	Electrocardiography
ED	Eliciting Dose
ED’s	Eliciting Doses
EDIS	Emergency Data Information System
EH	Environmental Health
EEA	Equivalent Administrative Arrangements
EHO	Environmental Health Officer
ELISA	Enzyme-Linked Immunosorbent Assay
EO	Eosinophilic oesophagitis
FA	Food Allergy
FSS	Food Safety Supervisor
FSSRU	Food Safety Standards & Regulation Unit
FSANZ	Food Standards Australia and New Zealand
FSP	Food Safety Program

GALT	Gut Associated Lymphoid Tissues
G-Rating	General Rating
GERD	Gastroesophageal Reflux Disease
GG (LGG)	Lactobacillus rhamnosus
GP	General Practitioner
HERs	Electronic Health Records
H&HS (HHS)	Hospital & Health Services
HLA	Human Leukocyte Antigen
HREC	Human Research Ethics Committee
ICD	International Classification of Disease
ICD-10-AM	International Classification of Disease, version 10, Australian Modification
ICD-9-AM	International Classification of Disease, version 9, Australian Modification
IgE	Immunoglobulin E
iNQ	Innovation NQ
JCU	James Cook University
LOAELs	Lowest-Observed-Adverse-Effect levels
MHC	Major Histocompatibility Complex
NOAEL’s	No-Observed-Adverse-Effect levels for each allergen.
NHMRC	National Health and Medical Research Council
OFC	Oral Food Challenge
OIT	Oral Immunotherapy
P&C	Parents & Citizens
PAL	Precautionary Allergen Labelling
PHU	Public Health Units
PIN	Penalty Infringement Notice
PU	Penalty Unit
QHAPDC	Queensland Hospital Admitted Patient Data Collection

QHFSS	QLD Health Forensic and Scientific Services
RAST	(sIgE's) Radioallergosorbent Test
RSS	Rich Site Summary
rDNA	Recombinant DNA
RIAMS	Regulatory Information and Management System
s	Section
SEO	Search Engine Optimisation
SIT	Specific Immunotherapy
SLIT	Sublingual Immunotherapy
SPT	Skin Prick Test
Th-1	T-helper 1 cells
TPHU	Townsville Public Health Unit
USA	United States of America
VITAL	Voluntary Incident Trace Allergen Labelling
WHO	World Health Organisation
VITAL	Voluntary Incidental Trace Allergen Labelling

Abbreviations

C-Section	Caesarean Section
Cwlth	Commonwealth
The Code	Australia New Zealand Food Standards Code
The Act/Food Act	*Food Act 2006*

Chapter 1. An overview of food allergy and undeclared food allergens in Australia.

1 Introduction

This Chapter is a literature review of recent publications in the field of food allergy, with a specific focus on food allergy in Australia. Of particular relevance is undeclared food allergens, food recalls and food labelling regulatory compliance. In addition, this chapter will examine web-based tools for the dissemination of food recall information. Primarily PubMed literature search was performed using key search terms. Primarily, search terms included: 'Food Allergy', 'Food Allergy Australia', 'Food-related anaphylaxis', 'Undeclared Food Allergens', for example. In addition, for Australian specific publications an Author search was conducted, for example 'Zurzolo'. The scope of this review is to define limitations in the aforementioned research topics, whereby contribution to the body of research and development can be made and defined further chapters of this thesis.

1.1 Food Allergy Definition & Mechanisms

The Australian Society of Clinical Immunology & Allergy (ASCIA) defines allergy as an immune reaction to a substance in the environment that is usually harmless (1). Most food allergies are caused by immune reactions involving Immunoglobulin-E (Ig-E) antibodies to food proteins, although non-IgE mediated mechanisms can occur (2, 3). Non-IgE mediated food allergy does not cause anaphylaxis (4). Severe IgE mediated food allergy can cause anaphylaxis, which is a rapid onset immune reaction, that may be life threatening (5).

Mechanisms of food allergy are poorly characterised and understood (6). Food allergy is classified by its immunological mechanism, as a Type-1 Hypersensitivity reaction.

Sicherer S & Sampson H(7) cited the National Institute of Allergy and Infectious Diseases' Expert panel (USA) identification of four food reactions that are immune–mediated: "IgE-mediated, non-IgE-mediated, mixed, or cell-mediated reactions". Therefore the National Institute of Allergy and Infectious Diseases (USA) defines food allergy as "an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food" (7, 8).

Rather than thinking of food allergy tolerance as the body's immune system 'ignoring' food antigens or 'unaware' of them, it can be considered as active non-responsiveness (9). Cox H (10) speculates that chronic eczema patient autoantibodies suggests that an initial allergic reaction may lead to autoimmune disease. Correlations between food allergy and other

allergic conditions such as eczema and asthma can be found. Zicari AM et al, found that amongst children who were positive reactors to food allergy skin prick testing in the first 3 years of life, half developed asthma during childhood, which was double that of the general population (11). There is a relationship between dermatitis and food allergy. It has been recognised that a third of atopic dermatitis patients have food allergy (12). 27% of severe eczema patients have mutations in the filaggrin gene, which causes disruption of the epidermis. There appears to be an association between skin barrier disruption causing eczema and food allergy, as Cox H (10) points out, infants 0-2 years of age often have combined food allergy and eczema. Also, environmental pollutants and some viruses are known to cause defective skin epithelium resulting in conditions such as food allergy, asthma, and atopic dermatitis (13).

Often food related conditions are miss-diagnosed as food allergy. Examples include Gastroesophageal Reflux Disease (GERD) and Eosinophilic oesophagitis (EO) (14), histamine and histamine-like toxins in spoiled meats, scrombroid fish histamine poisoning, spicy food induced gustatory rhinitis. These may be associated with food allergy, however, are separate conditions (7).

1.2 Gut Associated Lymphoid Tissues (GALT)

Dramatic developmental changes occur in the growing infant during the first year of life including the transitional development from liquid to solid foods and the innate physiological modifications that take place during this phase. Developmental process changes include modifications in the ability to digest solid foods, the subsequent changes in stool consistency, the interplay between the infant's developing mucosal immune system – the Gut Associated Lymphoid Tissues (GALT), and the development of established microbial communities. The microbial communities include differing colonizing bacteria relative to either a solid or liquid diet and differ between breast-feeding diet and formula diet (15). Some studies have administered probiotics containing bacterial strains including *Lactobacillus rhamnosus* GG (LGG), and *Lactobacillus reuteri*, which appear to have reduced infant eczema and sensitisation, respectively (16).

1.3 Food Allergy Symptoms & Diagnosis

Some common symptoms of food allergy include: oropharyngeal pruritus, urticarial, gastrointestinal reactions, respiratory reactions, cutaneous reactions, multi-system reactions,

itchy or sore throat, cough/wheeze, rhinoconjunctivitis, lower and upper respiratory conditions (8).

Table 1 “Differential diagnosis for FA”, by Grazon DL et al (17), details the clinical presentation for determining differential diagnosis of food allergy. Clinicians should be trained in assessment of clinical symptoms for determining food allergy differential diagnosis and how these can assist in excluding Type 1 Hypersensitivity food allergic reactions.

Treating physicians may sometimes miss-diagnose food allergy or food related reactions for other conditions which appear symptomatic of food allergy. For example, the neurological condition auriculotemperal syndrome – increased salivation produces cheek vasodilation (7), and even viral conditions such as ‘slap cheek’ otherwise known as Fifth Disease caused by a parvovirus, with symptoms of rosy cheeks and a skin rash.

Table 1: “Differential diagnosis for FA”, adapted from Grazon DL et al, Primary care management of food allergy and food intolerance (17).

Differential	Clinical presentation
Eosophagitis	Dysphagia, feeling that food “gets stuck”, abdominal/chest pain, vomiting, and regurgitation. More common in males and peaks in age between 1-4 and 10-14 years.
Eczema flare from non-food exposure	Decreased humidity, dry skin, bacterial infections, and skin friction may cause worsening of eczema. Symptoms include maculopapular eruptions of the flexural skin folds and face, generalized skin dryness, and lichenification.
Food chemical effect	Facial flushing with spicy food, phototoxic reaction between lemon juice and sunlight causing contact dermatitis.
Infection from contaminated food	Nausea, vomiting, diarrhoea, abdominal cramping, and flatulence.

Food exacerbated conditions	Migraine symptoms (unilateral, throbbing headache with or without aura) following ingestion of foods containing vasoactive amines (chocolate, aged cheese, red wine, beer). Spicy foods can worsen gastroesophageal reflux.
Protein induced proctocolitis/enterocolitis	Allergic proctocolitis causes blood streaking in an otherwise asymptomatic infant (usually breast-fed). Protein-induced enterocolitis causes blood in stool, vomiting, failure to thrive in a formula-fed infant. Symptoms disappear within 2-3 days of cow's milk protein removal diet.
Food Intolerance	Abdominal pain, nausea, bloating, flatulence, and diarrhoea that begins within 30 min to 2 hrs of ingesting milk products.
Heiner syndrome	Rare disease that affects infants and causes pulmonary disease characterized by pulmonary infiltrate, wheezing, cough, rhinorrhoea, fever, hematochezia, anaemia, and failure to thrive.

1.4 Treatment of Food Allergy - Diagnostics & Clinical Practice

Determining food allergy symptoms is the first step in diagnosing a patient with suspected food allergy. This should be followed by diagnostic testing and then referral for specialist diagnosis.

Primary care action plan for FA diagnosis	
Step 1: History and physical exam	Thorough patient history Family history of atopy or FAs. Patient medical history of atopy (including eczema, asthma, rhinitis). What symptoms occur? When do the symptoms occur In relation to foods eaten? Do the symptoms happen at any other time? What treatments have been tried in the past? Physical exam Although physical exam findings are not diagnostic, findings such as eczema, urticarial, or wheezing may be suggestive of atopy, increasing the risk of FA.

Step 2: Food allergen specific serum IgE (sIgE) testing	sIgE If history and physical are suggestive of FA and possible trigger foods are identified, sIgE can confirm causative foods but is not diagnostic.
Step 3: Referral	Referral to allergy specialist If history and physical are highly suggestive of FA or sIgE testing is positive. Oral food challenge is the gold standard for diagnosis of FA. Skin Prick Test may be helpful to identify allergens.

Table 2: “Primary Care Action Plan for FA Diagnosis”, adapted from Grazon DL et al, Primary Care Management of Food Allergy and Food Intolerance, p.37-38.

Food allergy symptom presentation can be of two types: immediate or delayed-type reactions (12). Food allergy diagnostics can utilise the speed of the reaction. For example, oral food challenge diagnostic is often used because it relies upon immediate type hypersensitivity reaction, while diagnostics such as the Atopic Patch Test (APT) are useful for diagnosis in delayed-type hypersensitivity reactions (12). A systematic meta-analysis review concluded that APT has high specificity and low sensitivity(18). Therefore, APT may provide false positives for non-IgE mediated food reactions, such as eczema (18). Some experts do not recommend the use of APT’s, amongst applied kinesiology, intradermal tests, measured basophil histamine, allergen-specific IgG4, and electrodermal tests. Furthermore, APT does not appear useful in diagnosing protein-induced enterocolitis (7).

There is a selection of diagnostic food allergy tests, which include the Skin Prick Test (SPT), serum specific Immunoglobulin-E Radioallergosorbent Test (IgE RAST) / (sIgE’s), and oral food challenge (OFC) available to health professionals. A systematic review by Soares-Weiser K et al, concluded that sIgE’s and SPT were sensitive but not specific for IgE food allergy diagnosis (7). There are advantages of using one diagnostic over another. Some are more sensitive (e.g. SPT and sIgE’s), while others are more specific to food allergy (e.g. APT).

Oral food challenge is also termed ‘provocation test’ (19). It is considered to be the “golden standard” of food allergy testing, but must be carefully controlled. The prime of this test is the DBPCFC (double-blind, placebo-controlled food challenge) (18). A USA survey study of 2,355 children by Gupta RS et al (20) revealed that one out of five doctors who diagnosed food allergy in a child, was diagnosed via oral food challenge.

Grazon DL et al (17), review clinical diagnosis of food allergy and recommend that clinicians avoid panel tests because they often diagnose food sensitivity that is not clinically significant. Gupta RS et al (21) found that among physician-diagnosed food allergy 32.6% was not evaluated with diagnostic tests, 47.3% was assessed with Skin Prick Test, and 39.9% with serum specific IgE test. Peters RL et al (22), noted that SPT has a low clinically significant food allergy specificity. However, some allergists have suggested that SPT should replace OFC if the wheal size from a SPT is of a predictive size. Cox H reiterates this by stating that SPT’s and serum specific IgE tests are highly sensitive approximately 90% of the time, while specificity is approximately 50% (10).

Advances in diagnostics are proving to be valuable tools for researchers, yet health professionals may be unaware of available novel diagnostics and the application of such. For example, Kattan & Wang (2012) (21) propound the potential advantages of allergen component-resolved diagnostics (CRD) over traditional SPT and specific IgE serum tests, particularly in applications assessing allergy to peanut; milk; and egg. However, poor communication and lack of specific ongoing training of clinical health professionals in advances in laboratory diagnostics and how these can be applied in clinical diagnoses, is not readily understood or absorbed by the profession. For example, a review by Lopata AL & Lehrer SB noted poor correlation of IgE reactivity and clinical symptoms (23).

The complex experimental details of how food allergens interact with the immune system are often ill conveyed to the clinical health profession. One such example from seafood allergens, tropomyosins are known for molecular and clinical cross-reactivity between crustaceans, molluscs and even insects including house dust mites (24).

Treatment of severe allergic reaction is predominately injection of adrenaline. Recent advances in immunotherapy have been increasingly adopted in clinical settings, for example, heated milk and egg tolerance treatment, modified food protein vaccines, cytokine therapy,

probiotics, anti-IgE monoclonal antibody adjuvant therapy, Chinese herbs, helminth parasite therapy, oral immunotherapy (OIT), sublingual immunotherapy (SLIT), epicutaneous immunotherapy (9). Also Specific Immunotherapy (SIT) including: DNA vaccines, immunostimulatory DNA, recombinant allergens, peptides, and bacterial products (25).

Heating foods is known to affect foods via chemical reaction in which functional molecular changes occur. It is recognised that heating peanuts causes a chemical reaction whereby sugars and proteins form glycated end products (Maillard reaction) (7). This causes roasted peanuts to be more allergenic than raw. On the other hand, cooked egg, milk, and fruits is known to lead to these foods to become less allergenic after cooking (7).

OIT and SLIT therapies provide food allergy sufferers with small doses of a particular food allergen over a period of time, in a controlled fashion, which in some individuals builds a tolerance to that allergen. OIT, as the name suggests, is given as a small (usually milligrams) oral dose, whereas SLIT is a small dose (usually micrograms) placed under the subject's tongue and held under the tongue, typically for a minute or two (8). The dose depends on the type of allergen as some food allergens elicit an adverse reaction with smaller amounts than others e.g. peanut v's egg.

OIT, SLIT and OIT/SLIT combined studies have been performed. Such studies have been performed on children or infants for foods including: egg; milk; peanut; hazelnut; peach; and kiwifruit (8). Often these are performed in DBPCFC over months or even years, and followed up with SPT's and blood tests to determine response. The advantage of OIT treatment is that, from studies, it is evident that more participants reach tolerance than with SLIT and greater challenge thresholds can be achieved. The disadvantage with this treatment is that there is the likelihood of more adverse reactions as a larger dose is given, which is swallowed. In comparison, the advantage of SLIT treatment is that the reactions are milder as a smaller dose is placed under the tongue. The disadvantage is that babies and infants will have difficulty to 'hold' the sample under the tongue for any length of time and often doses are spat out (aspirated) (8).

New diagnostics have arisen such as Component Resolved Diagnostics (CRD) where allergenic food proteins derived either from purification or recombinant DNA technology (rDNA) are produced to elicit a patient's IgE response (26). Thus, tailored allergic proteins or

components of allergens are manufactured for diagnostic use. CRD testing has shown most promise in diagnostics for detection of peanut allergenic proteins, for example, Ara h 1, 2, 3 allergens. CRD diagnostic has been useful in determining cross-reactive proteins e.g. Ara h 8 protein of birch pollen (26). Nevertheless, CRD is limited in its applications due to a narrow range of component food allergens available for testing (21). Regardless of the diagnostic, Turkalj M et al (6) concede that there is no safe and efficient treatment for food allergy and therefore treatment currently relies mainly on prophylactic avoidance. However, simply avoiding foods containing the allergy deprives consumers of choice (27). Mulier S et al, concede that because there are a limited number of foods responsible for the bulk of food allergy cases (i.e. peanuts, milk, egg etc.) an avoidance diet or eviction diet should be the first treatment (19, 28).

Sommer I et al, identify that due to influencing choice factors, food allergic sufferers should be provided advice beyond avoidance (27). When physicians advise patients on diagnostic choice, they should divulge information sufficient for patients to make informed choices. This premise is based upon the physician having sufficient knowledge and or experience with food allergy diagnostics, initially via training.

Patients will likely weigh up advantages and disadvantages of diagnostics or treatments including: cost, convenience and invasiveness, and time delay to results. Patient's probably give little thought to the sensitivity or specificity of the diagnostic, and physicians may choose a diagnostic based upon 'ease of use' rather than accuracy or sensitivity. Elavunkal J et al, recognise in the Cocraine review of decision aides for patients facing treatment or screening decisions, that when patients are faced with diagnostic options, patients should be provided with aides (e.g. videos, pamphlets, web-based media) to enable informed decision (29).

1.5 Food Intolerance

In contrast to food allergy, food intolerance does not involve an immune reaction to food or cause anaphylaxis, yet intolerance symptoms may resemble those of allergy (5, 29). Food intolerance is defined by the National Institute of Allergy and Infectious Diseases (USA) as a non-immune reaction (7). Common causes of food intolerance include: malabsorption of lactose found in milk products, sensitivity to sulphites, and gluten intolerance from a variety of cereals.

The most common reported food intolerance is lactose intolerance. Lactose intolerance is not considered for inclusion in the definition of ‘food allergy’. Lactose intolerance can also mimic symptoms of food allergy. This is because lactose intolerance is caused by a lack of the enzyme lactase. Lactase is essential in cleaving the carbohydrate lactose sugar into galactose and glucose. There is a genetic predisposition for production of this enzyme, which appears to subside with age based upon genetic predisposition (30).

1.6 Wheat Allergy, Gluten Intolerance & Coeliac Disease

‘Gluten’ is a collective term to describe a range of proteins derived from cereals including wheat, rye, barley, and oats. Grain storage proteins (prolamins) found in wheat are termed gliadin proteins (31). Gliadin is an indicator of the presence of gluten. Food Standards Code 1.1.2 defines gluten as “the main protein in wheat, rye, oats, barley, triticale and spelt relevant to the medical conditions coeliac disease and dermatitis herpetiformis” (32).

It is estimated 5% of global population experience gluten-related disorders (33). Gluten avoidance is an important health consideration, particularly for people suffering from Coeliac Disease. In Australia, the prevalence of Coeliac Disease is estimated at less than 1% of population (34, 35). The World Health Organization International Food Standard Codex Alimentarius (CODEX STAN 118/1979) prescribes gluten content in foods. For products claiming ‘gluten free’ status the threshold is 20 mg/kg or less and foods that have been processed to reduce the level of gluten content the standard allows from 20 mg/kg up to 100 mg/kg (36).

Human Leukocyte Antigen (HLA) are families of genes on Chromosome 6 and code for the Major Histocompatibility Complex (MHC), these are associated with presentation of antigens on immune cells.(37) Individuals who suffer from Coeliac Disease have a genetic immune disorder caused by deficiencies of HLA DQ2 & HLA DQ8 genes (38). Genetically susceptible persons possess one or both genes HLA DQ2 and HLA DQ8 (4). However, only 1 in 40 persons who possess these genes will develop the disease. The immune system of Coeliac Disease sufferers reacts abnormally to gluten causing damage to the lining of the small bowel (38). The British Society of Gastroenterology classifies Coeliac as an “immune-mediated systemic disorder excited by gluten and prolamines in genetically susceptible individuals.” (39). Coeliac disease causes the villi of the small bowl to be flattened (atrophy) and inflamed, giving rise to a variety of symptoms shared by food allergy sufferers. Coeliac disease can be

defined as a non-IgE-mediated food disorder (7). Coeliac Disease is not typically included in the immunological definition of food allergy as it is not a Type-1 Hypersensitivity Reaction. For coeliac disease sufferers the daily limit should be in the range of 10-100 mg/day (40).

Although wheat is commonly associated with Gluten Intolerance and Coeliac Disease, wheat can elicit IgE-mediated allergic immune reactions to gluten proteins in susceptible individuals – a true wheat allergy (31). Substances, listed in Food Standards Code, Standard 1.2.3-4 Mandatory declaration of certain foods or substances in food, can be considered allergens as they are able to elicit a food allergic reaction in susceptible individuals (41).

1.7 Cross-reactivity

Cross-reactivity is a term used to describe allergic reaction to a protein found in similar types of foods (42, 43). Examples include: people who can be allergic to proteins present in both cashew nut and pistachio nut, cow's milk and goat's milk, duck egg and hen egg, hazelnut and coconut and walnut etc. (42, 43). Seafood allergens, particularly tropomyosins are known for molecular and clinical cross-reactivity between crustaceans, molluscs and even insects including house dust mites (24).

Cross-reactivity is a dilemma for diagnostics because several different plants or animals may share the same or similar antigens. Therefore, a patient can potentially be found to be allergic to peanut, but also not recognise that the same patient is also allergic to pine nut because of a shared allergen. A study of seafood allergy in children performed by Turner P et al (3), on 2999 children in Australia found 50% of children allergic to crustaceans were fish tolerant. However, a third of the children tested possessed a cross-reaction between crustacean and two or more species of fish.

Interestingly cross-reactions have been cited, for example, between shellfish and cockroaches, and pig meat allergy cross-reaction to cat serum albumin (7). Most often food allergens are proteins but occasionally they are not. This is the case for a delayed-type food allergy to mammalian meat, which is induced by a carbohydrate galactose-α-1,3-galactose (α-Gal) derived from the bite of a tick (*Ixodes ricinus*) in sufferers who are B-Blood group (type) (7).

Such nuances between clinical manifestation and diagnostics mean clinical health professionals struggle to correlate them. This is particularly so of clinicians correlating patient symptoms with diagnostic tests that present a poor correlation between IgE reactivity and symptoms (23).

1.8 Food Allergy Causation

A variety of studies have been performed to attempt to correlate food allergy with a plethora of variables. Often, these appear to be desperate clutches at attempting to provide an answer as to why food allergy is increasing. Therefore, association studies have been performed. Such studies have included: season of birth relationship (44); climate change (45); latitude (46); changing diet including the change in microbiota (47), the “hygiene hypothesis” and parasites (48); environmental and demographic risk factors such as caesarean section (C-section) delivery, genetic predisposition of family members, country of origin, pets, maternal age, antibiotic use, childcare attendance (49).

C-section has been a focal point for some researchers because infants acquire an adult-like mircobiome within the first 3 months of life. Vaginal birth delivery imparts different colonizing microbes to the baby than does a C-section delivery (47). Vaginal microbiology during pregnancy and birth alters to reduce microbial diversity with *Lactobacilli predominate* (47). The relationship between establishment of gut microflora and fauna, changing diet, and the developing immune system is extended to hypothesize that a changing microbiome influence food allergy. Breast-fed infants and formula-fed infants differ in microbime gut colonization. These are major influences within the early months of life.

An Australian, A.C.T. study examined seasonal births of children with food allergy and found no relationship between the two. However, their results indicated an increase of children born with food allergy in Autumn/Winter and therefore surmised that UV or Vitamin D might be implicated as a contributing factor. Vitamin deficiencies have been known to impair the immune function (44). Vitamin D3 (Calcitriol) is thought to be involved in reducing Dendritic Cell (DC) maturation and therefore autoimmune response via T-helper 1 (Th-1) cells (16). Others, have examined global incidence of food allergy and proposed associations between food allergy and latitude (46). Food allergy predisposition association lack of Vitamin D hypothesis has been propounded by researches examining correlations between lack of

sunshine with latitude and seasonal birth (7). A USA study has even implicated climate change as a potential reason for increased incidence of allergy (45).

Recently, an interesting meta-analysis review by Lodge CJ et al titled “Overview of Evidence in Prevention and Aetiology of food allergy: A Review of Systematic Reviews” presents some clarity regarding association food allergy studies. Their analysis of reviews focused on three main environmental association trends – 1) Infant and maternal diet; 2) changes in microbiota and diet (“The Hygiene hypothesis”); and 3) Vitamin D and pollution causes (50). A review of the reviews concluded that there was no strong association between the three main environmental association trends and food allergy risk in children. A comparative synthesis of systematic reviews was not able to be achieved for all trends. Vitamin D review analysis was omitted by this review. C-section relationship to food allergy atopy, for example, could not be synthesised by the authors. However, this systematic review clarified that there was no strong association between delaying introduction of solid foods to infants nor infant formula on food allergy reduction (50).

An Australian study of egg allergy in infants and small children performed by Koplin JJ et al (49) discovered an association between egg allergy and dogs. That children with dogs at home were more likely to have reduced egg allergy. Also they reported that children from an East Asian heritage were more likely to have egg allergy form a genetic predisposition (49). Cox H (10) recognises that infants with atopic eczema are highly predictive of having egg allergy.

1.9 Food Allergy Prevalence

Developed nations from around the world have report increasing incidences of food allergy amongst children. Turkalj M et al (6) reports 5-8% of children and 1-3% of adults with incidence of food allergy in Europe. Husby S reports 7-8% of children in Denmark (14). USA study estimates 8% of adults and 2% of children suffer (26). Sicherer S & Sampson H (7), more cautiously place estimates at between 1-10% of the population, due to study variables in estimates including: age; diet; exposure; geographical variation; the study population; methods of study; and food allergy definition in studies (7).

Alarmingly, Australia and New Zealand attribute among the highest rates of allergic disorders in the Developed World and these rates have been increasing in recent years. Researches

such as Miles et al (2007); Venter et al (2006); Osterballe et al (2005); Sicherer & Sampson (2006), cited in Economic Impact of Allergic Disease: not to be sneezed at (51), agree that estimates of 6% of children and 3-4% of adults are affected by food allergy. This was a 2007 Report. Mulier & Casimir (19) declare children presenting food allergy represent between 4% and 8% of population. A 2011 Australian systematic review by Peters RL et al, recognised children presenting food allergy represent between 6% and 8% of population (22).

Mullins et al (52), in 2007 found an increase in allergy-related disorders in children aged 0-5 years over an 11year period in a private practice in ACT Australia. Refer to Figure 1 (No.1) What is markedly noted is the dramatic increase in eczema and food allergy patient referrals. It is noteworthy that eczema and food allergy trend mirror each other.

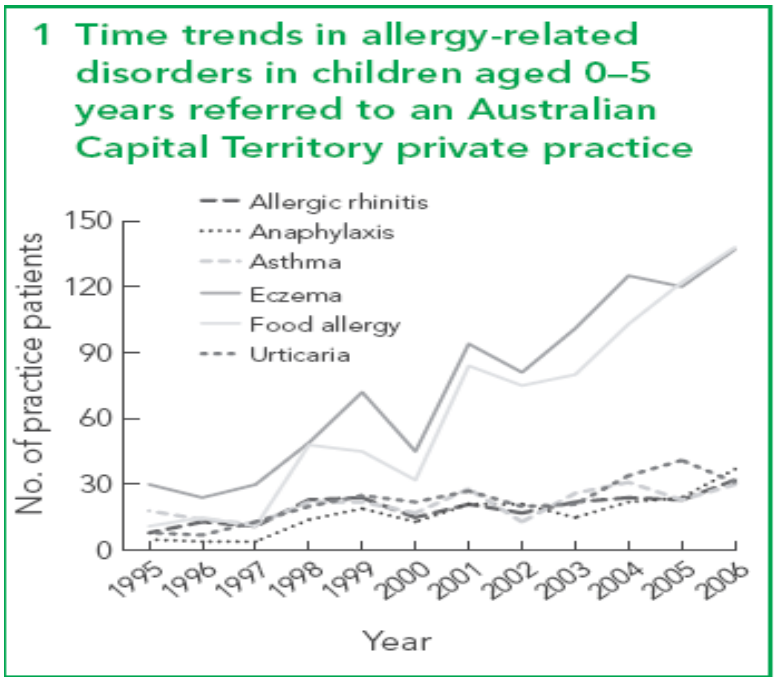

Figure 1: Time trends in allergy-related disorders in children aged 0-5 years referred to an Australian Capital Territory private practice. (Mullins RJ, Dear KB, Tang ML. Characteristics of childhood peanut allergy in the Australian Capital Territory, 1995 to 2007. J Allergy Clin Immunol. 2009;123(3):689-93) (52).

Currently, Australia appears to have the highest reported incidence of food allergy in the world. These figures are believed to be increasing to 10% for children in Australia, as recently reported by Prof Katie Allen, Murdoch Children Hospital (53). The largest population-based

food allergy cohort study (n=2848), termed the HealthNuts study, found greater than 10% of twelve-month-old infants to be allergic to cow's milk (54, 55). Food allergy is estimated to occur in 4-8% of children younger than five, and around 2% of the adult population (1). The highest prevalence of food allergy can be attributed to 8 foods. These are milk, eggs, peanuts, wheat, soy, tree nuts, fish, shellfish contribute to more than 90% of food allergy cases (8, 17, 19).

1.10 Food Allergy Anaphylaxis, Morbidity & Mortality in Australia

Food related anaphylaxis, a potentially life-threatening allergic reaction, has doubled in the last ten years (56). Mullins R et al. report that between 2005-6 and 2011-12 (7-year period) Australian food-related anaphylaxis hospital admission rates increased from 5.6 to 8.2 (per 10^5 population per year); a 1.5-fold increase. For ages 0-4 years with a 1.4-fold increase from 21.7 to 30.3 (per 10^5 population per year), and those aged 5-14 years with the greatest proportionate increase (5.8 to 12.1/10^5 population per year) (56). According to Yue D et al food allergy is the primary cause of anaphylaxis amongst children (2, 57). Food anaphylaxis fatalities rose 9.7% per year between 1997-2013 (58). A 2018 Australian survey found allergy clinicians reported, over a three-month period, 14 incidents of anaphylaxis due to suspected consumption of packaged food where the allergen was not disclosed on the label as an ingredient (59).

1.11 Trends in Hospitalisation

In an Australian study by Poulos et al (2007), reviewed hospital admissions and deaths for anaphylaxis, angioedema, and urticaria, for all Australian hospitals; derived from the Australian morbidity and mortality databases, over three time periods, discovered a "continuous increase in the rate of hospital admissions for angioedema (3.0% per year), urticaria (5.7% per year), and, most notably, anaphylaxis (8.8% per year)" (60). Note that these increased rates refer to all allergic conditions, not food related only. Therefore, the results of this study must be interpreted cautiously in the light of building a profile of food allergy related allergic conditions, given that declared increasing trends incorporate all allergic conditions in the summaries. Food related allergic conditions make up a component of these trends but may differ depending upon age and sex, and not necessarily representative of food related allergic conditions.

Worm et al (61) and Satya N & Keet C (8), recognise that foods are the most common cause of anaphylaxis. In Australia a recent study of anaphylaxis hospitalizations has exclaimed a

350% food-related anaphylaxis increase in children (0-4 year age) from 1994-2005 (62). This appears to be an incredible explosion in food allergy anaphylaxis among infants and small children.

It is interesting to note, in the study by Poulos et al, of age differentials indicate that for urticarial hospital admissions children aged 0-4 years were approximately three times higher than for any other age group and food related anaphylaxis was particularly higher in this age group also. A trend of increased anaphylaxis attributed to food was discovered “between 1994-1995 and 2004-2005, admissions for anaphylaxis caused by food, had an average annual increase of approximately 13.2%”. Refer to Figure 3 Hospital admissions for anaphylaxis caused by food by broad age group, Australia, 1994-1995 to 2004-2005. Angiodema was found to be lowest in children (5-14 years) and highest in age group 65 years and older (60).

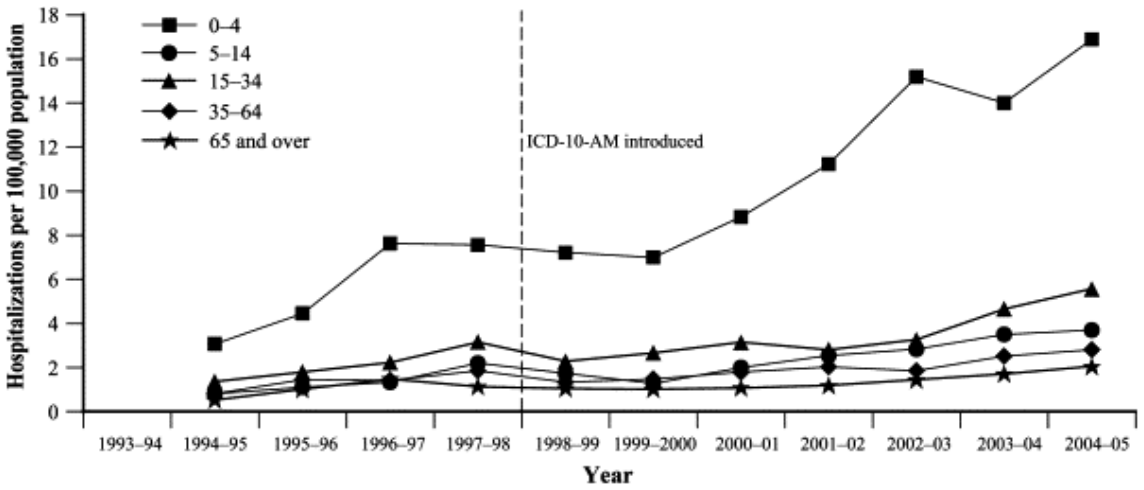

Figure 2: Hospital admissions for anaphylaxis caused by food by broad age group, Australia 1994-1995 to 2004-2005 (Poulos LM, Waters AM, Correll PK, Loblay RH, Marks GB. Trends in hospitalizations for anaphylaxis, angioedema, and urticaria in Australia, 1993-1994 to 2004-2005. J Allergy Clin Immunol. 2007;120(4):878-84.) (60).

There also appears to be sex differences in representation. Poulos et al (60) discovered that non-food related anaphylaxis admissions were higher for boys aged 0-14 years. Whereas, this reversed in ages 15 years and older. It is noteworthy that the authors do not include anaphylaxis attributed to food in the 0-4 years age group for sex differences analysis and give a notation stating that “rate ratios changed significantly over the study period” for this data and was therefore excluded. No comparison could therefore be made for this age group sex

differential based upon food relation. However, it is clear that urticarial rates of hospital admission for ages 0-4 years were higher for boys, and the same occurred for angioedema. Female rates of admission for angioedema and urticaria were higher in ages 15 years and older (60).

1.12 Food Allergy Public Health Guidelines, Policy & Practice

In Australia, in recent years, food allergy policy regarding childhood exposure has completely reversed previously held practice due to the recognised increase in childhood food allergies, subsequent to the 'years of avoidance policies'. A historical analysis of timing of infant solid feeding guidelines in Australia by J. Koplin & K. Allen (15) remind that in the 1960's it was standard practice to introduce solids to most infants by 4 months of age. However, by the 1970's guidelines recommended delayed introduction until after 4 months of age (due to perceived link between introduction of gluten and coeliac disease), and by the 1990's guidelines recommended delaying introduction until after 6 months of age, and recommended families with a history of food allergy delay introduction of highly allergenic foods until 2 years of age (15). Ralf G et al (16), report on maternal elimination diets - UK government 1990's recommendations - for mothers to avoid peanut consumption during pregnancy, which did not prove reduced sensitivity in infants. Meanwhile the incidence of food allergy among children increased contrary to the desired effect of the guidelines.

While allergen avoidance policies have been removed from guidelines, little in the way of evidence based guidance has been added to guidelines since. A 2011 paper by Prescott S et al, concludes that the only current evidence based avoidance guideline recommendations stipulate to use hydrolysed formula, promote breast feeding, and recommend against smoking (63).

In the past, there was less collaboration between policy makers and guidelines, but as the global network of research and collaboration has increased in recent years, we now find that policy adoption across countries is often mirrored. The USA, UK, and Australia recently published guidelines in unison. This indicates that adopted policies and practices by collaborating countries may now have a more widespread impact for a given prescribed policy. In Australia, the current policy advice for introduction of solids to children, which was introduced in 2008, was amended to remove delaying introduction of solids at 6 months of age (15).

The National Health and Medical Research Council (NHMRC) proclaim diet related health outcomes as having the most significant impact for a host of food health related conditions. Although, dietary guidelines appear most concerned with nutrition, obesity related food conditions, food borne illness, rather than food allergy (5). Sommer I et al estimate that 35% of a population with food allergies will modify their diet to reduce or prevent adverse reactions (27).

Husby S (14), points out that modifying diets, particularly for growing children, may adversely affect growth and development. To prevent this, diets must be properly guided. A meta-analysis systematic review revealed that there was no strong association between delaying introduction of solid foods to infants nor infant formula on food allergy reduction (50).

Bacterial colonisation is of crucial import in a developing mucosal immune system, which is 'educated' and/or 'primed' to respond to pathogenesis from food and pathogen antigens and at the same time maintain immune homeostasis. Formula fed infants have higher *Bacteroides* and *Prevotella*, while breast-fed infants possess lower levels of *Clostridium difficile* than formula fed. The World Health Organization (WHO) now recommends mother's breast feed for at least the first 6 months of infancy, exclusively (16).

1.13 The Hygiene Hypothesis

The "hygiene hypothesis" was propounded as the possible causation that a 'clean environment' may be reducing exposure to antigens in a developing child's immune system and therefore the development of the immune response to allergens is reduced (64). Interestingly, mice which were bred in sterile condition developed impaired oral immune tolerance – such was the impairment: underdeveloped GALT; less IGA plasma cells; less CD4+ cells; less intra-epidermal lymphocytes; smaller Payer's Patches lacking germinal centres (15).

The timing of dietary allergen exposure is controversial because there is some evidence to suggest that allergen exposure during pregnancy but not breast-feeding cause higher sensitization rates for peanut allergy, while there is growing research suggesting that early introduction of allergenic foods may have a preventative effect (26). Paradoxically, there is

suggestion that a food tolerance ‘window’ may occur between 4-6 months of age, when infant diet alters from liquid breast-fed diet to a solid food diet (16).

Today, official Australian food allergy policy encourages childhood exposure to allergenic foods, once again. This philosophy is based upon exposure building immune tolerance. Researchers including Mullins RJ et al (52) have noted that severity of allergic reaction appears to increase with delayed age of first exposure. One exemplary study by Koplin JJ et al (65) titled *Can Early Introduction of Egg Prevent Allergy in Infants? A Population Based Study*, suggested introduction of egg at 4-6 months of age may protect against egg allergy and recommended infant feeding guidelines be amended. Egg allergy is the most common food allergy amongst infants and toddlers in Australia (49).

Government endorsed public health guidelines generally reflect recommendations made by peak expert bodies. In Australia, the peak expert body most frequently relied upon, is the Australasian Society of Clinical Immunology and Allergy (ASCIA).

Clinicians (medical practitioners/doctors) have at their disposal an arsenal of practices to assist them in diagnosing food allergy as the root cause of an allergic condition in a patient. Standard practice is for the clinician to obtain a patient history. The patient history helps set the context of what the problem, as perceived by the patient and doctor is, and the circumstances surrounding the onset and duration of the problem.

Policy guidelines are an attempt by overarching bodies to standardise clinical practices. Clinical practice with regard to food allergy patient care varies widely between clinicians as each clinician approaches patient diagnosis differently. One clinician might recommend a panel of tests be performed from a patient’s blood sample, while another clinician may rely on clinical history only. Of course, there is the factor of patient willingness to perform a phlebotomy as well as the disincentive of cost for panel RAST testing, which can be expensive. The patient likely weighs the potential benefit of the test in diagnosing the problem against the frequency and/or severity of allergic reaction and the cost of diagnosis.

Steps toward standardisation of clinical practice in patient care for food allergy are continually undertaken by public health agencies. Continual adaptation of guidelines is necessary as new

research and diagnostics further our knowledge of food allergy and its treatment. One of the most recent and comprehensive food allergy guidelines was developed in the USA in 2010, titled: “Guidelines on the diagnosis and management of food allergy”, commissioned by the National Institute of Allergy and Infectious Disease (26). The elements of this guideline are propounded by S. Jones & W. Burks (26) to include “directed Clinical Care, Advocacy, Research, and Education”, from which they derive the acronym ‘CARE’.

1.14 Public Perception

Recognition of food allergy is largely based upon symptom presentation and thus may be under-represented in the community. Sufferers or their carers often resort to ‘self-diagnosis’. Miles et al recognise the growing cost associated with consumer self-informing via internet; books; travel for training; and self-help groups (66). In recent years, a novel predictor of disease trends, particularly infectious diseases, is the use of digital surveillance and social media as an extension in generating health data. Researchers in the USA have used these techniques to predict Flu trends (67). Termed ‘Dr Google®’, researchers have used Google® search engine algorithms to form models of disease trends (68). This may be of use for food allergy researchers in obtaining data on public perceptions regarding food allergy prevalence.

The internet offers the public the opportunity to search for a wealth of medical and scientific information with relative ease. The major drawback is that the internet user must be able to filter and interpret the myriad of information presented on the internet. Social media such as Twitter® and Facebook® offer the public the opportunity to report medical conditions, comment on them, and offer advice to others in social networks. There is also the opportunity for experts and expert authoritative ‘bodies’ to present information based upon the latest scientific findings. Analysis of social media trends can inform on public perception. Some research studies regarding food allergy representation have been performed at medical centres and also using hospitalization data. However, little is known of social media and search engine usage for self-diagnosis and treatment of food allergy.

Interestingly, some researchers have reported that prevalence of food allergy may not be accurate and actual over-reporting may be occurring (66). A kind of psycho-somatic or imagined allergic disorder. Grazon D et al (17), report that an estimated 50-90% of presumptive food allergy is not an actual food allergy and therefore caution should be exercised when clinicians perform case history (patient histories).

According to a survey of populations in the USA, 25% of people believe they have a food allergy. Diagnosed estimates of food allergy prevalence are much lower than this, for children in the range of 3-4% (17). A study of 4333 school children in Vilnius, Lithuania, report that half of the school children self-reported food allergy (69). Inaccurate reporting mechanisms, diagnosis accuracy, and unrealistic public perception of food allergy are likely reasons for this disparity.

A USA survey study by Gupta RS et al (20) revealed that 30% of parents reporting food allergies in children were not diagnosed by a doctor. An Australian study by Kljakoviv M et al (70) on parent reporting of nut allergy in school children in ACT identified 1 in 30 parents reported their child to have strong allergic reaction to nuts and 1 in 50 had diagnostic tests confirm. Husby S (14), report that only one-third of people with suspected food allergy actually confirm such with diagnostic testing. This demonstrates a lack of parental awareness regarding identification, reporting, and the availability of diagnostic options. The most prevalent current method for food allergy diagnosis is evaluation by skin prick testing and oral food challenge. The USA survey study of 2,355 children by Gupta RS et al (20) revealed that one out of five doctors who diagnosed food allergy in a child was diagnosed via oral food challenge.

An Australian paediatric food allergy study by Osborne NJ et al (71), titled: *The HealthNuts population-based study of paediatric food allergy: validity, safety and acceptability, report on the studies methodological efficacy*. They suggest that few paediatric food allergy studies have been performed due to issues of subject recruitment and therefore most prevalence data is obtained by other methods. The methodology employed in the HealthNuts population study was to align the study with childhood immunization sessions. A questionnaire was performed, as well as skin-prick tests on infants. This methodology reported a high engagement rate of over-all response at 73.4% of 2171 participants (71). Gaining accurate food allergy prevalence data is important as predictors of potential causation, to enable health agency directed interventions, and also for health budget allocation.

A U.K. study by Barnett J et al, examined perceptions of nut allergy patients with regard to food labelling and found that three main strategies were employed by individuals to manage food allergy risk and make informed choices when purchasing packaged foods. These included: 1) the quality of the product and country of origin, 2) previous experience consuming

the particular product, and 3) sensory appreciation risk (72). This personal psychological risk assessment raises the important aspect of accurate labelling of packaged foods derived from overseas, especially non-English speaking countries. There has been some research into consumer perceptions regarding precautionary labelling, while little research has been focused on mandatory labelling perceptions. This may be due to the fact that mandatory labelling does not leave room for ambiguity in labelling. In a further qualitative study by Barnett J et al, looking at precautionary labelling perceptions, it was reaffirmed that nut allergic consumers, based food choices not only on the labelling but on previous experience with the product, trustworthiness of the manufacturer, and the type of product (72). Sommer I et al concur that consumers base choice on awareness and emotional choice (27). There is a growing trend of wealthy consumers who are willing to pay more for food purchases that are perceived to be ‘safe’ (66).

1.15 Food Allergy Hospitalization Trends

Hospitalization data obtained from databases is utilised by researchers for the purpose of analysis to compile time trends or provide absolute numbers for statistical analysis with regard to patient morbidity and mortality. This is true of some food allergy researchers. For example, Poulos L. et al in a study of food allergy trends in hospitalization use compiled hospitalization data for producing morbidity and mortality time trends (60). However, when researchers propound conclusions drawn from analysis of hospitalization data, these need to be provisioned by clauses revealing the inherent potential inaccuracies of using such data. Belzberg H. et al, informs that there are issues associated with data entry accuracy and reliability (73).

Generally, a number of hospitals feed data into a centralized database. The task of entering ‘raw’ clinical data falls to health professionals employed as ‘Data Coders’. This is an administrative role sometimes termed “medical scribe” (74). The raw data is presented to the Data Coder in the form of Patient Discharge Summaries and patient clinical records. The main emphasis for deriving coded data is derivation from the Discharge Summaries. Data Coders may not even take into consideration the full patient clinical records. The Data Coder’s task is to interpret the Patient Discharge Summaries, written by physicians and nurses, and classify the ‘raw’ data. This is achieved by interpreting the Patient Discharge Summary to ‘best fit’ the interpretation with a codex (tabular) classification. Electronic Health Records (HERs) are now

an almost essential function of the health care system, especially in larger health care facilities. In the U.S.A it is reported that three out of four physicians rely on HERs (75).

The assumptions are that physicians and nurses have accurately described the patient's morbidities and co-morbidities, and have summarised these accurately enough to correspond closely enough to enable the coder to match them to specific "International Classification of Disease" (ICD) codes. This calls into question the clinical acumen of health professionals, consistency of clinical diagnosis and the ability of health professionals to obtain enough information from patients, within a limited time-frame (4 hours prescribed maximum patient stay in Emergency Departments [ED] in QLD), to form an accurate clinical opinion with limited or no diagnostic test results. It is evident that there may be issues with a physician or nurses' personal consistency when diagnosing a particular condition, and this may vary depending upon patient morbidity and co-morbidity characteristics. Thus, patient diagnosis may differ depending upon the nurse or physicians' diagnostic consistency. Furthermore, there is the issue of consistency amongst clinicians with regard to diagnosis and consistency of Patient Discharge Summary recording and patient records. There are many variables that attribute to patient case inconsistency, lack of confirmatory diagnosis, for example: ability of the physician to interview the patient; shared co-morbidities for a condition etc. A study by Morrison Z et al, discovered that many heath care professionals did not perceive coded data as relevant (76). Clinicians would need to be familiar with the terminology used to define a condition in the ICD to be able to accurately specify the appropriate code to enable accurate coding. Otherwise the Data Coder may likely choose the 'unspecified' coding option(s).

This brings to mind the old adage: "garbage in, garbage out". If a morbidity or co-morbidity is not accurately diagnosed and transcribed in the Patient Discharge Summary, it follows that the data is non-reliable and should not be coded. However, it is not the 'job' of the Data Coder to review the clinical diagnosis, but to 'best fit' Patient Discharge Summary morbidity and co-morbidity information to an ICD code. There is 'room' for Data Coder interpretation here, or lack thereof (75). Although, there are classification structures and conventions inherent to the ICD tabulars to enhance consistency, there is 'room' for human error. The Data Coder must be able to accurately read and interpret the physician or nurse's diagnosis and then have the clinical understanding to be able to 'match' that diagnosis with a code. This leaves 'room' for interpretation bias and miss-match errors. Besides the obvious potential for lack of accuracy and consistency, Clinicians and Data Coders may put patients at risk and endanger patient

care (77). Belzberg H et al (78) recognises the plight of Data Coders, stating that databases "must not demand unrealistic amounts of effort on those responsible for data entry."

Recently, hospital emergency department food allergy data coding has been called into question by a United States study performed by Clark S et al, titled, *ICD-9-CM coding of emergency department visits for food and insect sting allergy* (79). This study reviewed ED patient charts alongside ICD-9-CM patient coding for food allergy and insect sting allergy. This was done to identify if any additional patients could be coded as either food allergy or insect sting allergy from patients who had been previously coded with codes signifying that they were either 'allergy unspecified' or 'other anaphylactic shock' ICD-9-CM codes. The results were startling, as it was discovered that almost fifty per cent of food allergy patients had been excluded by inappropriate coding. Therefore by utilising the allergen specific coding only for these morbidities and co-morbidities, the coders had missed almost half of the food allergy patients (79). Under-representation of food allergy is important for several reasons, namely, allocation of hospital and health care funding to perceived health needs, informing public and health care professionals to educate for greater surveillance, and for promotion of food allergy research and funding determined by significance.

The World Health Organisation (WHO) develop and disseminate ICD tabulars, which are country specific (80). This is part of WHO's International Classification of Health Interventions (ICHI). ICD tabulars are country specific where feasible. For example, in Australia the tabular differs in slight modifications from that of the United States. Therefore the Australian tabular is given the distinguishing postfix of –AM (Australian Modification), while United States is –CM (81). Currently, version (revision) 10 (2010 Edition) (82) ICD is in use and the update version ICD-11 is currently being produced to replace version 10. ICD tabular codes are a rooted tree structured taxonomy with both parent and children relationships (75). ICD-10 is divided into 27 Chapters consisting of categories and sub-categories (blocks, three-character, four-character, and supplementary sub-divisions) (83).

Data Coders assign a Diagnostic Related Group (DRG) to each episode of care. A Principal Diagnosis (PD) is given and co-morbidities or sequelae are added. The abbreviations NOS "Not Otherwise Specified" and NEC "Not Elsewhere Classified" are frequently used where a condition cannot be qualified. The ICD-10 International Statistical Classification of Diseases and Related Health Problems – Instruction Manual (83) raises the importance of Data Coders

to code as specifically as possible before choosing to rely on unspecified coding. Chafen et al points out that there is no uniform definition for food allergy in the tabular (84).

Manifestation of food allergy symptoms can affect individuals differently and to varying degrees, with allergic responses such as urticaria, anaphylaxis, and vomiting (85). There are a variety of symptoms food allergy sufferers may exhibit, which are also shared with other illnesses and therefore make food allergy diagnosis difficult. This is particularly so in an ED setting where clinicians rely predominantly upon case history, visual inspection, and vital signs monitoring such as heart rate, blood pressure, and Electrocardiography (ECG). There is no time to send and receive samples for lengthy diagnostic tests. This is performed for 'stay' patients only.

Worm M et al concur the problematic nature of obtaining data from ICD-10 codes for the epidemiology of anaphylaxis (61). Nevertheless, anaphylaxis due to food allergy appears to be readily clinically diagnosed based upon case history. There is potential for data coder interpretation both at the point of identifying what a clinician has written and how it has been applied to the patient, and at the point of the data coder selecting the appropriate codex ICD-10-AM code that most appropriately describes the clinical diagnosis interpretation. This interpretation aspect of data coding has not been considered as a potential skew of entered data even before it can be analysed. In correlation with this potential for misinterpretation is the potential for clinicians themselves to misdiagnose conditions based upon inappropriate use of terminology and misunderstanding of definitions. Data Coders may not be familiar with some medical terminology synonyms e.g. wheal refers to urticaria. The study by authors Poulos et al recognise this as a potential for underrepresentation of anaphylaxis reports (60).

The coding of food allergy based on symptom presentation is problematic and difficult to define in ICD-10. There is no ICD code directly stating 'food allergy' as a coded condition. The reason is that food allergy, apart from food allergy anaphylaxis, requires diagnostic confirmation or oral food challenge confirmation to identified causality. For example, ICD-10-AM coding for Anaphylactic shock due to adverse food reaction, is designated the code T78.0, which is fairly strait forward, unless a case history cannot determine food as a culprit. In that case, a Data Coder would likely code the PD as T78.2 Anaphylactic Shock, Unspecified. If the primary symptom of the food allergy is urticarial, then the Data Coder may choose L50.0 Allergic Urticaria. However, food allergy can also fall into the category of T78.4 Allergy, Unspecified.

Patient information is de-identified by use of the ICD tabular. Queensland Health Hospital & Health Services Data Coders employ the use of 3M Coder Software to enter ICD data. Queensland Hospital admittance data is collected by Queensland Hospital Admitted Patient Data Collection (QHAPDC) system and emergency department data collected by the Emergency Data Information System (EDIS) (86).

There are several issues regarding the reliability of extracted hospitalization data 'mined' from central databases and the validity of conclusions reached and their limitations (87). Chafen JJS et al report that a study by Branum AM & Lukacs SL, titled, *Food allergy among U.S. children: trend in prevalence and hospitalizations*, showed that when ICD codes specific to food allergy were excluded the resultant data was no longer statistically significant (84). These kinds of limitations are revealed in the study by Poulos et al that from 1997-2001 the number of deaths caused by allergic conditions had remained relatively constant, according to their analysis. The number of deaths caused by allergic conditions doubled between 2002-2004 (60). However, food related allergic conditions occasioning death made up only a component of the total deaths by allergic conditions. Out of 106 deaths caused by allergic conditions between 1997-2004 only 6 deaths were defined as anaphylaxis involving food (60). The representative number of deaths attributed to anaphylaxis involving food could be much higher than represented under this recorded definition as it may have been included in other definitions of conditions of death, but not specified as food related. Worm M et al (Causes and risk factors for anaphylaxis) express concern that ICD-10 codes for defining anaphylaxis events do not provide sufficient scope to include relevant well-defined co-factors.

It is noteworthy that the Poulos et al reflects only hospitalisations in Australia and as the author points out does not account for "treatment of allergic conditions in the emergency department of hospitals, unrecognised conditions, treatment by general practitioners, successful treatment elsewhere, spontaneously resolved cases, or death on the way to hospital." (60).

During the analysed time periods in the study by Poulos et al (60) the data coding guidelines ICD-9-CM was out dated by the newest version, ICD-10-AM. There appears to be no attempt by the authors to reconcile or compare differences between tabulars. Furthermore, Data Coders who interpret the data from patient charts, given the definitions of clinician's recordings on the patient charts, assign clinical diagnosis to definition codes found in the codex (currently ICD-10-AM).

Jette N et al (81) recognises that due to the difference in country specific ICD modifications, comparison of international data is problematic. Researchers will need to bear these differences in mind when utilizing ICD data and contrasting data derived from several countries. Furthermore meta-analyses of food allergy research performed by comparing statistics or trends derived from research preformed in different countries may possess the additional variable of in-compatible underlying country specific ICD comparisons.

1.16 Thresholds

Proposed dose thresholds, termed the Eliciting Dose (ED), is the lowest dose that can elicit an allergic reaction in susceptible individuals, have been proposed for several common priority allergens such as peanut, for example. There is debate among researchers attempting to standardise ED thresholds (88, 89).

In Australia, Giovanni A et al (90) report a very low amount of detectable allergen in precautionary labelled foods. The Australian developed precautionary food labelling system is termed VITAL (Voluntary Incidental Trace Allergen Labelling) and was employed for The Allergy Bureau of Australia & New Zealand (ABA) (91, 92). The VITAL process consists of acceptable allergen reference thresholds for common allergens, and a risk matrix (action level grid) to enable manufacturers to determine precautionary labelling based upon assessed cross-contamination. The VITAL system (or process) seeks to encourage manufacturer labelling consistency, basing this on accepted reference allergen thresholds (90).

Taylor SL et al, establishment of Reference Doses for residues of allergenic foods: report of the VITAL Expert Panel, report that VITAL 1.0 allergen reference doses were established based upon statistical dose-distribution models relying upon NOAEL's (No-Observed-Adverse-Effect levels) and LOAELs (Lowest-Observed-Adverse-Effect levels) for each allergen. These assisted establishing Eliciting Doses (ED's). Reference ED's were established for peanut; cow's milk; wheat; soybean; cashew; shrimp; sesame seed; mustard; hazelnut; egg; and lupine (91).

A revision of VITAL 1.0 was performed, dubbed VITAL 2.0, which re-examined ED reference thresholds based upon a survey examining amount of detectable allergen present in

precautionary labelled foods in Australia. This study by Giovanni A et al, found of 128 labelled food product samples tested, tree nut (hazelnut), milk, egg, soy, and lupin did not yield detectable allergen. However, peanut allergen was detected in 7% of these samples. The authors point out that the level of ED peanut allergen may not have been sufficient to have caused an adverse reaction in most individuals (90).

VITAL 1.0 risk management tool recommended that manufacturers, who have performed this tool on their manufacturing process for a given packaged product utilise the precautionary label of 'may be present' (93). Zorzolo GA et al, reveal that in 2008, 65% of Australian packaged products possessed at least 1 precautionary label. Of the 882 products found to have precautionary labels, the most common precautionary label was 'may contain traces of…'. This label statement was highly associated with tree nuts and peanuts (93).

As a consequence of the study by Giovanni A et al (90) & Zorzolo GA et al (93), propounding low levels of detectable allergen in precautionary labelled foods, analysis of the extent of precautionary labelling has led to a revision of VITAL 1.0. The revision determined to raise the ED thresholds to help mitigate perceived overuse of precautionary labelling by manufacturers.

Katrina L A, et al's (94), formulation of VITAL 2.0 provided ED references for 'priority allergens', including: peanut; egg; cow's milk; and hazelnut, in a variety of processed preparations. ED's differed between processed allergenic ingredients. This study derived its data from published clinical oral food challenge studies. Because of the lack of clinical oral food challenge data available for the remaining foods modelled in VITAL 1.0 it appears that VITAL 2.0 revision of ED's applied only to peanut; egg; cow's milk; and hazelnut. Dose-distribution models had to consider variables such as age and dose, health of the individual, and the amount of allergen exposure. Therefore, the models predict that the developed VITAL 2.0 ED's for the selected allergens would not be protective for 1% of the population. This was perceived as an acceptable risk given its variable dependency (94). Thus VITAL 2.0 was able to revise EDs for peanut; egg; cow's milk; and hazelnut, applicable to 1% of the population who may be sensitized (94).

In Australia, Voluntary Incidental Trace Allergen Labelling (VITAL), an industry initiative to formalise PAL based upon scientific evidence for allergen thresholds, performed dose-distribution modelling for PAL recommendations and proposed threshold reactions in 1% of the representative population (ED_{01}). For example, VITAL ED_{01} for peanut protein is 0.2 mg

(10, 95). The Food Standards Code does not recognise ED's when determining mandatory allergen labelling requirements.

1.17 Mandatory Substance Declarations & Labelling Requirements

Undeclared allergen in food for retail sale present a serious health risk to allergic consumers. Label information and interpretation has been associated with perceived level of risk and therefore purchasing behaviour amongst consumers (92, 96). Accurate and complete food label information is a risk management control to assist allergic consumers to avoid potentially contaminated foods (97).

Certain food allergens are of greater concern than others due to their ability to elicit allergic reactions in a larger proportion of the population. These are termed 'Priority Allergens'. Allergens, which require mandatory declaration of their presence, are listed in the Food Standards Code – Standard 1.2.3-4 (41). In general, there are two situations which increase allergen risk to a consumer. The first circumstance occurs when a customer at a food service establishment is provided with incorrect information about the allergen status of a menu item, or an allergen is found in a meal that was specifically requested not to contain that allergen. The second situation is when the label of a packaged food, or information provided in relation to an unpackaged food, does not declare the presence of an allergen that is found in the food.

Standard 1.2.3 - Information requirements – warning statements, advisory statements and declarations in the Food Standards Code requires mandatory declarations of the presence of certain foods or substances in foods which are known to trigger allergy, intolerance or autoimmune conditions. Most food allergies are caused by an adverse, immunoglobulin E (Ig-E) mediated immune reaction to food proteins (3, 41). Once an individual develops an Ig-E-mediated sensitivity to a food protein/s, the presence of this food protein can cause anaphylaxis (5). In addition, some people may present with intolerance to some of these substances. These include: sulphites greater than 10mg/kg; cereals containing gluten, namely wheat, rye, barley, oats, spelt and their hybridized strains, excluding cereals containing gluten present in beer or spirits and alcohol distilled from wheat. For glucose syrups made from wheat starch, gluten protein not exceeding 20 mg/kg and having been refined to remove gluten to the lowest achievable level. Also, crustacea; egg; fish except isinglass from swim bladders used to clarify beer or wine; milk including alcohol distilled from whey; peanuts; soybeans excluding soybean derivatives that are tocopherol or phytosterol, or soybean oil that has been degummed, neutralised, bleached and deodorized; tree nuts (excluding coconuts); and in

addition, sesame (41). The Food Standards Code Standard 1.2.3-4 Mandatory declaration of certain foods or substances in foods prescribes the following allergens/substances: sulphites greater than 10mg/kg; cereals containing gluten, namely wheat, rye, barley, oats, spelt and their hybridized strains, excluding cereals containing gluten present in beer or spirits and alcohol distilled from wheat. For glucose syrups made from wheat starch, gluten protein not exceeding 20mg/kg and having been refined to remove gluten to the lowest achievable level. Also, crustacea; egg; fish except isinglass from swim bladders used to clarify beer or wine; milk including alcohol distilled from whey; peanuts; soybeans excluding soybean derivatives that are tocopherol or phytosterol, or soybean oil that has been degummed, neutralised, bleached and deodorized; tree nuts (excluding coconuts); and in addition, sesame (41). Lupin was recently included, to be declared from the 25th May 2018 (41, 98, 99).

The Food Standards Code Standard 1.2.1-8(1)(d) prescribes food that is required to bear a label to include declarations (i.e. as listed in Food Standards Code Standard 1.2.3-4) (41, 100). For food that is not required to bear a label, certain information must be accompanied or displayed with the food or provided to the purchaser on request, in accordance with Food Standards Code Standard 1.2.1-9 (100).

Two types of allergen declarations are applied to food package labelling. These are termed mandatory labelling and voluntary Precautionary Allergen Labelling (PAL) - also called advisory labelling. An example of a PAL declaration is “May contain traces of nuts”. Mandatory labelling is prescribed by legislation, while PAL is voluntarily added by the manufacturer. The Code does not specify the format for displaying mandatory allergens on the product label, other than legibility requirements (100). Therefore, mandatory substance(s) listed in the ingredient list fulfil the Code requirement regarding mandatory substance declarations (Standard 1.2.3-4(1) (41). There is no requirement for manufacturers, importers, wholesalers or distributors to distinguish mandatory allergen wording from other ingredients (e.g. “highlight” or “embolden” mandatory allergen wording), therefore a product label may display a mandatory allergen in the ingredients list only.

Mandatory declaration labelling is prescribed by legislation, while Precautionary Allergen Labelling (PAL) or Advisory Labelling may be voluntarily added by the manufacturer, importer, wholesaler or distributor. PAL is often included as a disclaimer statement to foods suspected

of cross-contamination e.g. “May contain traces of…”. PAL statements are uncertain and do not constitute a firm declaration.

1.18 Undeclared Allergen Food Recalls & Food Categories

Food Standards Australia and New Zealand (FSANZ) coordinates and administers food recalls in Australia (101). Food recalls are a public health intervention to remove food products, suspected of contamination, from sale to the public.

Australian food recall statistics reveal that undeclared food allergens were responsible for the majority (36.7%, n=230 of 626) of food recalls for the previous 10-year period, 1 January 2008-31 December 2017 (102). For the years 2015, 2016 and 2017 these represented 48.1%, 45.8% and 49.3%, respectively (102). The most common undeclared food allergens responsible for food recalls in Australia during this period were dairy (31%), peanut (20%), followed by multiple allergens (15%), wheat/gluten (10%), tree nuts (6%), egg (6%), soy (5%), sesame (3%), sulphites (2%), and fish (2%) (102).

In 2017, undeclared allergens in food accounted for over 49% of food recalls nationally (34 out of 69 recalls). Recalls due to undeclared allergens have increased and since 2013 have consistently been the main reason for recalls (102). Categorisation of foods assists regulatory agencies in monitoring and reporting. Although globally, regulatory agencies differ with food recall grouping categories, typically they include: ‘Processed Foods’; ‘Baked Goods’; and ‘Confectionery’, which are attributed with the highest frequencies of undeclared allergens (103). A comparison of food recall categories for 10 jurisdictions (including Australia), between 2011 to 2014, found aggregated food recall totals of 27% performed for the defined food category ‘Prepared Dishes and Snacks’ and 21% for ‘Cereals and Bakery Products’ (103). For the previous 10-year period (1 January 2008-31 December 2017) the majority of food recalls were for the food categories ‘Processed Food’ (33%, n=76), ‘Confectionery’ (15%, n=34), and ‘Baked Goods’ (11%, n=26), representing over 59% of recalls (102).

1.19 Cross-contamination

Cross-contamination or cross-contact allergens can occur during manufacturing processes when residues or trace amounts of allergen are unintentionally incorporated into a food product. Therefore, Allergen Management strategies are recommended to prevent the

likelihood of cross-contamination. These strategies include, for example, Hazard Analysis and Critical Control Point (HACCP) programs, which includes Food Safety Programs (FSP), segregation of stored products, separation of food preparation areas for “allergen free” meals, effective cleaning, staff training etc. (30).

1.20 Allergen Practice at Retail Food Services in Australia

There is a great diversity of retail food services on offer in Australia. This is due to a host of variables including, but not limited to, type of food service, food offering, structural differences, location, and demographics. The *Food Act 2006* and the *Food Standards Code* regulate food businesses to ensure the mitigation of the sale of unsuitable or unsafe food. Several requirements such as food business licensing, food recall system, Food Safety Supervisors (FSS), Food Safety Programs (FSP), and associated accreditation and auditing, function as controls. A survey of Melbourne food businesses advertising ‘gluten-free’ meals, found the odds of compliance was 75% less for food business that did not provide staff training, and in contrast, for franchised outlets there was a 7-fold increase in compliance (104). Many recent food recalls involving allergens have been linked to imported foods, with approximately a third of recalls in Queensland involving undeclared allergens in imported food. In 2016, the New South Wales Department of Primary Industries conducted a survey to determine allergen awareness of 75 food importers. Survey results indicated that about 80% of importers were aware of the need to declare allergens and reported asking suppliers about ingredients and checking allergen labelling. However only about 60% of inspected businesses could produce evidence that they had checked that the allergen and ingredient labelling of their products was correct (105).

Standard 3.2.2 is of particular relevance to the prevention of allergen contamination during the process of food preparation, storage and display. This standard specifies process control requirements to be satisfied at each step of the food handling process, for example, receipt, storage, display, food recalls. Other requirements, for example, relate to cleaning, skills and knowledge of food handlers and their supervisors (106).

For food allergic or intolerant customers there are two necessities:

1. That accurate communication regarding “allergen free food” be conveyed to the food handler, preparing and delivering food, to ensure that adequate measures are implemented to prevent contamination.

2. That accurate information is conveyed to the consumer about food ingredients via the food handler, product display or label.

Standard 1.2.1 provides provision for communication of food ingredient(s) from the food handler to the consumer – for food not required to bear a label, the declaration may either accompany or be displayed with the food, or provided to the purchaser on request (100). The National Allergy Strategy (NAS) (foodallergytraining.org.au) and A&AA provide food allergy training and resources for food services (allergyfacts.org.au). Links are also available from the ASCIA website (allergy.org.au) (39, 107, 108).

1.21 Regulatory Compliance in Australia

Food labelling is a legislated requirement in Australia, as it is in most countries. This was introduced in Australia and New Zealand in 2003 (90). There is no uniform global mandate for disseminating and applying universal food labelling laws. However, many countries have regulated ‘priority allergens’ (e.g. peanut) by enacting them into law (109). Package labelling laws are advanced by increases in food allergy incidence (110).

Similar State and Territory regulatory compliance exists due to the overarching *Food Standards Code*, of which Australia is subject to. In Queensland the *Food Act 2006* (*Food Act*) and Queensland State legislation, provides monitoring and compliance enforcement capabilities in relation to food. This legislation applies to all persons except binding the State or a Government owned corporation (s3). State or Government owned corporation exemption also applies to Hospital & Health Services (HHS). This means that State owned facilities such as public schools; hospitals; aged-care facilities; mental health facilities; and prisons, are exempt from the *Food Act* and therefore the *Food Standards Code*. This implies no liability should a food handling issue arise, no fines or prosecution is applicable. If there is a major non-compliance or an incident or complaint arising at a State or Government facility then officers may investigate and make recommendations. However, if it were a retailer or manufacturer, penalties in the *Food Act* may be applied (111).

There are many exemptions and intricacies applied to food labelling within the *Food Standards Code*. Some are specified in the *Food Act* and others in the *Food Standards Code*, also referred to as the *Food Standards Code (the Code)*. The *Food Standards Code* is regulated by Food Standards Australia and New Zealand (FSANZ) (101, 111).

In the *Food Act 2006*, s4(1)(a), food handled or for sale in a State School tuckshop run by a parents and citizens (P&C) association is exempt from labelling. Likewise, s4(1)(b) food handled in a person's home and intended to be given away to a non-profit organisation for sale by the organisation is exempt, for example. Exemptions also applies to the definition given to small packages and food served from assisted display cabinets.

Food legislation is different in each State or Territory of Australia, and is applied differently. Further food labelling exemptions prescribed in the *Food Standards Code* will be addressed in due course. Firstly, examine food labelling in the *Food Act 2006*.

Compliance with the *Food Standards Code* is regulated by the *Food Act 2006*, s39(1)&(2), where there are penalties associated with a person's non-compliance with the *Food Standards Code*. At the time of writing, the *Food Act* prescribes s39 Compliance with the *Food Standards Code "(1) A person must comply with a requirement imposed on the person by a provision of the food standards code in relation to the conduct of a food business or to food intended for sale or food for sale.Maximum penalty – 500 penalty units*

(2) A person must not sell food that does not comply with a requirement of the Food Standards Code that relates to the food.

Maximum penalty – 500 penalty units

The *Food Standards Code* itself does not contain any penalties. The penalties for non-compliance with the *Food Standards Code* and the *Food Act 2006* are contained within the *Food Act 2006*.

Fines or Prescribed Infringement Notices (PINS) can be issued for some offences, while others are prosecutionable, or both. PIN's are issued under the *State Penalties Enforcement Act 1999*. s39(2),(3), and (4) are PIN-able offences. Currently, at the time of writing, these offences 'carry' a penalty unit (PU) of "5" each offence. The cost associated with each PU is

$110 per offence. For example, a breach of the *Food Act 2006*, s39(3) relates to contravention of a section of the *Food Standards Code*, and therefore carries a fine of $550.

Food Standard Code PINS:

QH22239(2) Selling food that does not comply with a requirement of the Food Standards Code that relates to the food.

QH22339(3) Selling or advertising food that is packaged or labelled in a way that contravenes a Food Standard Code.

QH22439(4) Selling or advertising for sale food in a way that contravenes a Food Standard Code.

Enforcement in relation to the *Food Act* is conducted by Authorised Persons appointed by the Chief Executive s168, which includes, but is not limited to:

"(1)(a) a public service officer or employee; (b) a health services employee; (c) a person prescribed under a regulation." In addition, the Chief Executive Officer of a Local Government may appoint:

"(2)(a) an employee of local government; (b) if another local government consents – an employee of another local government; (c) another person under contract to the local government."

Each State or Territory in Australia appoints professionals to carry out food compliance and enforcement activities (112). Foods found to be labelled incorrectly with regard to mandatory warning and advisory statements, a food recall may be enacted by FSANZ in applicable areas across Australia. In QLD, Environmental Health Officers (EHO's) are tasked with surveying retailers and inform Local and State Government stakeholders during food recall's to ensure measures have been taken to remove the affected product from sale. Generally, in Queensland State Government EHO's monitor and enforce food labelling. As mentioned previously each State or Territory has unique food legislation and applies it in slightly different ways. For example, in Queensland food labelling non-compliances are generally enforced by State Government Environmental Health Officers (EHO's), while in Victoria this is enforced by Local Government EHO's. Local Government is also termed Council.

At the time of writing, the *Food Act 2006*, in Queensland, prescribes provisions that are administered by role of either State or Local Government (111). s22 of the *Food Act 2006* provides provisions to be administered by the State only, including s39(2) [s22(1)(a)]:

"(2) A person must not sell food that does not comply with a requirement of the food standards code that relates to the food."

s23 prescribes provisions that are to be administered by Local Government only and includes s39(1) [s23(1)(a)]:*"(1) A person must comply with a requirement imposed on the person by a provision of the food standards code in relation to the conduct of a food business or to food intended for sale or food for sale.*

Maximum penalty – 500 penalty units

However, s25 of the *Food Act 2006* allows for partnership administration between State and Local Government upon chief executive officer and chief executive agreement. Nevertheless, if Local Government does not administer or enforce this Act, the State has provision to action on behalf of Local Government if there is a perceived health risk, s26 of the *Food Act 2006*.

Food safety administrative regulation are governed by Government nutritional health policy; public health directives; State legislative and governance forums on food regulation; the *Food Act 2006* (111); and FSANZ Code (113).

The *Food Act 2006* describes particular definitions of words including the word 'food'. The meaning of 'food' in the *Food Act 2006* includes, but is not limited to, s12(1)(e) water for retail sale and intended for human consumption, and s12(1)(b)&(c) an ingredient or additive, and processing aides. Also, the meaning of 'handling food' (s15); 'manufacture' (s16); and 'sell' (s19) are defined. Of particular note is the definition of 'label', found in Schedule 3 Dictionary of the *Food Act 2006*, which is defined as:

"Label includes: any tag, brand, mark, statement in writing, representation, design or other descriptive matter on or attached to or used or displayed in connection with or accompanying food or a package of food."

This definition allows for provisions in interpreting the word 'label' in *The Act*.

The *Food Act 2006* allows for provisions for offenses in relation to food and some of these may be applicable to food labelling in that they relate to the sale of unsafe food, false descriptions of food, misleading conduct relating to the sale of food, and the sale of unfit packaging or labelling material. There are offences in the *Food Act 2006*, which rely upon the definition of label as stated in the Act.

Most food labelling compliance standards are captured in the *Food Standards Code*. The requirement to comply with a requirement of the *Food Standards Code (The Code)* directs interpretation away from *the Act* to *the Code*. Such as:

"The Food Act 2006, s39(2) A person must not sell food that does not comply with a requirement of the food standards code that relates to the food.

Maximum penalty—500 penalty units

Note— This provision is an executive liability provision—see section 260."

Therefore, once *the Code* is applied, it is defined in accord with the meaning of *the Code* in s14 of The Act:-

Meaning of food standards code:

"(1) Subject to subsection (2), food standards code means the Australia New Zealand Food Standards Code as defined in the Food Standards Australia New Zealand Act 1991. (Refer to Appendix A.) In the Code - Part 1.2 Labelling and other Information Requirements, Standard 1.2.1 Application of Labelling and Other Information Requirements, Clause 1 defines Retail Sale as:

"Food for retail sale means food for sale to the public and includes food prior to retail sale which is –

(a) manufactured or otherwise prepared, or distributed, transported or stored; and

(b) not intended for further processing, packaging or labelling."

The definition of 'retail sale' is important given the many labelling exemptions found in the Code.

Part 1.2, Standard 1.2.1, Clause 2 of the Code states labelling requirements for food for retail sale. (Refer to Appendix A. ii.)

The word "made" from Part 1.2, Standard 1.2.1, Clause 2 – "(C) made and packaged on the premises from which it is sold", is important when interpreting the requirement for labelling foods that are simply cut then packaged for sale at the premises. The exemption that food is 'made' implies manufactured rather than simply 'cutting' food.

Unless the food for retail sale falls under a food label exemption, the food must bear a label setting out all of the information prescribed in *the Code*. For information prescribed in *the Code* for labelling as set out in Appendix A. iii.

Standards 1.2.1-11, when requiring a label on a package always words the requirement that a label is “on a package of food”. Exemptions are provided to enable labelling to be in association with the food, only where a food is not required to bear a label pursuant to clause 2 of Standard 1.2.1. The same requirement applies to Standards 1.2.2-11.

1.22 Food Licenced Premises & Food Recall Procedure

1.22.1 Food Labelling Regulatory Compliance

To mitigate food labelling non-compliance in Australia, each State and Territory possess legislation to regulate and enforce food labelling requirements. In Queensland the *Food Act 2006* (*the Act*) is the prescribed legislation for this purpose (111).

Food labelling mandatory declaration statement requirements are not found in *the Act*, but in *the Code*.(41) The *Food Standards Code* (*the Code*) development and implementation (a mutually recognised agreement between Australia and New Zealand) was adopted as subordinate legislation by both countries. Section 39(2) of *the Act* states that “A person must not sell food that does not comply with a requirement of the *food standards code* that relates to the food.” (111). Therefore, *the Act* directs such compliance to *the Code*. FSANZ administer *the Code* and also manage food recall notifications.

Regulatory and enforcement compliance activities in relation to *the Code*, prescribed under s168, *the Act*, are administered by State Government (111). State Government officers, who have been granted an authorisation under *the Act* by the Chief Executive, perform such regulatory and enforcement compliance activities. Generally, in Queensland, Environmental Health Officers (EHO’s) perform this role. QLD State Government EHO’s are based at Public Health Units (PHU’s). As Authorised Persons, EHO’s perform surveillance of food premises to check packaged food products for retail sale to ensure food labels comply with *the Code*. This includes food label compliance with *the Code*, Standard 1.2.3, s(4) Mandatory Declaration Statement(s) (41). Under *the Act*, Authorised Persons have regulatory and enforcement powers including, for example, Penalty Infringement Notice(s), and Prosecution.

1.22.2 Food Licenced Premises

Food businesses that manufacture and/or sell food are required to hold a current food licence that has been assessed by Local Government (Council). A food licence for a particular

business is required to be displayed at the food premises at all times and the business is subject to a food safety inspection by a food inspector, generally an EHO, at any time during business hours.

1.22.3 Food Recall Procedure

Another requirement of *the Code* is the legal obligations of food businesses with regard to food recalls, under Standard 3.2.2, s12. (106) Here, *the Code* specifies that a wholesale supply food business, a manufacturing food business, or a food importation business must have a written documented system in place to implement a food recall. The food business is required to comply with their recall system when recalling unsafe food. Such a recall is known as a 'Trade Level' recall as it is the recovery of food from distribution that has not yet been sold to customers.

A 'Consumer Level' recall is the recovery of food from consumer possession e.g. retail sale. Consumer Level recall notification can originate from consumer complaints or from the wholesale supplier, manufacturer, or importer.

Food that is subject to a recall is 'food for disposal' under *the Code*, Standard 3.2.2, s11 (106). It must be quarantined by the food business and disposed of. Food recall notifications are communicated to FSANZ from the wholesaler, manufacturer, importer, or complainant. Food recall notifications are then directed to PHU EHO's for dissemination to key stakeholders including: State facilities such as hospital kitchens, or aged-care facility kitchens, for example; Local Government Environmental Health departments; and State School tuck shops run by Parents & Citizens Association (P&C). EHO's also contact and/or investigate selected retailers, wholesalers, importers, and manufacturers who are subject to a recall. This is to ensure that food recall information has been disseminated effectively and that the recalled product has been removed from sale and quarantined for disposal.

1.23 Initiatives - Food Allergy Strategy & Campaigns

The "National Allergy Strategy", hosted by Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy & Anaphylaxis Australia (A&AA) website offers training videos and website information including e-training courses and an app (114). In addition, several projects are described including "Food Services in Hospitals" and "Food Allergy Prevention".

Awareness, education, prevention and management of food allergy form the basis of these resources.

Located on a separate but linked web page is the “Food Allergy Aware” website, which shares resources with the “National Allergy Strategy” website (114). This website is a composite of resources from each of the partnered organisations, layered in sections that pertain to different industries, for ease of navigation. The splash page is telling in that it consist of four sections: 1. “Food Allergy Education”; 2. “Resources for Food Services”; 3. “Resources for the Community”; 4. “Resources for Schools and early childhood education and Care (ECEC)”; 5. “Resources for Health Professionals”.

“Food Allergy Week” is an awareness initiative by the organisation Allergy & Anaphylaxis Australia (A&AA) (115). The 24th-30th of May each year is designated by the organisation to raise awareness food allergy and food allergy sufferers and raising of funds. Typically, it encourages participants to share promotional material at the workplace and paint one fingernail as a talking point. Celebrities promote the initiative to further the campaign.

1.24 Australian Food Allergy Organisations, Tools & Resources

There are a variety of organisations and initiatives that government and non-for profit and business organisations have developed to assist consumers and the food industry in combating food allergy (30). These include resources such as Guides, Fact Sheets, Cards, Websites and apps.

In an attempt to simplify food labelling requirements for retailers, QLD Government has produced a summary document to guide food businesses, titled: Label Buster – A Guide to the Food Standards Code labelling requirements for food businesses (116).

There are several prominent organisations within Australia that endeavour to educate and promote food allergy management and compliance. Notably these include:

- Australasian Society of Clinical Immunology and Allergy (ASCIA) (43).
- Allergy & Anaphylaxis Australia (A&AA) (39).
- Allergen Bureau (117, 118).

Australasian Society of Clinical Immunology and Allergy (ASCIA) is a peak professional body in Australia providing information and best practice for schools, patients and clinicians, based upon current research. Its website includes allergy and anaphylaxis resources for health practitioners and clinicians for a host of allergic reactions including food allergy (3).

Allergy & Anaphylaxis Australia (A&AA), a non-for-profit organisation, is a one-stop shop for the wider community to obtain information about food allergy and its management including treatment for anaphylaxis, resources, news and alerts. In addition, food allergen cards are available to assist food businesses with allergen management, particularly to assist with determining hidden allergens (119, 120).

A USA article titled: *Real-time Consumer Recall Communications needed*, highlighted the importance of timely communication of adulterated foods as a public health initiative in the prevention of disease (121). It further details that the USA's CDC (Centre for Disease Control & Prevention) estimates under reporting of deaths due to adulterated food at 30 times the reported 3,000 cases per annum (121).

According to a Deloitte, a mobile device customer survey of Australians performed in 2015, approximately 15 million Australians (79% of the population) own and use a smart phone, collectively, more than 440 million times per day (122). Deloitte also found that 59% of Australians have access to a tablet device (122). Therefore, a significant proportion of the Australian population are mobile device active and given that the Deloitte study was published in 2015, it is anticipated that a far greater number of people are now utilising mobile devices and applications for everyday use.

There are a variety of food safety and food product information apps on the Australian market, the most comprehensive food information app is the GS1 GoScan app (123). However, this app does not include food product recall notifications. Likewise, an Australian coeliac disease and gluten intolerance app called FoodSwitch, developed by Bupa and The George Institute, is a bar code scanning information app that does not incorporate food recall notifications (124). Several studies regarding food interventions and app usage have been published both overseas and in Australia, for example, A case study of the Milk Man app (125); A pilot study

of the Recaller app (126). Yet, no published studies could be found regarding food recall app use in Australia.

Food recalls are disseminated by the Federal Government agency FSANZ and posted on the FSANZ website (102) sent to public health agencies at State, Territory and Local Government for action (112). FSANZ food recalls are also published on the Australian Competition & Consumer Commission (ACCC) website, along with a mix of other types of recalls are also available on the ACCC app (127). Some food recalls are incorporated into websites as feeds e.g. Allergy & Anaphylaxis Australia website. The Australian Government's ACCC website also displays food recalls along with non-food recalled products (128). Food Standards Australia & New Zealand (FSANZ) Australian Government website is a dedicated food safety website that displays food recall notifications (102). Nevertheless, FSANZ does not offer consumers a dedicated food recall notification app. The majority of food recalls are due to undeclared allergens on package labels (102). This is significant given that it is expected that a large Australian customer base having food allergies are members of Allergy & Anaphylaxis Australia (A&AA). These depend upon up-to-date or real-time alert level information for potentially life-saving information. Yet, mobile device food recall notification applications are lacking in Australia. In addition, there is no research to suggest the effectiveness of food recall information from mobile devices and how this information may be influence user experience.

1.25 Food Allergy Health Burden & Economic Impact

Food allergies have emerged as an increasing Public Health problem in recent years. A comprehensive 2007 Report commissioned by the Australasian Society of Clinical Immunology and Allergy (ASCIA), titled, *The Economic Impact of Allergic Disease in Australia: not to be sneezed at* (51) presents statistical analysis of both the increase incidence and economic impact of allergies in Australia. The cost burden of all allergies to Australian society was estimated at $29.4 billion p.a. in 2007 and is characterised by factors such as lost wellbeing and productivity, for example (51).

Food allergy-related financial costs vary from country to country and depend upon variables such as the predominant food allergy. It follows that where a certain type of allergy is most common, the associated costs with that allergy will be higher. For example, in Finland, a cost study analysed infant allergic disease and found that cow's milk allergy was the most expensive allergy for that society (129). In Denmark, the most common childhood food

allergies are to egg, peanut and milk (14). A prevalence study performed in Lithuania found the most common food allergy amongst children to be hazelnuts and milk (69).

Most children tend to overcome childhood food allergies by the age of 3-5 years.(28) This observation suggests developmental changes to the immune system as a child grows. Satya N & Keet C (8), cite that by the age of 16 years approximately 80% of children outgrow milk allergy and approximately 70% outgrow egg allergy.

A UK study by Miles S et al (66), titled, *A framework for measuring costs to society of IgE-mediated food allergy* recognise the importance of attempting to measure the cost of illness (COI) for food allergy (Refer to Table 2. Matrix of types of cost of food allergy by stakeholder).

Table 3: Matrix of types of cost of food allergy by stakeholder, from Miles et al, A framework for measuring costs to society of IgE-mediated food allergy. (Miles S, Fordham R, Mills C, Valovirta E, Mugford M. A framework for measuring costs to society of IgE-mediated food allergy. Allergy. 2005;60(8):996-1003.) (66).

	Consumers		Carers and proxy carers				Industry and employers		
	Individual	Household	Parents and other friends and relatives	Community and voluntary sector	Education sector	Health services	Food industry	All employers	Regulators and enforcers
Direct costs	Out of pocket expenses. Self-care	Out of pocket expenses	Informal care	Outreach and social care	Attendance in class. School and college programmes for allergy and food education	Hospital and primary care	Loss/gain of market	Lost output from affected workers	Inspection and monitoring
Indirect costs	Loss of education and income from employment	Housekeeping costs	Loss of income from employment		College, school and nursery organization	Public health campaigns	Costs of regulation. Costs of adaptation to market forces		Drafting, debating, consulting researching
Intangible costs	Quality of life	Quality of life	Quality of life				Consumer perceptions of products	Employee morale	Public opinion, public safety

The framework proposed identified direct costs, treatment for example; indirect costs, loss of employment, for example; and intangible costs such as quality of life, identified by the Matrix in Table 2 (66).

1.26 Limitations in the literature & Research Perspective

A review of the literature revealed a lack of targeted undeclared food allergen studies in Australia.

Deficiencies were found for food allergen management in Australia, with a lack of available tools and data to support evidence that mobile applications are effective tools for disseminating food recall notifications. There is a lack of mobile applications dedicated to informing food allergic sufferers. The implications of effective mobile device applications for the purpose of assisting food allergy sufferers is unknown. Hence, the development of a dedicated Australian food recall notification application (app) was considered an innovative tool for the Australian population for dissemination of food recall notifications; including undeclared food allergens. Data from the backend of the application could be extracted and analysed to inform important trends in app use.

Conclusion

The literature review defined food allergy and its mechanisms and informed on current understanding of symptom and diagnosis. Common diagnostics include RAST and Skin-Prick Test. Oral food challenge is considered the gold standard of diagnosis and Double-Blind Placebo-Controlled Food Challenge best practice for studies of food allergic individuals. Importantly, it was noted that avoidance is best practice for food allergic individuals and that there is currently no cure for food allergy. Government agencies have reversed previously held infant feeding guidelines to recommendations that parents not withhold foods to infants.

Food Allergy places significant Health Burden & Economic Impact upon Australia's health system and both direct and indirect costs upon individuals and families.

Food allergy prevalence in Australia, including morbidity and mortality, has increased dramatically over recent years and is evidenced by hospitalisation and clinical presentation trends. A variety of theories have been proposed as to why food allergy is increasing, particularly in developed countries, primarily amongst these is the hygiene hypothesis. Undeclared food allergy studies in Australia are limited, particularly for imported food products. This should be further explored.

Food Intolerance, Wheat Allergy, Gluten Intolerance & Coeliac Disease were also examined. The importance of food allergy cross-reactivity and thresholds was noted, particularly in regard to aiding of a better understanding of the innate mechanisms of allergens. The industry based organisation Allergen Bureau has been actively researching in this space to assist food manufacturers. Australian imported food products require analysis to better determine labelling compliance and levels of food allergens, particularly for food allergens of concern in children.

Public perception was reviewed and found that people are turning to web-based information to inform regarding food allergy diagnosis and that public perception is an important consideration as food allergy risk management is dependent upon perceived risk assessment. This was particularly important for food allergic individuals when assessing food labelling. Of particular importance is undeclared allergens and timely consumer notifications. Means for enabling rapid notification should be explored.

Mandatory substance declarations & labelling requirements including precautionary allergen labelling were examined. Importantly, the government agency Food Standards Australia & New Zealand administer the *Food Standards Code* and disseminates and coordinate food recalls for Australian Federal, State and Territory Government agencies to perform regulatory and compliance activities in relation to food recalls and food labelling compliance.

Research regarding food allergy safety practices at Australian retail food services was examined. Cross-contamination of foods was of particular importance in the transmission of food allergens, along with the ability of food service staff to inform customers of ingredients and accurate food labelling. Of particular importance, is food services adherence to regulatory requirements including Food Safety Programs, Food Recall Procedures and Food Licencing for food safety inspections by regulatory enforcement officers such as Environmental Health Officers.

In addition to government agencies, Food Allergy Organisations have produced tools & resources, generally web-based. It was noteworthy that there is a lack of mobile applications dedicated to informing food allergic sufferers. Government agencies also disseminate resources to aid in food safety compliance. These were reviewed. Most prominent organisations in Australia included the Australasian Society of Clinical Immunology and Allergy and Allergy & Anaphylaxis Australia. These have developed and implemented important strategies and programs including, amongst others, the National Allergy Strategy and Food Allergy Week, respectively. Collaborative partnerships between agencies could better assist in consumer adoption of tools. Therefore, partnerships and affiliations should be explored with regard to dissemination of innovative technologies for the purpose of assisting food allergic consumers. No research was identified that shows consumer attitudes with regard to undeclared food allergy information from web-based applications. This should be explored further.

Chapter 2. Undeclared Allergens in Australia

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Abstract

The *Australia New Zealand Food Standards Code* (*the Code*) requires a declaration of the presence of eleven different allergens made through the label on a food product. Most food recalls in Australia are now due to undeclared allergens (46%). This survey determined the extent of undeclared allergens in imported food products on the Asian retail market in Australia.

Fifty imported packaged foods were selectively purchased from four 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). Thirty-seven undeclared allergens (gluten n=12, milk n=12, peanut n=6, and egg n=7) were detected in 23 of the 50 products analysed, with 18% containing multiple undeclared allergens. The high number of undeclared allergens are alarming and in line with the increasing number of food recalls and anaphylaxis recorded in Australia.

2 Introduction

The prevalence of food allergy is increasing globally with Australia having one of the highest incidences of confirmed food allergy among children (130). Results conducted by the HealthNuts study (130) 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 (130, 131).

Food-induced anaphylaxis hospital admissions rose in Australia by approximately 350% between 1997 and 2005 (132). Mullins et al found hospital admission food anaphylaxis rates increasing 1.5-fold over 7 years (2005/6 to 2011/12) (133). In addition, Mullins et al revealed a 10% per year increase in food anaphylaxis admissions in Australia from 1997-2013 (134). Also, hospital fatal food anaphylaxis rates increased by 9.7% per year over the same period (134).

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 (135).

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 (97). Consumer interpretation of label information has been associated with perceived level of risk and consumer behaviour (136, 137). A study from Canada on 1,454 peanut allergic respondents demonstrated that 47% attributed accidental exposure to inappropriate labelling (138). 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 (139). 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 (140). 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 (141).

Food labelling is a legislated preventative consumer confidence measure to assist consumer choice when purchasing food. Consumers rely upon labelled food to provide sufficient information to allow for informed choice. Customers who suffer from a known food allergy or suspected food allergy can read a label and choose to avoid consumption of that food based upon the information provided on the label.

The importance of mandatory food labelling warning and advisory statements and declarations cannot be overstated. A newly introduced precautionary food labelling initiative in Australia known as Voluntary Incident Trace Allergen Labelling (VITAL) attempts to capture potential trace amounts of allergen in foodstuffs, and are important initiatives to heighten consumer awareness (92).

Currently in Australia and New Zealand, there are two types of labelling applied to packaged foods. These are mandatory labelling, which is legislated for, and voluntary precautionary labelling, which is not (90). An example of mandatory labelling requirement for a product containing cashews is to label ‘cashews’ in the ingredients list and also possess a warning statement, such as “Allergy Advice: Contains Tree Nuts”. An example of voluntary precautionary labelling is: “May Contain: Peanuts and Other Tree Nuts”.

Mandatory labelling requirements can be found in the Food Standards Code (113), regulated by the *Food Act 2006* (111). Mandatory labelling requirements are prescriptive requirements. On the other hand, voluntary precautionary labelling is being taken up by manufacturing industry in an attempt to placate potential litigation, and prevent a lack of consumer confidence in their products. Because, precautionary labelling is not mandatory, there it is not applied consistently across manufacturing (94).

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 (142). 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 (143).

Zurzolo et al found that the wording of the precautionary statement made a big difference to consumer perceptions. It was found that 65% of parents of food allergy and food allergy anaphylactic children studied had no regard to the statement “made in the same factory”, while 22% had no regard to the statement “may be present” (144). In an American study by Remington B.C. et al (145) recognised that many products labelled with precautionary labelling: “may contain”, did actually contain high levels of peanut allergen. This is troublesome, as the consumer perception may lean toward a label interpretation that makes the consumer feel it is unlikely that the product would contain the allergen. There is inconsistency among industry in how precautionary labelling is applied, as industry is not regulated with regard to voluntary labelling (90). Consumer frustration, anxiety, and stress have been related to overuse of precautionary labelling, which lessens consumer product choice. Furthermore, there is the risk that staff who assist consumers with food allergen or ingredient information when purchasing non-packaged foods sold by food businesses, may be ill-informed and provide misleading information to the consumer (66). This level of uncertainty may cause stress to consumers.

In a USA study Remington B.C et al found that nutritional bars had the highest levels of detectable peanut allergen, and recommended that nut-allergic individuals should avoid such products altogether, regardless of the precautionary labelling (145). 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 (146). 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 (147).

In Australia, FSANZ also coordinates and monitors food recalls due to contamination (148). 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 (148). Categorisation of food groups enables regulatory bodies, including FSANZ, to partition food recalls for better monitoring and reporting (149).

The Department of Agriculture and Water Resources (DAWR) are responsible for inspection and sampling of imported foods entering Australia in accordance with the *Imported Food Control Act 1992* (Department of Agriculture and Water Resources (150). Under section 8A of the Act it is an offence for a person to deal with food imported into Australia, unless the food meets applicable standards of labelling relating to information on labels for packages containing food, namely *the Code* (150). A penalty of 10 years imprisonment is determined for this labelling offence.

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 (151). 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 (152). 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.

A search of the literature did not find any published study from Australian, focusing on the presence of mandatory labelling of undeclared food allergens in food products. Primarily a PubMed literature search was performed using key search terms. In addition, for Australian specific publications an Author search was conducted. Online searches were performed periodically from Jan 2017 until September 2019. The current study therefore aims to determine the frequency of four undeclared allergens namely, egg; milk; peanut; and gluten for four food categories; 'Mixed and/or Processed Foods'; 'Bread and Bakery'; 'Confectionery'; and 'Non-Alcoholic Beverages'. This study focuses specifically on imported Asian packaged food products for sale in Asian retail grocery stores in Australian. In addition, compliance with mandatory labelling of undeclared substances will be examined. **T**he objective of this study was to quantify the frequency of undeclared allergens in selected packaged foods for retail

sale, in Asian grocery stores in Melbourne, Australia and to determine compliance with the Food Standards Code Standard 1.2.3-4 (153).

Materials and Methods

2.1 Food Recall Statistics

Fifty (50) 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 3.

Food products were purchased covertly. That is, without the awareness of sampling for analysis by the retailer. Seventy-three (73) food products in total were selectively purchased, within the same week, from six Asian stores located in Melbourne, Australia. These were purchased on the basis that they were "packaged foods for sale" and be able to be sorted to fit within one of the publicly available FSANZ guidance list of food recall categories: 'Mixed and/or Processed Foods', 'Bread and Bakery', 'Confectionery' or 'Non-Alcoholic Beverages'. These 50 food products were sorted for sampling on the basis of these categories. Sufficient food products were purchased to ensure the desired sampling number could be reached i.e. n=50.

Table 4: Food product categories.[a] (Food Standards Australia and New Zealand. Food Recall Statistics: Federal Government Australia; 2018) (102).

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.

[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' (148).

Allergens were decided by several factors including 1. ELISA kit availability and 2. On the basis of literature review indicating most commonly found food allergens eliciting reactions in Australian children. Gluten was added because of the recent increase in ‘gluten free products’ available in stores due to consumer preference.

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.

2.2 Sample Preparation

Products were photographed. Each food package was representative of one sample and each sample was designated a unique sample identification number. Sample preparation involved homogenization of dry food samples using stomacher bags, transferred and weighed into sterile containers for a representative sample of at least 5g. Samples that were difficult to homogenize such as candies were placed in a freezer at -20°C overnight to freeze solid, prior to homoginization. Liquid samples were decanted into sterile containers for a representative sample of at least 5ml. All samples were labelled with the corresponding original packaging identification number. Care was taken to prevent cross-contamination utilizing disposable consumables and extraction performed under extraction fan in a safety cabinet.

2.3 Enzyme-linked Immunosorbent Assay (ELISA) Kits

Enzyme-linked Immunosorbent Assay (ELISA) quantifications performed by R-Biopharm RIDASCREEN® test kits (r-Biopharm AG, Darmstadt, Germany). Substances of concern were limited to the following: peanut; egg; milk; and gluten. ELISA was performed for each sample for each of the afore-mentioned substances.

An automated (Tecan) plate washer was prefilled with Wash Buffer for each kit and performed repeated 250µl/well buffer washes.

Duplicate analysis of each sample was performed for this study. Samples results outside the standard curve required further dilution to attempt quantification within the dynamic range. Positive samples were repeated.

2.4 Peanut Analysis by ELISA

Peanut protein was analysed using RIDASCREEN® FAST Peanut (Art. No.: R6202) methodology & immunoassay test kit. For each sample 1g of extract was weighed in Eppendorf® Tubes. Additional preparation of samples suspected of containing tannin or polyphenol, such as spices (e.g. pepper, paprika) or chocolate had 1g of skim milk powder added prior to extraction. Determination of such additives was based upon label information.

Proprietary Allergen Extraction Buffer (100ml) was prepared by first dissolving any crystals in a water bath at 37°C and diluted with distilled water (900ml). Following, 20ml of heated (60°C) proprietary diluted Allergen Extraction Buffer was added to each 1g sample, or for liquid samples 19ml of heated (60°C) proprietary diluted Allergen Extraction Buffer was added to 1ml of sample. These were mixed intensively and incubated for 10min at 60°C, and shaken. Samples were centrifuged at 2500g for 10min. Proprietary Wash Buffer was prepared by first dissolving any crystals in a water bath at 37°C and diluted 100ml with 900ml of distilled water.

To prevent time drift a pre-plate was filled with 200µl of standards and samples. 100µl of supernatant aliquots dispensed per well in the assay prior to edition of conjugate. Duplicate standards and negative control (Wash Buffer) were pipetted into wells on the 96 well microtitre plate. The plate was gently shaken and incubated for 10min at room temperature. Afterward the liquid was poured out and the plate tapped upside down on absorbent paper three times. After washing 100µl of proprietary Allergen Enzyme Conjugate was added per well, the plate gently shaken and incubated for 10min at room temperature. After washing 100µl of prepared proprietary Substrate/Chromogen was added per well, the plate was mixed gently and incubated for 10min at room temperature in the dark. After washing 100µl of proprietary Stop Solution was added per well, the plate gently shaken and read within 10min.

2.5 Egg Analysis by ELISA

Egg protein was analysed using RIDASCREEN® FAST Ei/Egg Protein (Art. No.: 6402) methodology & immunoassay test kit. Proprietary Allergen Extraction Buffer (100ml) was

prepared by first dissolving any crystals in a water bath at 37°C and diluted with distilled water (900ml). For each sample 1g of extract was weighed in Eppendorf® Tubes. Additional preparation of samples suspected of containing fenugreek, cloves, mustard or celery, had 1g of casein powder added prior to extraction.

Following, 20ml of heated (60°C) proprietary diluted Allergen Extraction Buffer was added to each 1g sample, or for liquid samples 19ml of heated (60°C) proprietary diluted Allergen Extraction Buffer was added to 1ml of sample. These were mixed intensively and incubated for 10min at 60°C, afterward allowed to cool down. Samples were centrifuged at 2500g for 10min. 100µl of supernatant aliquots dispensed per well in the assay. Conjugate and Wash Buffer was prepared as follows: Proprietary concentrated Conjugate was diluted 200µl concentrate with 2ml of distilled water. Proprietary Wash Buffer was prepared by first dissolving any crystals in a water bath at 37°C and diluted 100ml with 900ml of distilled water.

To prevent time drift a pre-plate was filled with 200µl of standards and samples. 100µl of supernatant aliquots dispensed per well in the assay prior to edition of conjugate. Duplicate standards and negative control (Wash Buffer) were pipetted into wells on the 96 well microtitre plate. The plate was gently shaken and incubated for 10min at room temperature. Afterward the liquid was poured out and the plate tapped upside down on absorbent paper three times. After washing 100µl of proprietary diluted Conjugate was added per well, the plate gently shaken and incubated for 10min at room temperature. After washing 100µl of prepared proprietary Substrate/Chromogen was added per well, the plate was mixed gently and incubated for 10min at room temperature in the dark. After washing 100µl of proprietary Stop Solution was added per well, the plate gently shaken and read within 10min.

2.6 Milk Analysis by ELISA

Milk protein was analysed using RIDASCREEN® FAST Milk (Art. No.: R4652) methodology & immunoassay test kit. For each sample 1g of extract was weighed in Eppendorf® Tubes. Prior to extraction, additional preparation addition of 0.5g BSA was not necessary as no samples were suspected of containing sunflower seeds, pumpkin seeds or pine nuts.

Proprietary Extraction Buffer (100ml) was prepared by first dissolving any crystals in a water bath at 37°C and diluted with distilled water (900ml). Proprietary Extraction Buffer containing

additive 1 (A-AEP) 15ml of 1M NaOH was added to 1.35g of A-AEP in a glass beaker and stirred until dissolved. A measuring cylinder was pre-filled with 700ml of diluted Allergen Extraction Buffer. To this 15ml of A-AEP was added and the adjusted to pH 9 with 1M HCl. This was then made up to 750ml with diluted Allergen Extraction Buffer. Allergen Extraction Buffer 2 (30ml) was prepared by diluting with distilled water (30ml).

Following, 4ml of proprietary Allergen Extraction Buffer 2 was added to each 1g sample, or for liquid samples 4ml Allergen Extraction Buffer 2 was added to 1ml of sample. These were mixed intensively and cooked for 10min at 100°C in a water bath and allowed to cool. 16ml of heated (60°C) A-AEP was added to the cooked solid samples and 15mls to the liquid samples. Samples were mixed vigorously and placed in a heated (60°C) water bath for 10min extraction. Cooled samples were centrifuged at 2500g for 10min. Finally, sample preparations were diluted 100µl with 400µl of diluted Allergen Extraction Buffer.

Proprietary Wash Buffer was prepared by first dissolving any crystals in a water bath at 37°C and diluted 100ml with 900ml of distilled water. Sufficient Conjugate was prepared at a dilution of 200µl per 2ml of Conjugate Buffer.

To prevent time drift a pre-plate was filled with 200µl of standards and samples. 100µl of supernatant aliquots dispensed per well in the assay prior to edition of conjugate. Duplicate standards and negative control (Wash Buffer) were pipetted into wells on the 96 well microtitre plate. The plate was gently shaken and incubated for 10min at room temperature. Afterward the liquid was poured out and the plate tapped upside down on absorbent paper three times. After washing 100µl of proprietary diluted Conjugate was added per well, the plate gently shaken and incubated for 10min at room temperature. After washing 100µl of prepared proprietary reddish Substrate/Chromogen was added per well, the plate was mixed gently and incubated for 10min at room temperature in the dark. 100µl of proprietary Stop Solution was added per well, the plate gently shaken and read within 10min.

2.7 Gluten Analysis by ELISA

Gluten prolamins (gliadin, secalin, hordein) was analysed using r-Biopharm RIDASCREEN® Gliadin (Art. No.: R7001) methodology & immunoassay test kit.

Proprietary Buffer was diluted 3ml of concentrate per 12ml of distilled water. Sufficient Conjugate was prepared at a dilution of 200µl of Conjugate Buffer per 2ml of distilled water. Proprietary Wash Buffer was prepared by first dissolving any crystals in a water bath at 37°C and diluted 100ml with 900ml of distilled water.

2.8 Additional sample preparation for Gluten extraction

To 0.25g of homogenized meat sausages 2.5ml of Cocktail mixture was added and mixed well. This was necessary to determine gluten content of composite meat as wheat products are often used as binding agents in comminuted meat sausages. For liquid samples 2.5ml of Cocktail mixture was added to 0.25ml of sample and mixed well. For food samples containing soy or quinoa 2.5ml of Cocktail mixture was added to 0.25g of sample, and mixed well. To samples containing tannin and polyphenol (e.g. chocolate, coffee, cocoa, buckwheat, millet and spices) 0.25g of gluten free skimmed milk powder was added, along with 2.5ml of Cocktail mixture and mixed well. To homogenized food samples containing oats 10ml of Cocktail mixture was added to 1g and mixed well. Samples were incubated for 40min at 50°C, allowed to cool and mixed with 7.5ml of 80% ethanol, except oat samples added 30ml of 80% ethanol. Vials were placed on a rotary shaker for 1hr. Samples were centrifuged at 2500g for 10min. Each sample was then diluted 1:12.5 with Buffer?

To prevent time drift a pre-plate was filled with 200µl of standards and samples. 100µl of supernatant aliquots dispensed per well in the assay prior to edition of conjugate. Duplicate standards and negative control (Wash Buffer) were pipetted into wells on the 96 well microtitre plate. The plate was gently shaken and incubated for 30min at room temperature. Afterward the liquid was poured out and the plate tapped upside down on absorbent paper three times. After washing 100µl of proprietary diluted Conjugate was added per well, the plate gently shaken and incubated for 30min at room temperature. After washing 50µl of prepared proprietary Substrate and 50µl of Chromogen was added per well, the plate was mixed gently and incubated for 30min at room temperature in the dark. 100µl of proprietary Stop Solution was added per well, the plate gently shaken and read within 30min.

2.9 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.

Sample analysis occurred between the 2nd of October 2017 and the 6th of October 2017. Analysis was performed at the National Measurement Institute Food Allergy Laboratory, Analytical Services Branch, 1/153 Bertie Street, Port Melbourne, VIC, Australia, 3207.

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 (154-156). 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, (154-156).

R-Biopharm RIDASCREEN® (R-Biopharm AG. Darmstadt. Germany): R-Biopharm; RIDASCREEN® FAST Peanut Art. Nr. R6202, RIDASCREEN® FAST Ei/Egg Protein Art. Nr. 6402, RIDASCREEN® FAST Milk Art. Nr. R4652 and RIDASCREEN® Gliadin Art. Nr. R7001. Supplied by R-Biopharm Australia. 34 Woodfield Boulevard. Caringbah N.S.W.; RIDASCREEN® FAST Peanut Art. Nr. R6202. R-Biopharm AG. Darmstadt. Germany. Refer to Table 4 for R-Biopharm RIDASCREEN® Limit of Detection (LOD) and Limit of Quantification (LOQ).

Table 5: R-Biopharm RIDASCREEN® analysis limits (lower limits) for limit of detection and quantification.[a] (R-Biopharm RIDASCREEN® (R-Biopharm AG, Darmstadt, Germany Supplied by R-Biopharm Australia, 34 Woodfield Boulevard, Caringbah, N.S.W.).

	Peanut (whole peanut) mg/kg	Gliadin (Gluten) mg/kg	Milk (Protein) mg/kg	Egg (whole egg powder) mg/kg
Limit of Detection (LOD)	0.13	0.5 mg/kg gliadin or to 1 mg/kg gluten	0.7	0.5
Limit of Quantification (LOQ)	2.5	2.5 mg/kg gliadin or to 5 mg/kg gluten	2.5	1.0

[a] R-Biopharm RIDASCREEN® FAST Peanut Art. Nr. R6202, RIDASCREEN® FAST Ei/Egg Protein Art. Nr. 6402, RIDASCREEN® FAST Milk Art. Nr. R4652 and RIDASCREEN® Gliadin Art. Nr. R7001.

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. The reason for positive sample retesting was to confirm weak results. 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.

2.10 Quantification

Quantification was performed using a plate-reader with Tecan software and plate reader (Hydroflex model, Tecan, Austria) read at 450nm absorbance. Standard curves were produced in unison with the manufacturer supplied standard curves.

2.11 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.(153) In addition, assessment of English legibility requirements, Standard 1.2.1-24 (157) and for 'hidden allergens', *the Code*, Standard 1.2.4-4 (158) were conducted.

2.12 Statistical Analysis

The risk of detecting undeclared allergens in food products was determined using the generalized linear models (GLM) for binomial family. The statistical method chosen was GLM

for binomial family for assessment of risk profiles. This was deemed an appropriate methodology due to the statistical ability for dealing with a wide range of data with different response variable types such as binomials. Descriptive analysis was used for all results other than risk profiles. 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 ($p<0.05$). All computations were performed using the Stata/MP 13.1 statistical package (StataCorp LP, USA). Refer to Appendix B for data for statistical analysis.

Results

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 4. 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 (159). A total of 37 allergens detected in all, with 18 per cent of all products contained multiple undeclared allergens.

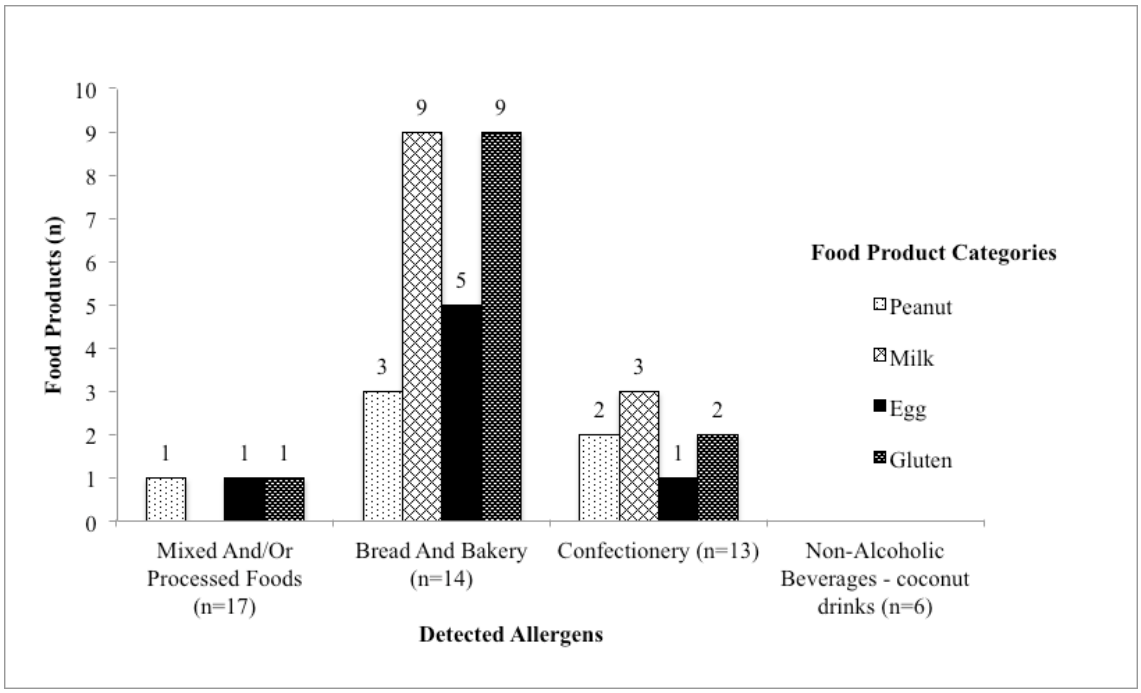

Figure 3: Distribution of detected allergens in food product categories.

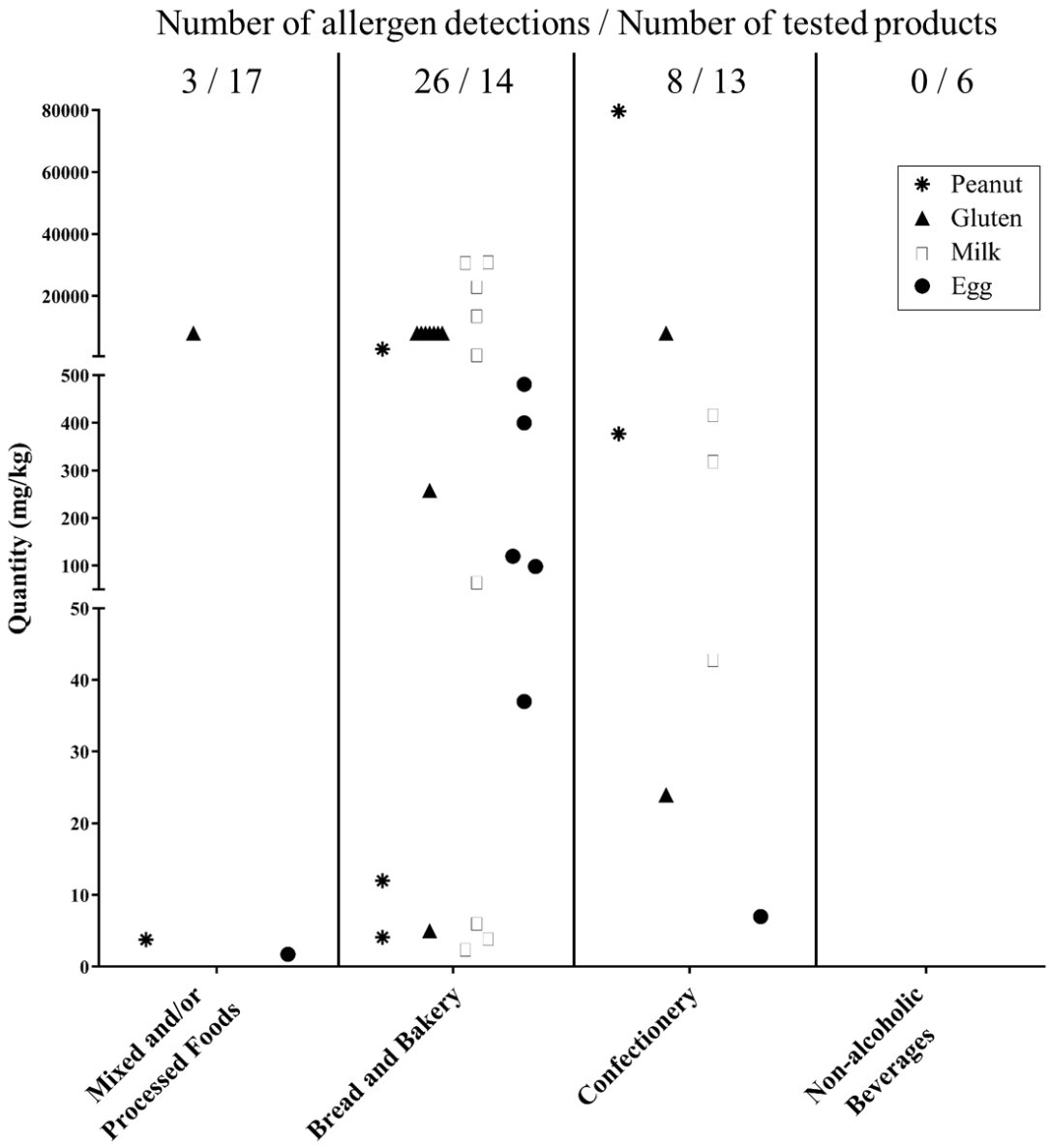

Figure 4: Distribution of detected food allergens within the four food product categories.

The highest number of undeclared allergens was in the category ‘Bread and Bakery’ products for gluten and milk (Figure 5), followed by egg and peanut. The overall risk of detecting undeclared allergens is shown in Table 5, 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 6). Other food categories analysed in this study were also analysed using GLM. However, the most meaningful results were displayed with particular comparison to FSANZ statistics, namely the risk of allergen found in the ‘Bread & Bakery’ category.

P-values were significant with 95% Confidence Intervals. For Undeclared allergen risk profile, Peanut (RR 1.35, p<0, 95% CI 1.3521-1.3538), Gluten (RR 2.19, p<0.001, 95% CI 1.40-3.43), Milk (RR 1.95, p<0.001, 95% CI 1.33-2.84), Egg (RR 1.21, p<0.0, 95% CI 1.215-1.216).

For 'Bread & Bakery' undeclared allergen risk profile. Peanut (RR 0.70, p<0, 95% CI 1.7056-1.7059), Gluten (RR 4.31, p<0, 95% CI 1.94-9.57), Milk (RR 3.44, p<0.002, 95% CI 1.56-7.55), Egg (RR 1.37, p<0, 95% CI 1.37-0.22)."

Table 6: 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

Note: Top 4 undeclared allergens most likely to cause food contamination are: gluten > milk > peanut > egg. The effect size (risk ratio) was determined using generalized linear models (GLM) for binomial family.

Table 7: '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

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.

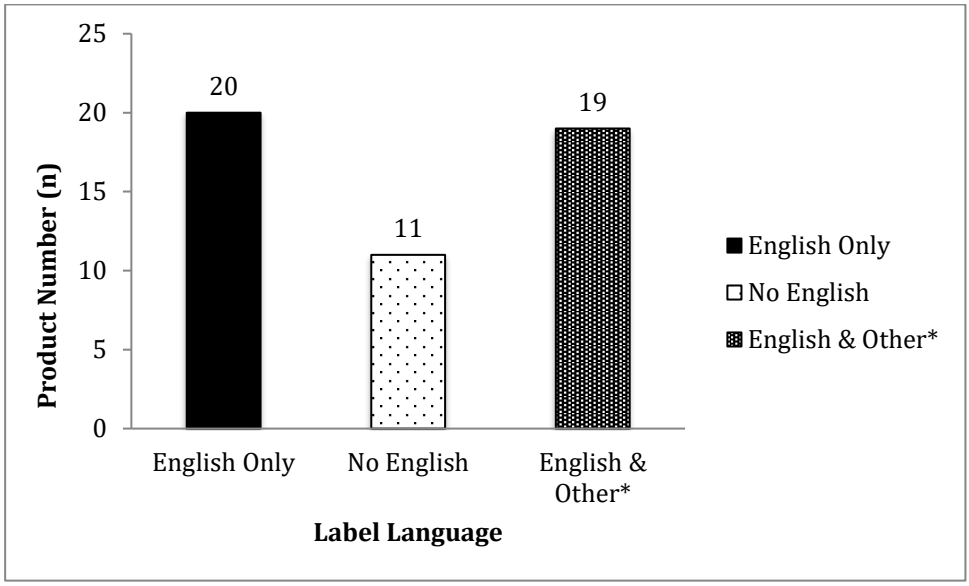

Figure 5: Label language comparison for all samples (n=50).

Note: 'English & Other' refers to a combination of both labelling in English and in a language other than English.

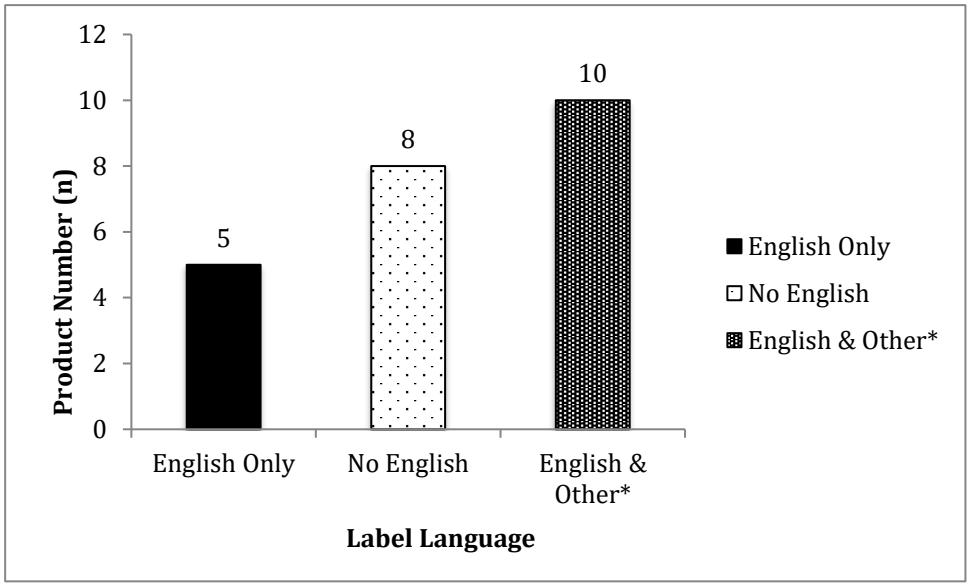

Figure 6: Label language comparison for positive samples (n=23).

Note: 'English & Other' refers to a combination of both labelling in English and in a language other than English.

The highest representation of food products analysed in this study came from China and Thailand followed by South Korea (Figure 8): 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.

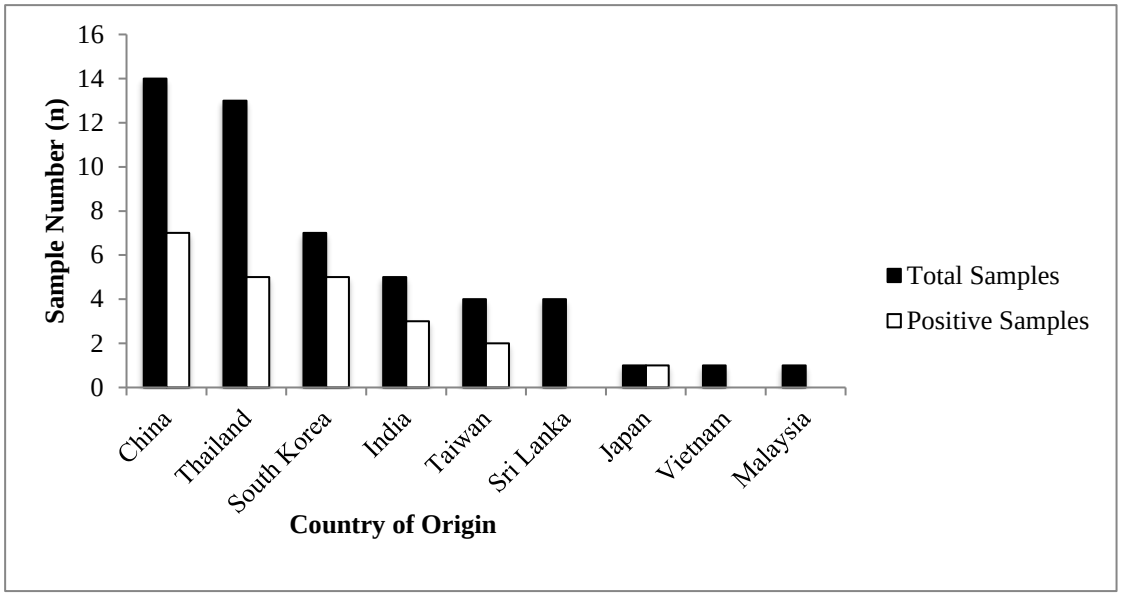

Figure 7: Comparison between total products sampled and products containing detectable allergens by country of origin.

Discussion

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 (153). 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}) (117). These recommendations include 0.2 mg for peanut protein, 0.03 mg for egg protein and 0.1 mg cow's milk protein (160). The "Summary of the VITAL Scientific Expert Panel Recommendations" includes a wheat protein threshold of 1.0 mg (117). It was noted that for wheat-allergic consumers, foods containing <20 mg/kg, would be largely protective (117). 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 5 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.

ELISA systems are the most utilized technique for the detection of food allergens in various food matrices (151). 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 (161).

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 (153). 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}) (117). These recommendations include 0.2 mg for peanut protein, 0.03 mg for egg protein and 0.1 mg cow's milk protein (160). The "Summary of the VITAL Scientific Expert Panel Recommendations" includes a wheat protein threshold of 1.0 mg (117). It was noted that for wheat-allergic consumers, foods containing <20 mg/kg, would be largely protective (117). 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 5 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.

Table 6. 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' (148). Nevertheless, FSANZ statistics include all food recalls for the period, not only undeclared allergen recalls, thus not corresponding to our methodology and findings.

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} (162). Similarly, Ford et al found peanut more likely in products bearing a PAL statement (163). 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 (163). 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} (164). 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 (161). While several studies have been cited for comparison, each differs in its approach, sample size, food category, allergens of analysis, and importation status. Therefore, study comparisons must be made within the scope of this context.

The highest occurrence of undeclared priority allergens for seven regulatory jurisdictions (European Union, USA, Canada, Hong Kong, Ireland, Australia & New Zealand) from 2011 to 2014 was found for ‘Prepared Dishes and Snacks’ (range 12-53%), and ‘Cereals and Bakery Products’ (range 14-25%). In addition, food recall aggregated totals reveal 27% of food allergen recalls were performed for the defined food category ‘Prepared Dishes and Snacks’; 21% ‘Cereals and Bakery Products’, and 9% ‘Confectionery’ (149). These food categories can be considered high-risk for undeclared allergens. A review of the literature, pertaining to this study and performed by the author, found very few comparable studies of high-risk food categories for mandatory undeclared allergens of high-risk food categories for mandatory undeclared allergens. The majority of studies in the literature focus on analysis of priority allergens in PAL packaged foods from high-risk categories.

Australia and New Zealand’s geographical position in the South Pacific means that a great deal of our foods, and increasing amounts, are imported from Asian countries. Furthermore, many foodstuffs can be obtained on-line via postal or delivery services form overseas countries, with differing laws and requirements. This issue was highlighted in a 2011 (unpublished) food labelling project conducted by Maria Toressan, a student of the University of Western Sydney, who sent 24 packaged Asian food products purchased from 4 stores in Townsville to Queensland Health Forensic and Scientific Services Laboratory, for analysis. The results of this study found 50% of analysed samples did not comply with the Food

Standards Code requirement: 1.2.3 Mandatory Warning Statements and Mandatory Advisory Statements. Warning or advisory statements were not included on the product labels for present allergen (165).

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 (166). 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 (153, 157, 167).

In Australia, food for sale is required to adhere to labelling provisions for substances that must be declared in accordance with *the Code* (153). 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 (157, 168). 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 6, while labelling for products found to contain detectable allergens are summarized in Figure 7. 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…” (158). 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 (168) and *Unexpected Allergens in Food* to assist with identifying ‘hidden allergens’ (120, 137, 169, 170). 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.

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 (171). Another survey of 1,355 food products identified that 65% had a PAL advisory statement (172). 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 (172). 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 (152).

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. Further targeted food category and alternate method studies, including larger sample size studies, are necessary to validate these findings, providing important information for regulatory compliance agencies to protect allergic consumers. Media publicity generated by the findings of this study, in December 2019, was

brought to the attention of Australian Government agencies, in particular Food Standards Australia and New Zealand (FSANZ) and the Department of Agriculture and Water Resources (DAWR). Both of which, have responsibilities for imported food safety compliance.

2.13 Acknowledgement

R-Biopharm RIDASCREEN® ELISA test kits were donated for the purpose of this study by Australian branch of r-Biopharm AG, Darmstadt, Germany.

2.14 Informing Government Agencies

Media publicity generated by the findings of this study was brought to the attention of Australian Government Agencies, in particular Food Standards Australia and New Zealand (FSANZ) and the Department of Agriculture and Water Resources (DAWR) in December 2019. FSANZ contacted both the Supervisor and myself, on several occasions, and requested further detailed information and data pertaining to this study for the purpose of following up with importers and distributors of products found to contain undeclared food allergen(s). This information was promptly forwarded to the relevant departments for action.

Chapter 3. Food Recall Innovation Tool

Published In Part:

1. M. Sheridan, A.L. Lopata, (Aug/Sep 2016), Food Australia, *Life Saving Food Recall App*, Vol 68, Issue 4, pp.28-29, Australian Institute of Food Science & Technology (AIFST). ISSN: 1032-5298.

https://search-informit-com-au.elibrary.jcu.edu.au/fullText;dn=611458029034688;res=IELAPA

2. www.FoodRecallAus.com.au website developed and published via www.Weebly.com platform.

3. FoodRecallAus app (application) developed and published via www.Goodbarber.com platform for dissemination via Google Play™ and iTunes® stores.

Publication in Preparation:

1. **Michael John Sheridan**, Erik Biros, & Andreas Ludwig Lopata, *Food recall app user trends: A case study of the FoodRecallAus app*.

Abstract

Australian food recalls have continued to increase over recent years, with a total of 586 recalls between 2005 (January) to 2014 (December), an average of 59 per year. The majority of food recalls are due to undeclared allergens not declared on food package labels. These foods present a serious health risk to allergic consumers as there is no cure for food allergy, so management relies on strict food avoidance.

Food Standards Australia and New Zealand (FSANZ) coordinate and disseminate food recall notifications, including undeclared food allergen recalls. This is achieved via display of food recall notifications on the FSANZ website, including an RSS (Rich Site Summary) feed, and dissemination to government agencies for action. In addition, the *Australian Competition & Consumer Commission* (ACCC) recall app (ACCC Recalls) was found to be the only available application (app) that displays Australian food recall notifications, derived from FSANZ feeds. However, this Australian Government app notifies of all recalls, and therefore is not solely dedicated to food recall notifications, making it difficult for consumers to rapidly assess current food recall notifications amongst the many non-food recalls posted alongside them. A survey of Australian food recall tools revealed limited food recall advice in the form of mobile applications available for consumers.

In 2015, in response to the lack of available mobile device resources dedicated to undeclared food allergen recall notifications, a graphically designed food recall notification app - FoodRecallAus was developed, which was made available for download from the Google Play™ and iTunes® stores. This app incorporated ease-of-use, and aesthetically pleasing integrated aspects for ease of navigation. This innovative tool was developed for the primary purpose of alerting Australian food allergic consumers to undeclared food allergen recall notifications. This is the first and only dedicated food recall notifications app for use in Australia. An accompanying website www.FoodRecallAus.com.au was also developed to complement and advertise the app. Downloads were available for tablet, iphone or android devices. Push notifications were incorporated to instantly alert users to the latest food recalls along with an enabled RSS feed. The FoodRecallAus app gained national endorsement from Environmental Health Australia (EHA) and key partnerships with food safety websites were formed, including Allergy & Anaphylaxis Australia (A&AA) and Food Legal, RIAMS, Nutrition Buff and Environmental Health Australia.

FoodRecallAus app download data was extracted and analysed from the backend of the app platform (www.GoodBarber.com) for the 7th May 2015 - 17th July 2017, with a total of 596 downloads. Linear regression modelling was performed against variables including 129 total food recalls, 63 undeclared food allergen recalls, 7 food recall media publicity events and 8 FoodRecallAus app affiliation and publication events. P-values are significant ($p<0.05$).

A comparison between undeclared food allergen recalls and total food recalls for app downloads showed a correlation between media attention indicated that app downloads increase at first media attention and then drop off over time. It was noted that undeclared food allergens did not usually receive media attention during this period. This research suggests media attention for food recalls increased uptake of the FoodRecallAus app.

3 Introduction

In recent years, food allergy has emerged as an increasing public health problem in developed countries, particularly among children (19, 51). Australia has the highest reported rates of childhood food allergy in the world, estimates as high as 10% (7, 55, 173). From the few Australian food allergy prevalence studies, it is recognised that food allergy morbidity and mortality is rising. Recent Australian hospitalization time trends also reveal an increase in food allergy admission (60).

Mandatory undeclared food allergen, required on packaged food labels, remains the largest cause of food recalls in Australia (148). Food recall numbers have increased in recent years. Between 2005 (January) to 2014 (December) there were a total of 586 recalls, an average of 59 per year. The highest number of recalls was recorded in 2015 with 81 food recalls (148). There has been a steady increase of undeclared allergen food recalls in the last three years, 16 in 2013; 27 in 2014; and 39 in 2015 (148). Between the 7th May 2015 - 17th July 2017, there were 129 food recalls actioned by FSANZ (148); 63 of these included undeclared food allergens and 66 other food recalls (See Appendix D).

In recent years, unfortunate anaphylactic reactions have highlighted the importance of accurate food labelling of mandatory declared food allergens on packaged foods. From August through to November 2015, the Australian Department of Agriculture & Water Resources (DAWR), responsible for food importation compliance (150), were directed to test every imported coconut milk product for undeclared allergen. This generated a spike in food recalls due to the compulsory testing of coconut milk products containing undeclared dairy allergen (food adulteration), with at least 18 imported coconut milk products recalled (148). This increased surveillance of imported coconut products resulted from the unfortunate death of a 10 year old boy in 2013 who consumed a can of coconut juice containing undeclared dairy allergen (174). There was unfortunately a substantial delay between the death of the child and testing of all coconut imports.

In 2015, Australian media highlighted and highly publicised a food recall, known as the ‘Patties mixed berry scare’, which caused public outcry. This recall involved frozen mixed berries imported from China, re-packaged and sold in Australia, and subsequently found to be contaminated with Hepatitis A virus linked to 34 cases of illness in early 2015 (175). This incident highlighted demand for better Country of Origin Labelling (CoOL) (128). As a

consequence, the Federal Government introduced new country of origin food labelling laws to help clarify the current ambiguous labels and assist consumers in making better informed purchase choices (128). These came into force on the 1st July 2016 (176). The Australian media publicity surrounding this scare appeared to play an enormous role in influencing public opinion and consequently government policy.

A USA article titled: *Real-time Consumer Recall Communications needed*, highlighted the importance of timely communication of adulterated foods as a public health initiative in the prevention of disease (121). It further details that the USA's CDC (Centre for Disease Control & Prevention) estimates under reporting of deaths due to adulterated food at 30 times the reported 3,000 cases per annum (121).

According to a Deloitte, a mobile device customer survey of Australians, performed in 2015, approximately 15 million Australians (79% of the population) own and use a smart phone, collectively, more than 440 million times per day (122). Deloitte also found that 59% of Australians have access to a tablet device (122). Therefore, a significant proportion of the Australian population are mobile device active and given that the Deloitte study was published in 2015, it is anticipated that a far greater number of people are currently utilising mobile devices and applications (apps) for everyday use. Hence, the development of a FoodRecallAus app was considered an apt tool for the Australian population for dissemination of food recall notifications; including undeclared food allergens (177).

There are a variety of food safety and food product information apps on the Australian market, the most comprehensive food information app is the GS1 GoScan app (123). This is a barcode scanning information app linked to a comprehensive database with major corporate sponsors. However, this app does not include food product recall notifications. Likewise, an Australian coeliac disease and gluten intolerance app called FoodSwitch, developed by Bupa and The George Institute, is a barcode scanning information app that does not incorporate food recall notifications (124). Several studies regarding food interventions and app usage have been published both overseas and in Australia, for example, *A case study of the Milk Man app* (125); *A pilot study of the Recaller app* (126). Yet, no published studies could be found regarding food recall app use in Australia, due to a lack of app availability with food recall notification specificity.

Australian food recalls are disseminated by the Australian Federal Government agency FSANZ and posted on the FSANZ website (102) sent to public health agencies at State, Territory and Local Government for action (112). FSANZ food recalls are also published on the Australian Competition & Consumer Commission (ACCC) website, along with a mix of other types of recalls, also available on the ACCC app (127). Some food recalls are incorporated into websites as feeds (e.g. Allergy & Anaphylaxis Australia website) and the ACCC website also displays food recalls along with non-food recalled products (128). The FSANZ website is a dedicated food safety website that displays food recall notifications and statistics (102). Nevertheless, FSANZ does not offer consumers a dedicated food recall notification app. The majority of food recalls are due to undeclared allergens on package labels (102). This is significant given that it is expected that a large Australian customer base having food allergies do not have easy access to real-time food recall data to a mobile device.

Food allergic members of Allergy & Anaphylaxis Australia (A&AA) depend upon up-to-date or real-time alert level information for potentially life-saving action. Yet, mobile device food recall notification applications are lacking in Australia. In addition, there is no research to suggest the effectiveness of food recall information from mobile devices and how this information may influence user experience.

Therefore, the development of a dedicated Australian food recall notification application (app) is an innovative tool, for use by the Australian population, for dissemination of food recall notifications; including undeclared food allergens. Data from the backend of the application can be extracted and analysed to inform important trends in app use. Nothing is known of food recall mobile device use in Australia due to lack of research in this field. This present study will inform future research in this space and context and inform the body of knowledge for research performed by FSANZ and other agencies. To the best of our knowledge, this study will be the first of its kind in Australia, and the first globally, to examine food recall app usage. We anticipate that consumer app usage trends mirror official FSANZ notifications and media publications.

<u>The aim of this study is two-fold:</u>

1. To develop an online tool application (app) that enables ease of use and provides up-to-date food recall information for users - FoodRecallAus app (Food Recalls Notification Australia application).

2. To analyse trends in consumer usage of the FoodRecallAus app for the period 7th May 2015 until the 17th July 2017. A comparative analysis and time trends of app downloads in relation to FSANZ official food recall notifications will be made. The target group includes all customers who have downloaded the FoodRecallAus app from either of the (Google Play™ and iTunes®) stores during the afore mentioned period.

This study will determine whether consumer use of the FoodRecallAus app mirrors FSANZ food recall dissemination, how public media reports of food recalls influence consumer use, and how co-branding affiliation impacts app downloads. The proposed research project will assess this gap in knowledge via analysis of food recall app data variables and time trends.

Web-based technology is evolving at a rapid pace, including within the food traceability space. The advent of decentralised apps (dapps) has commenced and brings provenance to the food industry to enable a greater degree of traceability via distributed ledger technology (blockchain technology) (178, 179). However, this present study was performed prior and during this technological advent, which has seen the introduction of distributed ledger technology used for food traceability, and is excluded from this present study.

Method

3.1 Research Approach

In formulating a research approach, the following key research questions were asked:

1. What is the frequency of FoodRecallAus app consumer downloads?
2. How do FoodRecallAus app downloads correlate with FSANZ food recall publications?
3. How do FoodRecallAus app downloads correlate with public media food recall publications?
4. Is there any seasonal variation of FoodRecallAus app downloads, particularly with regard to undeclared food allergen recalls?
5. Is there any association of FoodRecallAus app downloads with co-branding affiliation commencement and/or FoodRecallAus app promotions?
6. Is there a consumer download delay of the FoodRecallAus app post FSANZ and media publication?

3.2 Food Recall Notification App Survey

App store searchers (Apple™ App Store & Google Play™ Store) were performed to ascertain whether there is, at the time of the search, any other website or app that is similar in concept and functionality to the FoodRecallAus app concept.

A search was performed on Google Play™ on the 12th October 2014 for the words “food label” and a separate search for the words “food labelling compliance”. The search for the terms “food label” provided a host of apps. The most relevant apps were apps designed to scan barcodes of products and provide dietary information or consumer choice information. A search was also performed on the Apple™ App Store for the terms “food label” and a separate search for the words “food labelling compliance”. The terms “food label” produced 2 pages of results, none of which appeared to have anything to do with food labelling. The search for the words “food labelling compliance” returned no results.

The following searchers were made on the 12th October 2014 with search term: *“food standards code food labelling app”*, in the Google™ search bar, for the first 10 web pages, with the following relevant results:

i) 'FoodSwitch' app is able "to rate 20,000 packaged food products found in Australian supermarkets" (124).

ii) 'GS1 GoScan' app developed by the "Australian Food and Grocery Council together with not-for-profit body GS1 Australia and industry support. Provides "real time" product data to consumers, including ingredients, nutritional content, RDI information, dietary statuses etc" (123).

In addition, searches were made on the 12th October 2014 (not mentioned in previous search above), with search term: "food labelling app", in the Google™ search bar, for the first 10 web pages, with the following relevant results: Again resulting in the "FoodSwitch" app.

3.3 Correlation between paid and free downloads

Initially, the FoodRecallAus app was offered as a paid application costing AU$1.29 and then increased to AU$1.49. Since the 5th January 2017 the FoodRecallAus app was offered as a free download from the app stores. This was the 727th day the period analysed.

3.4 FoodRecallAus app co-branding affiliations

FoodRecallAus app advertised affiliations and co-branding dates were posted on social media and therefore time-stamped captured via this method.

3.5 FSANZ Food Recall Statistics

FSANZ publish food recall statistics on the FSANZ website (148). These were correlated with app user downloads for the specified time period. In addition, FSANZ publicly displays current and past food recall notifications on its food recalls web page. These are publically available, however for this current study, food recall notification product information has been de-identified.

3.6 Data Extraction, Storage and Security

Data was extracted from the commencement to the conclusion of the FoodRecall Aus app hosting from the backend of the www.Goodbarber.com platform (180) and analysed from

between and inclusive of the 7th May 2015 until the 17th July 2017, 803 days of data. Downloaded data from the backend of the www.GoodBarber.com website provides the total number of downloads per day; Android, iPhone, and Tablet, respectively.

This data was extracted from the FoodRecallAus app hosting backend of www.GoodBarber.com and exported to an Xcel spreadsheet. Access to the app hosting backend was via a username and password known only to The Principal Researcher. Only the HREC, Supervisor, Statistical Analyst and JCU eResearch Director were aware of the data acquisition. Access to files was limited to the Principal Researcher and Statistical Analyst only, as custodians of the data.

3.7 Definitions & Categorization

For the purpose of this study, 'media publicity events' are categorised as events publicised in the Australian television media at a national level i.e. National televised news.

'App advertisements' refers to all displayed FoodRecallAus app advertisements inclusive of social media posts, the accompanying website, blog and corporate video.

'App affiliations' refers to reciprocal co-branding and endorsement affiliations with external organisations with the FoodRecallAus app.

'A publication' refers to the following publication: **M. Sheridan**, A.L. Lopata, (Aug 15, 2016), Food Australia, *Life Saving Food Recall App*, (Aug/Sep 2016), Vol 68, Issue 4, Australian Institute of Food Science & Technology (AIFST) (177).

3.8 Statistical Analysis

Linear Regression models of FoodRecallAus app download rate for total food recalls and undeclared food allergen recalls performed with media publicity and FoodRecallAus app affiliations and publication included in models as a covariate.

Download app total downloads was analysed (not per device e.g. Android). A constant rate of recalls per day was produced and "nil" downloads were excluded. A constant rate of recalls per day was produced and "nil" downloads were excluded for analysis of downloads against variables only. This method of regression analysis was chosen for the elimination of a

relationship between a dependant and independent variable. The results are presented as download rates over time with 95% confidence interval. P-value significance evaluated. Statistical significance was defined at the conventional 5% level ($p<0.05$). All computations were performed using the Stata/MP 13.1 statistical package (StataCorp LP, USA). Refer to Appendices C & D for data statistical data and analysis.

Results

3.9 App Hosting

The app was hosted on the www.GoodBarber.com app platform and an app template was used to generate the app design. Push notifications and an RSS feed was enabled. FoodRecallAus App download data was extracted from the backend of www.Goodbabrber.com app developer website and represents all category downloads including Android, Apple iTunes® iphone and Tablet. Refer to Appendix C for complete list of activities.

3.10 Graphical Design

A commercial graphic designer produced a logo for advertising and displays. Photos were taken of a supermarket isle for use as a backdrop for displays. These images were modified using graphic design software including Adobe Photoshop™ and Illustrator™ CS6 (Refer to Figure 9 Image of App Logo and Backdrop). These images were modified to form the app icon and app splash page backgrounds. The author took the photos and manipulated them using purchased software – the intellectual property rights are those of the author.

Figure 8: Image of FoodRecallAus app logo and backdrop.

3.11 Website Hosting

A www.weebly.com template webpage website was developed with graphically aesthetically pleasing and easy to use tabs containing information relevant to the app (181). Figure 10 shows an image of the www.weebly.com website splash page for the developed website www.foodrecallaus.com.au. The app was advertised via this web-based platform.

Figure 9: Weebly website splash page image for www.foodrecallaus.com.au

The URL (www.foodrecallaus.com.au) was purchased from www.crazydomains.com.au and hosted from the platform (182). Domain Name Services (DNS) were set in www.crazydomains.com.au for use and direction to the www.weebly.com website via a domain pointer.

3.12 QR Code

A QR Code was produced for ease of app use by customers, using a QR Code generator, and this was posted on the website, to enable automatic direction to the app upon scanning (Figure 11).

Figure 10: FoodRecallAus app QR Code.

3.13 Affiliations

The following organisational affiliations were obtained for co-branding. These took effort and negotiation skills over the telephone and via branded correspondences such as emails and letters:

Environmental Health Australia - The FoodRecallAus app gained national endorsement from Environmental Health Australia (EHA) (183); Allergy & Anaphylaxis Australia (39); Nutrition Buff (184); RIAMS (185); Food Legal – AusFoodNews (186); Healthy-Kids Association (187).

3.14 Advertisement & Promotions

FoodRecallAus website buttons with external web-links were enabled for ease of use to external pages. For correspondence via the webpage and app an email address was set up and links embedded on the app and website, along with other contact information and a Contact Form to enable users to directly email for correspondence. Additional features such as Google™ Search Engine Optimisation™ (SEO) was employed via Google™ Adwords™ and Adsense™. A Site Map was added to the website to enable monthly Google™ bot crawls for further website indexation. In addition, a blog was developed and added to the webpage. This was manually controlled. Automated push notifications were activated to enable direct user device notifications and an RSS feed was embedded for food recall posts, enabling users to obtain food recall notification feeds directly from the website.

The website was embedded with social media platforms links for joint posting. These included: Twitter™, facebook™, Linkedin™, Youtube™.

The FoodRecallAus app was promoted widely in Australian including generated media attention: ABC radio interviews; newspaper articles; featured in *Food Australia* journal (177);

magazines (e.g. DUO (188)); via affiliate/endorser mail outs and blog posts. A corporate poster was displayed at Townsville Innovation NQ (iNQ) (189).

3.15 App Stores

The FoodRecallAus website provided links to the online app stores (Google Play™ and iTunes®) for app download. Initially the app was offered as a paid application costing AU$1.29 and then increased to AU$1.49. The app was set to General Rating (G-Rating) on both online platforms. Since the 5th January 2016 the FoodRecallAus app was offered as a free download from the app stores.

3.16 Corporate Video

A corporate promotional video was produced by BlueKino (190) and was embedded in the website: www.FoodRecallAus.com.au and on Youtube™:

https://www.youtube.com/watch?time_continue=1&v=iWvsBUSWPOk

3.17 Downloads and Co-variants

FoodRecallAus app download data was extracted and analysed from the backend of the app platform (www.GoodBarber.com) from the 7th May 2015 to the 17th July 2017 (803 days), with a total of 596 downloads. During this period, 129 food recalls were actioned by Food Standards Australia and New Zealand (148). 63 of these included undeclared food allergens and 66 other food recalls actioned in Australia. During the same period, 7 media presentations regarding those food recalls appeared at a national level. In addition, during this period, the FoodRecallAus app affiliations and publications were published (Refer to Table 7).

Table 8: Number of FoodRecallAus app downloads, food recalls, media publicity and FoodRecallAus app affiliations/advertisements and publication from 7th May 2015 to the 17th July 2017.

App Downloads*	Total Food Recalls^	Undeclared Food Allergen Recalls^^	Food Recalls Excluding Undeclared	Food Recall Media	App Affiliations/Advertisements & Publication

			Food Allergen	Publicity Events	
596	129	63	66	7	8

*Note: App downloads were extracted from the backend of www.Goodbabrber.com app developer website and represents all category downloads including Android, Apple iTunes® iphone and Tablet. Refer to Appendix D for complete list of activities. ^Note: Total food recalls includes multiple recalls for the same product. ^^Note: Undeclared food allergen recalls include multiple undeclared allergens for the same recalled product and are inclusive of products recalled for reasons other than undeclared allergen where undeclared allergen was also a reason for the recall.

Significantly, during the analysed period, 18 of 63 (28.5%) were food recalled products containing coconut, including coconut milk products. Notably, all 7 media publicity events were correlated to food products recalled from major supermarket chains in Australia. Figure 12 identifies app download number over time distribution of media publicity events, while Figure 13 correlates app downloads with app affiliations, advertisements and publication.

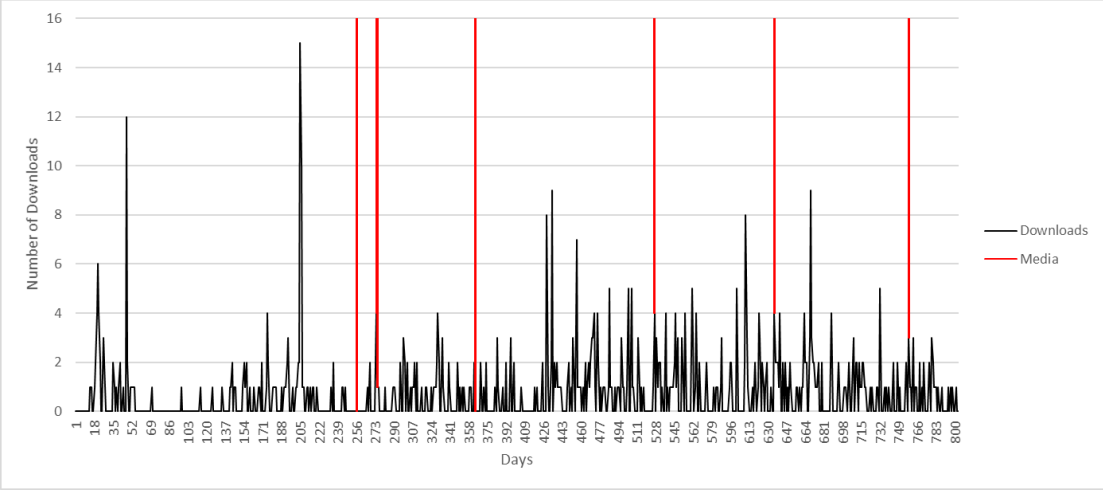

Figure 11: FoodRecallAus app downloads over time correlated with food recall media publicity events. *At 273 days two media events exist at approximately the same time as is shown by a darker red line.

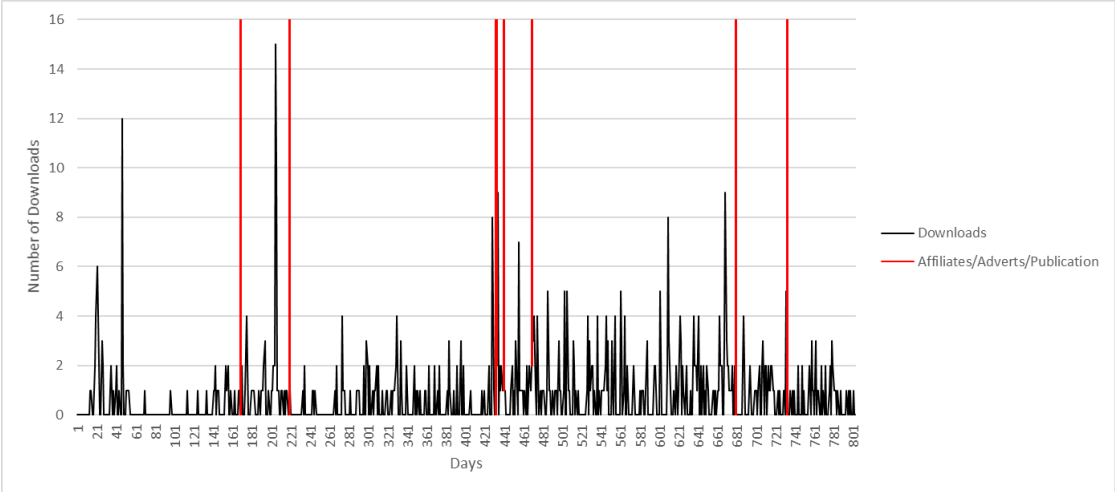

Figure 12: FoodRecallAus app downloads over time correlated with app affiliations, advertisements and publication.

3.18 Linear Regression models

Linear regression modelling was performed against variables including 129 total food recalls, 63 undeclared food allergen recalls, 7 food recall media publicity events and 8 FoodRecallAus app affiliations and publication events.

Table 8 Shows analysis for undeclared allergen food recalls, for FoodRecallAus app download rate against coefficients of media publicity events and FoodRecallAus app affiliation/advertisements and publication with p-values and 95% confidence intervals.

In comparison, Table 9 Shows analysis for food recalls other than undeclared allergen food recalls, for FoodRecallAus app download rate against coefficients of media publicity events and FoodRecallAus app affiliation/advertisements and publication with p-values and 95% confidence intervals. P-values are significant in both instances.

Table 9: Linear Regression Model analysis for undeclared allergen food recalls for FoodRecallAus app download rate against coefficients.

App Download Rate	Coefficient	P-value (p<0.05)	95% Confidence Interval	
Length in days	-0.0825398	0.003	-0.137055	-0.0280246
2016 year	0.0538818	0.893	-0.7306535	0.838417
2017 year	0.3038667	0.417	-0.4304849	1.038218
Constant	1.729286	0	1.089015	2.369558

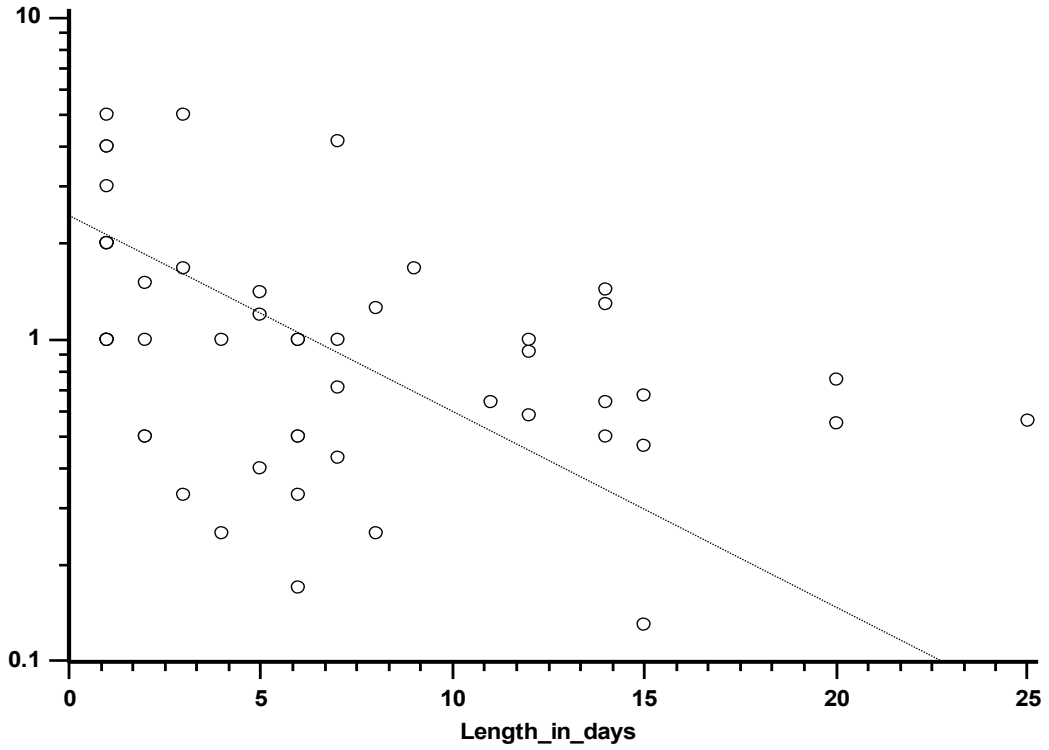

Figure 13: Linear Regression Model of undeclared allergen food recalls for app downloads against variables.

Linear Regression model comparison, between undeclared food allergen recalls and total food recalls for FoodRecallAus app downloads, showed a correlation between media attention indicated app downloads initial increase followed by subsequent reduction over time. This is graphically demonstrated in Figure 14.

This can be compared with linear regression modelling of total food recalls against co-variants and app downloads, for this period, in Figure 15, where it was noted that undeclared food allergens did not usually receive media attention during this period of study.

Table 10: Linear Regression Model analysis for food recalls other than undeclared allergen for FoodRecallAus app download rate against coefficients.

App Download Rate	Coefficient	P-value (p<0.05)	95% Confidence Interval	
Length in days	-0.251685	0.017	-0.0457632	-0.0045739
Media	0.631555	0.032	0.0541135	1.208996
2016 year	0.4222198	0.082	-0.0542798	0.8987194
2017 year	-0.1976677	0.042	-0.6777022	0.2823667
Constant	0.872901	0	0.4228374	1.322965

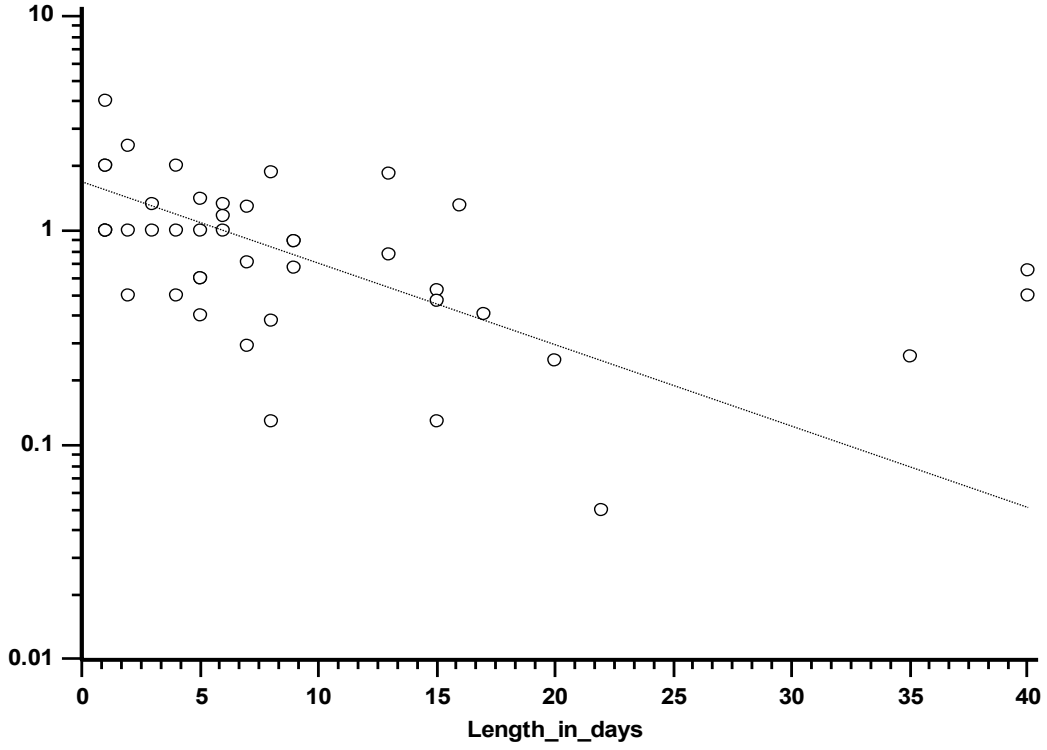

Figure 14: Linear Regression Model of food recalls, excluding undeclared allergen food recalls, against FoodRecallAus app download rate and variables.

Discussion

Timely and effective dissemination of food recall notifications inform consumers of potentially harmful foods, including undeclared allergens in packaged foods. In Australia, Food Standards Australia and New Zealand (FSANZ) coordinate and disseminate food recall notifications, and include public display on the FSANZ website 'Food Recall' web page and on the Australian Competition & Consumer Commission (ACCC) recall application (app) "ACCC Recalls" and web page (112, 127). However, a survey of the Apple™ App Store & Google Play™ Store could not find a dedicated food recall notification app. To the best of our knowledge no research exists regarding consumer access to food recalls derived from applications. This research is the first in Australia.

In response to the lack of available mobile device resources dedicated to the dissemination of timely food recall notifications in Australia, the FoodRecallAus app was developed, Australia's only dedicated food recall notification app. This app was made available for download from the Google Play™ and iTunes® stores and incorporated ease-of-use aspects. An accompanying website www.FoodRecallAus.com.au was also developed to complement and advertise the app. Other features including push notifications and an RSS feed enabled and embedded social media. This innovation delivered food recall notifications direct to consumer mobile devices.

3.19 App Advertising & Endorsements

The app gained national endorsement and key partnerships from food safety organisations including Environmental Health Australia and Allergy & Anaphylaxis Australia (39, 183), amongst others. These affiliations in conjunction with social media posts and garnered media attention, including a publication in *Food Australia* journal, were important app advertisements (177). Analysis of app downloads for this study did not find meaningful correlation between app affiliations and advertisements. It is surmised that this was likely due to narrow and targeted advertisement that did not capture a wide audience. However, broader studies are required to validate these findings.

3.20 Paid vs Free downloads

The FoodRecallAus app was offered as a paid application and then offered as a free download from the app stores on the 727th day of the period analysed. Total period of analysis was 803

days, so this change in user experience was 76 days from the conclusion of the analysed period and was not considered significant time to enable meaningful statistical analysis. Therefore, it is included for reference only. It was observed that the cost of the app, free or otherwise, did not appear to significantly alter the number app downloads. It was observed that the cost of the app, free or otherwise, did not significantly alter the number app downloads. Cost of app in relation to downloads was beyond the scope of this study and analysis was not performed. App cost was not considered in the analysis of the downloaded app data for this study.

3.21 Media attention

There were seven media publicity events for food recall notifications, during the time period of analysis, none of which were due to undeclared allergens. This analysis informed that undeclared allergens do not usually receive media attention. However, broader studies are required to validate these findings. There were a large proportion of coconut product undeclared allergen food recalls during this period and were related to increased surveillance of imported coconut products by DAWR undeclared dairy allergen food adulteration. However, these recalls were not nationally televised in the media and did not form part of the media publicity events for this study.

It was noted that all seven media publicity events were for products for sale at major supermarkets within Australia. This infers that media publicity is skewed on the basis of food recalled products that are widely distributed and therefore consist of a wide consumer base. Broad media publicity appeared to be tailored to wide audiences that may be impacted by the recall, whilst other recalls were generally ignored by the media. Nevertheless, this study did find correlation between media attention and app downloads, which initially increase, followed by a decline over time. Therefore, this research suggests media attention for food recalls increased uptake of the FoodRecallAus app.

Web-based technology is evolving at a rapid pace, including within the food traceability space. The advent of decentralised apps (dapps) has commenced and brings provenance to the food industry to enable a greater degree of traceability via distributed ledger technology. However, the findings of this present study do not detract from the relationship between this leap in technology, but are equally applicable. Future broader studies, are required to validate this relationship.

Research in consumer behaviour of food recall notification app use provides valuable information to the body of research in food allergy and food safety, informs food allergy research into food recalls and consumer confidence, and may benefit targeted public health initiatives. This research likely benefits Government agencies such as Food Standards Australia & New Zealand regarding media and mobile device application influence on food recall dissemination.

3.22 Acknowledgements

Acknowledge for statistical analysis by Dr Erik Biros, College of Medicine and Dentistry, James Cook University, Townsville, Australia.

Chapter 4. Conclusion & Future Directions

4.1 Findings

To the best of our knowledge, this is **the first study to be published of undeclared allergens, from food for sale in Asian retail stores in Australia.**

Mandatory substance declarations & labelling requirements including precautionary allergen labelling were examined in **Chapter 1**. No studies were found in the literature that examined imported foods for sale from Asian retail stores in Australia.

Importantly, the government agency Food Standards Australia & New Zealand administer the *Food Standards Code* and disseminates and coordinate food recalls for Australian Federal, State and Territory Government agencies to perform regulatory and compliance activities in relation to food recalls and food labelling compliance (112).

The present study, presented in this thesis (**Chapter 2**) revealed a high percentage (46%) of imported packaged foods with undeclared allergen with the highest number of allergens detected in the 'Bread and Bakery' category. 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' (148).

The highest number of undeclared allergens was in the category 'Bread and Bakery' products for gluten and milk, followed by egg and peanut. 18% of all products containing multiple undeclared allergens. The overall risk of detecting undeclared allergens was for gluten, followed by milk, peanut and egg. However, the risk was the highest for undeclared gluten in this category, followed by milk and interestingly the lowest risk was for peanut.

The concentration of some allergens, in particular milk, peanut and gluten was over 8,000 mg/kg. Some of the detected undeclared 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.

This present study determined the number of PAL statements on product labels. 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.

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 and 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.

The highest number of detectable undeclared allergens analysed in this study 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.

4.2 Limitations & Recommendations

The following limitations and recommendations are presented for future consideration.

The literature review of food allergy research, examined in **Chapter 1**, indicates that food allergy has risen dramatically in Australian children in recent years, particularly amongst 0-5 year old's and adolescents (2, 133, 134). Milk allergy being the most common childhood allergen in Australia (54, 55). Research literature indicates that for food allergy anaphylactic deaths in Australia, for those over 20 years of age, seafood was the most common trigger, followed by peanuts (133). Future undeclared allergen studies should be targeted in approach to encompass the burden of disease that reflects evidence-based research. It is therefore recommended that future undeclared food allergy studies target foods for allergens of significance based upon current scientific literature.

The scope of analysis of packaged foods for undeclared food allergen analysis should be carefully considered for future studies, as the scope of this studies was limited in its sample size should be increased to provide more meaningful results. This is reliant upon laboratory capacity.

Tailoring sample selection to certain food types within 'high-risk' food categories for common 'priority allergens' of concern, can provide more meaningful results, as evidenced by certain targeted studies such as, for example, analysis of muesli bars for peanut, milk and egg. This again, should be based upon future targeted studies for categories of foods containing undeclared allergens of significance to the allergic community, based upon current scientific literature.

This will inform regulatory compliance agencies for targeted sampling of packaged foods for retail sale. This would include stores selling large quantities of imported packaged foods suspected of lacking labelling compliance e.g. ethnic grocery stores. Finally, further studies to inform Government agencies to support regulatory surveillance and compliance.

4.3 Future Direction

This present study noted the difference between native language labelling in the 'country of origin' and applied English labelling should be further investigated and may require greater governance. Further targeted food category and alternate method studies, including larger

sample size studies, are necessary to validate these findings, providing important information for regulatory compliance agencies to protect allergic consumers.

Media publicity generated by the findings of this study, in December 2019, was brought to the attention of Australian Government agencies, in particular Food Standards Australia and New Zealand (FSANZ) and the Department of Agriculture and Water Resources (DAWR) (101, 150). Both of which, have responsibilities for imported food safety compliance. FSANZ contacted both the Supervisor and myself, on several occasions, and requested further detailed information and data pertaining to this study for the purpose of investigating importers and distributors of products found to contain undeclared food allergen(s). This information was promptly forwarded to the relevant departments for action.

Food Recall Innovation Tool

4.4 Findings

To the best of our knowledge no published Australian research exists regarding consumer access to food recalls derived from applications and therefore, **this research has not been performed in Australia.**

Chapter 1 reviewed Government agency food recall tools and identified Food Allergy Organisations having produced tools & resources, generally web-based. It was noteworthy that there is a lack of mobile applications dedicated to informing food allergic sufferers. Government agencies also disseminate resources to aid in food safety compliance. These were reviewed. Most prominent organisations in Australia included the Australasian Society of Clinical Immunology and Allergy and Allergy & Anaphylaxis Australia.

This present study, presented in (**Chapter 3**), consisted of development, marketing and affiliation of innovative web-based tools for the purpose of obtaining back-end data for analysis. **The FoodRecallAus app was the only dedicated food recall notification app available in Australia.**

This present study found correlation between media attention and app downloads, which initially increase, followed by a decline over time. Therefore, this research suggests media attention for food recalls increased uptake of the FoodRecallAus app. This present research

into food recalls and consumer confidence informs media influenced the behaviour of food recall app users. This research may likely benefit Government agencies such as *Food Standards Australia & New Zealand* (FSANZ) (101) regarding food recall dissemination as well as food allergy sufferers and non-for-profit organisations such as Allergy & Anaphylaxis Australia (A&AA) (39).

4.5 Limitations & Recommendations

The FoodRecallAus App tool was limited in functionality due to several factors. These included:

1. App administrator technical ability. The FoodRecallAus app and website development took a great deal of technical ability, often beyond the abilities of most lab-based researchers. In addition, the scope of technical skills needed for a rudimentary understanding of web-based software includes ability to enable functionality of web hosting, domain names and pointers, RSS feeds, push notifications, administration of web platforms, social media use and linkage, online blogs and links, search engine optimisation and Google™ Adwords™ and Adsense™ and importantly ability to direct apps to the app stores. Finally, graphic design software for aesthetic purposes. It is therefore recommended that future tools be developed through collaborative consultation with experts in the field.

2. Lack of funding for continuation. Funding is an important consideration for the continuation of web-based tools that require yearly payments for hosting and other functions (e.g. domain name platform, web platform for website and app platform). Due to lack of funding the FoodRecallAus app and accompanying website had to be disbanded in 2018.

3. Unwillingness for key partner affiliations (e.g. FSANZ). Government agencies including FSANZ and QLD Health were approached for affiliation, without support other than interest. In this present study no partnership nor Memorandum of Understanding was entered into with any Government agency. Government v's private affiliation is of a different nature. Generally, Government does not support private enterprise, unless there is a transparent process of incorporation. These processes are determined by department priorities and funding. Therefore, unless there is access to Government offered funding for support of a similar project and alignment of interests, it is unlikely Government is willing to be involved. On the

other hand, private entities are generally focused on consumer uptake and will not consider partnership or investment unless there is strong uptake of the application or service.

4. Duration of app analysis. This was limited due to time and financial constraints.

4.6 Future Direction

It is recommended that FSANZ develop and/or adopt a mobile application for dissemination of food recall notifications given the consumer adoption of the FoodRecallAus app, shown by the total number of downloads and due to the correlation between FoodRecallAus app downloads and media attention researched in this present study. Given the rapidly evolving nature of technology and innovation, FSANZ's mere reliance on website-based food recall notifications places consumers at risk, given that timely advice is essential to food allergic consumers.

It is anticipated that in the next few years applications (apps) will be replaced by dapps - decentralised applications, which operate on distributed ledger block chain technology. Therefore, it may be beneficial for FSANZ to research and adopt this technology rather than develop a centralised web-based application, such as an app.

General Conclusion

In conclusion, research activities in this thesis provide valuable insights into undeclared food allergens found in imported packaged foods in Australia, and highlight the need for innovative mobile application tools to better inform food allergic sufferers.

Appendix A. Food Standards Code excerpts

i. Meaning of food standards code:

"(1) Subject to subsection (2), food standards code means the Australia New Zealand Food Standards Code as defined in the Food Standards Australia New Zealand Act 1991 (Cwlth).

(2) In applying the food standards code for this Act—

(a) the code applies with the changes—

(i) stated in schedule 2; or

(ii) prescribed under a regulation made under section 278(2)(a); and

Note— A regulation made under section 278(2)(a) expires 1 year after it is made.

(b) standard 3.2.1, clause 4 of standard 3.2.2, standard 3.3.1 and chapter 4 of the code do not apply."

ii. *Part 1.2, Standard 1.2.1, Clause 2 of The Code states labelling requirements for food for retail sale.*

"(1) Subject to subclauses (2) and (4), food for retail sale must bear a label setting out all the information prescribed in this Code, except where –

(a) the food is not in a package; or

(b) the food is in an inner package not designed for individual sale. Despite this, individual portion packs in a container or wrapper with a surface area of 30 cm² or greater must bear a label containing information in accordance with clauses 3 and 4 of Standard 1.2.3; or

(c) the food is made and packaged on the premises from which it is sold; or

(d) the food is packaged in the presence of the purchaser; or

(e) the food is whole or cut fresh fruit and vegetables, except sprouting seeds or similar products, in packages that do not obscure the nature or quality of the fruit or vegetables; or

(f) the food is delivered packaged, and ready for consumption, at the express order of the purchaser; or

(g) the food is sold at a fund raising event; or

(h) the food is packaged and displayed in an assisted service display cabinet.

(2) Despite subclause (1), food for retail sale must comply with any requirements specified in

(a) subclause 1(2) of Standard 1.2.2 – Food Identification Requirements; and

(b) subclauses 2(2), 3(2), 4(2) and 5(2) of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations; and

(c) Reserved; and

(d) Standard 1.2.6 – Directions for Use and Storage; and

(da) subclause 24(5) of Standard 1.2.7 – Nutrition, Health and Related Claims.

(e) subclauses 4(2) and 4(3) of Standard 1.2.8 – Nutrition Information Requirements; and

(f) subclause 2(3) of Standard 1.2.10 – Characterising Ingredients and Components of Food; and

(g) subclauses 2(3) and 2(4), and clause 3 of Standard 1.2.11 – Country of Origin Labelling; and

(h) subclause 4(3) of Standard 1.5.2 – Food produced using Gene Technology; and

(i) clause 6 of Standard 1.5.3 – Irradiation of Food; and

(j) subclause 4(3) and clauses 5, 6, and 10 of Standard 2.2.1 – Meat and Meat Products; and

(k) clause 2 of Standard 2.2.3 – Fish and Fish Products; and

(l) subclause 3(2) of Standard 2.6.3 – Kava; and

(m) subclause 3(5) of Standard 2.6.4 – Formulated Caffeinated Beverages; and

(n) subclauses 3(1), 3(2), 3(3) and 3(4) of Standard 2.9.4 – Formulated Supplementary Sports Foods."

iii. Food labelling prescribed in *The Code*:

Standard 1.2.1 Application of Labelling and Other Information Requirements

Standard 1.2.2 Food Identification Requirements

Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations

Standard 1.2.4 Labelling of Ingredients

Standard 1.2.5 Date Marking of Packaged Food

Standard 1.2.6 Directions for Use and Storage

Standard 1.2.7 Nutrition, Health and Related Claims

Standard 1.2.8 Nutrition Information Requirements

Standard 1.2.9 Legibility Requirements

Standard 1.2.10 Characterising Ingredients and Components of Food

Standard 1.2.11 Country of Origin Requirements

Appendix B. Undeclared Allergen Statistical Analysis

4.7 Undeclared Allergen Statistical Analysis – Risk by product category.

Table 11: Undeclared allergen risk profile data analysis.

```
Generalized linear models                         No. of obs      =         50
Optimization     : MQL Fisher scoring             Residual df     =         45
                   (IRLS EIM)                     Scale parameter =          1
Deviance         =  38.73862651                   (1/df) Deviance =  .8608584
Pearson          =  25.74980891                   (1/df) Pearson  =   .572218

Variance function: V(u) = u*(1-u)                 [Bernoulli]
Link function    : g(u) = ln(u)                   [Log]

                                                  BIC             = -137.3024
```

alergen	Risk Ratio	EIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
peanut	1.352493	.0001656	2465.41	0.000	1.352168	1.352817
gluten	2.19374	.5026842	3.43	0.001	1.400028	3.437428
milk	1.952285	.3765612	3.47	0.001	1.337709	2.849213
egg	1.215969	.0001489	1596.59	0.000	1.215677	1.216261
_cons	.2894791	.0638844	-5.62	0.000	.1878312	.4461354

Table 12: 'Bread & Bakery' undeclared allergen risk profile.

```
Generalized linear models                         No. of obs      =         50
Optimization     : MQL Fisher scoring             Residual df     =         45
                   (IRLS EIM)                     Scale parameter =          1
Deviance         =  31.67019048                   (1/df) Deviance =   .703782
Pearson          =  27.28286354                   (1/df) Pearson  =  .6062859

Variance function: V(u) = u*(1-u)                 [Bernoulli]
Link function    : g(u) = ln(u)                   [Log]

                                                  BIC             = -144.3708
```

bakery	EIM Risk Ratio	Std. Err.	z	P>|z|	[95% Conf.	Interval]
peanut	.7058079	.0000864	-2844.77	0.000	.7056385	.7059773
gluten	4.311255	1.754141	3.59	0.000	1.942099	9.570532
milk	3.443748	1.381458	3.08	0.002	1.568817	7.559455
egg	1.378119	.0001688	2618.66	0.000	1.377788	1.37845
_cons	.0961495	.0411769	-5.47	0.000	.0415348	.2225777

The highest risk of detecting undeclared allergen in bakery is for gluten > milk > egg > peanut. In other words, the risk of detecting undeclared gluten in bakery is 4.3-times higher than any other undeclared allergen. Similarly, the risk of detecting milk in bakery is 3.4-times higher than any other undeclared allergen, etc.

Important Results:

- Most risky food is:
  - 100% bakery goods (14 of 14) contained undeclared allergen
  - 46% confectionery goods (6 of 13) contained undeclared allergen
  - 18% processed food (3 of 17) contained undeclared allergen
  - 0% coconut goods (0 of 6) contained undeclared allergen
  - There is no association between country of origin and undeclared allergen detected.

Table 13: Food products analysed with labels and raw data results.

Food Name	Store Name	Distributor	Translation of ingredients	English Ingredients	Peanut result	Milk result	Egg result	Gluten result
Granulated Chicken Flavor Soup Base Mix	Southbank Asian Supermarket	Rockman (Australia) Pty Ltd 375-381, Victoria Street Wetherill Park, NSW 2164, Australia Tel: 02 97560088	same as english	Monosodium Glutamate/E621, salt, rice, sugar, spices (chive, garlic, curry powder), disodium 5'ribonucleotide/E635, artificial chicken flavor, vitamin b2	ND	ND	1.75	ND

Not in English	Southbank Asian Supermarket	Not Stated	Noodle: wheatmeal, refined vegetable oil, starch, phosphate ester starch, salt, gluten, egg powder, white sugar, MSG, potassium carbonate, sodium carbonate, sodium tripolyphosphate, calgon, sodium pyrophospahte, xanthan gum, glycerol, phospholipids, sodium caseinate, curcumin, nucleotides disodium, gardenia yellow, riboflavin. Soup pack: water, chilli sauce, saleted and feremented soya paste, refine vegetable oil, butter, spieces, beef catchup (MSG, beef bone extracts, food grade flavours, yeast extracts, beef, burnt sugar, coloring), salt, white sugar, garlic juice extract, bone soup sauce (Chicken bone extracs, beef bone extracts, pork bone extracts, chicken	None/ Not in English	ND	ND	ND	greater than 4000 ppm gliadin or 8000ppm gluten

			oil, edible essence, salt, lard, refinde vegetable oil, MSG, Vitamin E), garlich, salted pepper, chicken seasoning powder (edible essenc, chicken meat, maltodextrin, MSG, salt, chicken bone extracts), seafood seasoning auce, edible alcohol, yeast extracts, spring onion, edible essence, disodium ribonucleotide, beef poweder seasoing sauce, dehydrated korean kimchi, dehydrated pumkin, dehydrated corn, dehydrated spring onion. Note: it contains: wheat products, soy products, egg products, fish products, sesame products, dairy products, may contain prawn, crab, shellfish and peanut					

Blueberry Candy	Southbank Asian Supermarket	Korea Food P/L (Bldg B, 12 Loyalty Rd North Rocks NSW 2151)(53-55 De Havilland Rd Mordialloc Vic 3195)	same as english	Sugar, Corn Syrup, Food acid (330), Blueberry powder 1%, apple powder, artificial flavor (blueberry, cream), food acid *tartaric), grape skin extract.	ND	ND	ND	24 ppm gluten 12 ppm gliadin
Rice Cracker	Southbank Asian Supermarket	Tae Han Food Import Pty Ltd	presumably same as english as the english lable is covering the original lable Produced in a facility that als producres products containing wheat and beef	Rice, suagr, Corn Syrup, Margarine	ND	4.10	n	ND
Mango Pineapple Candy	Southbank Asian Supermarket	A.A International Enterprise Pty Ltd Unit 4/10-12 Thornton Crescent Mitcham Victoria 3132	same as english	Sugar, Maltose (contains barley), palm kernel oil, acidity regulator (E296), flavour, salt, mango extract, pineapple extract, emuslifer (contains soy beans) colour (e102)	ND	419.00	ND	ND

Pineapple	Southbank Asian Supermarket	None/ Not in English	Pinapple white gourds sauce (pinapple paste, malt sugar, sweet potato, white gourds, sugar, palm oil, salt, edible essence, citirc acid), flour, sugar, butter (artificail butter), egg, full cream milk powder, edible essence, beta carotene, powdered soap, potassium sorbate	None/ Not in English	ND	greater than 67.5	481.00	ND
Jiashili Biscuits	Southbank Asian Supermarket	None/not in english	wheat flour, white sugar, vegetable oil, food additives (ammonium Hydrogen carbonate, phospholin, sodium hydrogen carbonate, sodium acid pyrophosphate), salt, strach) It contains wheat and soybean, it may contain peanut, cow milk, sesame and egg products	None/ Not in English	ND	ND	ND	greater than 4000 ppm gliadin or 8000ppm gluten

Shelly Senbei Rice Crackers	KFC Supermarket, Footscray	Imported by: Ettason Pty Ltd, 1 2B Birmingham Ave, Villawood NSW, Manufacturer: I Lan Foods Industrial co ltd Taipei	same as english	Rice, palm oil, sugar, corn, starch, salt, flavour enhancer E621, Gelatin	ND	2.60	ND	ND
Sugar	KFC Supermarket, Footscray	Imported & Distributed by: Lay Brothers Pty Ltd, 23-29 David St Dandenong VIC, Manufactured By: Beijing Hongluo Food Co Ltd, China Time-honored Brand	english lable is correct and contains peanut	Sugar, Maltose Syrup, Sesame, Salt	79692.00	ND	ND	greater than 4000 ppm gliadin or 8000ppm gluten
Candy Sugus Aerated Confections	KFC Supermarket, Footscray	Imported & Distributed by: Lay Brothers Pty Ltd, 23-29 David St Dandenong VIC, Manufactured By: Hong Mao Liuhe	same as english	Glucose syrup, sugar, Cocoa butter replicator, creamer (Glucose syrup, Shortening, Food Additives (Sodium Caseinate, dibasic Sodium Phosphate, Sodium Triphosphate, Glycerol Monostearate, Sodium stearyl lactate, silicone dioxide)), salt, food additives (Edible Gelatin, Glyceryl Monostearate, Flavouring agent, Sodium Citrate, Malic acid, Colouring agents 102, 110, 129, 133, 171.	ND	322.00	ND	ND

Rice Cracker	KFC Supermarket, Footscray	Imported & Distributed by: Lay Brothers Pty Ltd, 23-29 David St Dandenong VIC, Manufactured By: Hangzhou Hongkang Food Co Ltd		Flour, Vegetable oil, salt, sesame, shallot, food additive sodium bicarbonate	ND	ND	ND	greater than 4000 ppm gliadin or 8000ppm gluten
Pen Pen Xiang Mi Gao	KFC Supermarket, Footscray	Imported & Distributed by: Lay Brothers Pty Ltd, 23-29 David St Dandenong VIC, Manufactured By: Guangzhou Hongfeng Foods Co Ltd	same as english	Rice Flour (sticky rice), Sugar, glucose, Water, food additive (calcium propionate)	ND	6.20	ND	ND
Suruchi Sesame chikki	Asian supermarket Footscray	Packed for: P&R Patel Group Pty Ltd, 1/43 Henderson Rd, Rowville, Melbourne	complete lable in english	Sesame (Til), Jaggery, sugar, liquid glucose.	377.00	ND	ND	ND
Hot Chana Dal	Asian supermarket Footscray	Produced & Packaged by: OM Indian Cuisine, 4 Rochdale Square, Lalor VIC	complete lable in english	Chana dal, canola oil, salt, chilli, mixed spices & condiments.	3.80	ND	ND	ND

Kopiko Classic	Asian grocery Footscray	10 Diamond Drive, Sunshine West, Victoria 3020 Australia	same as english	Sugar, Glucose, Vegetable Oil, Coffee extract, Butter, Emulsifier (soy), Caramel colour, salt, coffee flavour	ND	43.00	7.00	ND
Pocky - Matcha Green Tea Flavour (x3)	Asian grocery Footscray	none	Powder, Sugar, palm vergetable oil, milk, lactose, butter. Green tea (from Japan), Emulisfier , natural colour statements: HALAL; Allergy: Braley, Mlik, yellow nuts, oats, almonds	None/ Not in English	ND	31218.00	ND	greater than 4000 ppm gliadin or 8000ppm gluten
Pocky - Strawberry Taste (x2)	Asian grocery Footscray	none	Powder, Sugar, palm vergetable oil, milk, lactose, butter. Green tea (from Japan), Emulisfier , natural colour statements: HALAL; Allergy: Braley, Mlik, yellow nuts, oats, almonds	None/ Not in English	ND	31421.00	ND	greater than 4000 ppm gliadin or 8000ppm gluten
Madhuaseva	Indian Spice World 16a Waterview Walk Docklands Vic3008	Asiatic Importers Pvt. Ltd. 29/11 Bryants Road, Dandenong Vic 3175	complete lable in english	Basin Flour (gram flour), Rice flour, Sugar, Cardamom powder and refined vegetable oil	ND	ND	ND	lower than 5 ppm gluten or 2.5 ppm gliadin

Not in English	Footscray Asian Grocer	not stated	Wheat, cake powder (wheat , sugar, whole egg), canola oil, shortening, beef fat, sugar syrup, glycerin, dreid milk, gold 1, sorbitop, ethanol, corn strach, acid, modified food statch, dextrin, lecithin, flavours (butter, vanilla, palm extract) This product contains: wheat, egg, milk, soybean, peanut and beef	not in english	2864.00	1318.00	greater than 400 ppm	greater than 4000 ppm gliadin or 8000ppm gluten
Green Tea Matcha ---------- (cake)	Footscray Asian Grocer	not stated	Sugar, wheat, sugar syrup, shortening from palm oil, vegetable oil, dried skim milk, coca powder, whole milk powder, whole egg, gelatine from pork, green tea powder, modified strach, dextrine, lactose, flavours (vanilla, milk) colour This product contains: egg, wheat, milk, soybean, beef and pork	not in english	ND	23345.00	120.00	greater than 4000 ppm gliadin or 8000ppm gluten

Real ----------'	Footscray Asian Grocer	not stated	Wheat, sugar, shorteing form palm oil, vegetable oil, vegetable cream, beef fat, whole egg, syrup, sorbitol, dextrine, coca prperation, coca powder, ethanol, mixed dried milk, edible oil, water, falvour (vanilla, butter, wheat), emulsifier, coca mass, pH controler, vegetable oil This product contains: Milk, wheat, soybean, beef and egg	not in english	12.00	14002.00	98.00	greater than 4000 ppm gliadin or 8000ppm gluten
Thai Coconut Roll	Footscray Asian Grocer	LIM Australia Pty Ltd, 10-12 Eileen Rd Clayton Sth VIC	same as english	Coconut Milk, Tapioca Starch, Sugar, Taro, Sesame, Salt, FD&C blue, FD&C red (no preservatives)	ND	ND	37.00	ND
Cashew nut Cookies	Footscray Asian Grocer	Xiao trading pty.,ltd 10 Diamond drive, sunshine west Victoria 3020	.	Cashew nut, sugar, water and sesame	4.10	ND	ND	258.00

Appendix C. Food Recall App and Website Pages

URL

http://www.foodrecallaus.com.au/about-us.html

About FoodRecallAus and Terms & Conditions

FoodRecallAus™ is Australia's Number 1 Food Recall app.
It is the only app in Australia dedicated to disseminating Food Recall Notifications.

'Quick Recall' RSS feeds, 'Food Watch News' RSS feeds, & 'Food Recalls'
'Quick Recall' RSS feeds are derived from © Food Standards Australia New Zealand (FSANZ), as are food recall notifications posted in the 'Food Recalls' section of this app. No modification of food recall notifications derived from FSANZ is performed. FSANZ does not endorse the content of, or is any way associated with FoodRecallAus app.

FSANZ copyright and attribution information can be found at: www.foodstandards.gov.au
Attribution is performed under the FSANZ CC BY 3.0 Licence found at:
http://creativecommons.org/licenses/by/3.0/au/

FoodRecallAus app takes no responsibility for the accuracy or completeness of the information derived from FSANZ or from news stories posted in the 'Food Watch News' section of this app.

Copyright

FoodRecallAus (Australia) app was created in 2015 by Sheridan & Lopata owned under the business name FoodRecall. Australian copyright applies. All Rights Reserved.
FoodRecallAus is an Australian Trade Mark (™) name.

Should an entity or person wish to advertise or affiliate FoodRecallAus or the FoodRecallAus app website: www.foodrecallaus.com.au please contact the authors to gain written permission at: contacts@foodrecallaus.com.au

App Store is a registered trademark of Apple Inc. Google Play is a registered trademark of

Google Inc.

Third Party Information

No third party information is collected from users other than what is necessary for the app to function, except for de-identified app statistical user information, which may be used for research and in publications.

Personal information in the form of information provided via the website's contact for is collected for response to enquiries. www.foodrecallaus.com.au is hosted by www.weebly.com and FoodRecallAus app is hosted by www.goodbarber.com

Update Notifications & Push Notifications

Continual streaming of RSS feeds will occur from FSANZ as new food recall information is posted online. Also, 'Food Recalls' information posted on the 'Food Recalls' tab of this app will continue to update as new FSANZ food recall notifications are posted.

'Food Watch News' media modified food news stories are update to FoodRecallAus app when available via RSS feed. No guarantee is made as to the timing of these updates.

'Food Recalls' section is updated manually and every attempt is made to update this section as soon as practicable after a food recall has been posted on the FSANZ website. It is recommended that customers also check the FSANZ website should there be concerns regarding particular food(s). Every attempt is made to manually update food recall notifications in a timely manner.

Re-builds of app functions may result in delays of updates due to backend functions of app developer being locked while app store submission occurs. Delays of up to 20 days may occur. No refunds may be given.

'Food Watch News'

'Food Watch News' is a collection of Australian food news stories. These are adaptations of news stories in the current media.

FoodRecallAus has incorporated a 'Food Watch News' section. This section is an RSS news feed derived from www.ausfoodnews.com.au, which delivers news updates related to food safety, food industry, and food policy. Permission has been obtained from

www.ausfoodnews.com.au for use of RSS feeds derived from it's website to operate on FoodRecallAus app. FoodRecallAus app has no affiliation with, or between, or endorsement or sponsorship of FN Media and Australian Food News.

'Food Watch News' updates are a complementary add-on to the FoodRecallAus app as they empower consumers by providing timely food news information enabling consumers to make relevant food purchase choices.

Often food recall information is portrayed in the news media in a broader light than food recall notifications and progress further than simply a food recall notification.

For example, a food borne pathogen outbreak from a particular recalled packaged food may progress to Public Health notifications, media stories, political engagement, and pressure from consumer groups. Furthermore, not all foods in the marketplace are represented by food recalls. Food recall notifications are specific to non-exempt (Food Standards Code) packaged foods for retail sale and do not represent primary production (produce). For example, predatory fish for sale in a retail fish and chips store may have ciguatera toxins that may cause health problems if consumed. This example would not be captured in a FSANZ food recall. Hence, Food Watch News updates supplement food recall notifications in informing food safety. Also, note that trade level food recalls are not published on the FSANZ website.

Food Recalls ('Quick Recall' & 'Food Recalls')

FoodRecallAus has incorporated two food recall sections into the app - 'Food Recalls' and Quick Recall'.

This first section, 'Food Recalls', is derived directly from FSANZ food recall website pages. Food recall notifications are not altered in any way and include colour images of the product(s) where provided.

The second section, 'Quick Recalls', is an RSS feed derived from www.foodstandards.gov.au, which delivers food recall notification updates. These appear as brief food recall summaries on the FoodRecallAus app and generally include: the title of the food, the date of the food recall, and a brief description of the reason for the food recall.

Both food recall notification sections of FoodRecallAus app are useful to consumers,

because some consumers prefer the fast reference option 'Quick Recalls' provides, while others prefer the greater detail provided by full 'Food Recalls'.

Advice

Nothing on FoodRecallAus app constitutes legal advice. For food regulation and enforcement enquiries contact your local food safety enforcement agency (e.g. Public Health Unit, Local Government Environmental Health Department). Refer to the FSANZ website at www.foodstandards.gov.au should you wish to obtain detailed information about the Food Standards Code and food recalls. To lodge a food product complaint that may result in a food recall please contact your local food safety enforcement agency and/or refer to FSANZ website.

Designs, Photos & Images

Graphically designed photo images have been taken and developed by the authors of this app. Occasionally, commercial images are purchased from image libraries and stock photo libraries for use.

Who Needs FoodRecall Aus?

http://www.foodrecallaus.com.au/need-food-recall-aus.html

FoodRecallAus is Australia's No. 1 dedicated Food Recall Notification app on the market. It is an essential and convenient tool to enable customers to quickly navigate food recall information in an easy-to-use, stylish and aesthetically pleasing, easily navigable, and easy to read template.

Who Needs FoodRecall Aus:

Concerned Parents

Principal's of Schools

P&C Associations and School Tuck Shop Convenors

Child Care Centre Kitchens

Aged Care Facility Kitchens

Hospital Kitchens

People with Allergies and Intolerances

Food Regulatory Compliance Officers e.g. Environmental Health Officers (EHO's), Public Health Units.

Food Manufacturers, Wholesalers, & Distributors

Restaurant Chefs and Kitchen Staff

Retail Food Outlets e.g. Cafe's

Parents are frequently concerned about potential foodborne illness e.g. bacterial or viral. Rapid notification will enable parents to make informed decisions and take fast action to prevent children from consuming affected product(s).

Parents of children, and adults, with food allergies and intolerances will have access to food recall notification information that empower consumer choices, as some food products are recalled due to undeclared allergens and/or labelling irregularities.

It is important for high risk population customers to be aware of food recall notifications, particularly school tuck shops, child care centre kitchens, as well as aged care facilities, and hospital kitchens. Rapid notification information conveyed to a mobile device will assist timely removal of potentially hazardous or contaminated food from consumption.

Principal's of schools that have a tuck shop, and Parents & Citizens Association's (P&C's) convenor in charge of a school tuck shop, and Team Leaders and Managers of Child Care Centres will benefit greatly by possessing up-to-date food recall information at their fingertips. This will enable school tuck shop kitchen staff and Child Care Centre kitchens to be informed of the need to remove recalled products as soon as possible.

Chefs and Kitchen Staff at restaurants and cafe's and other food retail outlets will benefit by being made aware of potential food safety product hazards, in a timely manner.

This food recall app may assist Manufacturers, Wholesalers, Food Distributors in timely removal of food products from the food distribution chain and thus reduce transportation costs.

Food recall regulatory compliance and enforcement is conducted by State and Territory agencies. These differ between State's and Territories. These are usually Food Safety and

Public Health agencies or Local Government (Council) Health agencies. Generally, Environmental Health Officers (EHO's) in Public Health Units or Local Governments perform the task of following a food recall notification through the trader (e.g. the retail store) to ensure recalled food products are removed from sale and distribution. FoodRecallAus is a handy tool to enable EHO's and other public health professionals, performing compliance activities, to rapidly identify food recall notifications and show consumers and traders the exact food recall notification.

Country of Origin Food Labelling (CoOL)

http://www.foodrecallaus.com.au/country-of-origin.html

Australian Country of Origin Food Labelling such as 'Made in Australia', for example, is a compulsory requirement for packaged food for retail sale and for fruit and vegetables. Packaged food must display Country of Origin Labelling on the label, while Country of Origin Labels may be in association with a display of unprocessed fruit and vegetables.

Country of Origin Food Labelling requirements are found in the Food Standards Code 1.2.11 and apply only in Australia, not New Zealand.

The following Food Standards Code 1.2.11 requirements apply for packaged foods:
Packaged Fresh Fruit and Vegetables:-
3(1) This section applies to a food for sale that:
(a) is unprocessed fruit and vegetables, whether whole or cut; and
(b) is displayed for retail sale in a package that does not obscure the nature or quality of the fruit and vegetables.
(2) For the labelling provisions, the country of origin information is a statement that:

(a) identifies the country or countries of origin of the fruit and vegetables; or

(b) indicates that the fruit or vegetables are a mix of local and imported fruit and vegetables; or

(c) indicates that the fruit and vegetables are a mix of imported foods.

Packaged Food Other than Fresh Fruit and Vegetables:-
4(2) For the labelling provisions, the country of origin information is:

(a) a statement on the package that identifies the country where the food was made, produced or grown; or

(b) a statement on the package:

(i) that identifies the country where the food was manufactured or packaged; and

(ii) to the effect that the food is constituted from ingredients imported into that country or from local and imported ingredients.(1.)

Statements where food is made or grown may include: ‘Product of…’, ‘Made in…’, ‘Grown in…’, or ‘Australian Made’, or ‘Australian Grown’. Also, ownership claims such as ‘Proudly Australian’, or ‘100% Australian’ may be displayed on food labels. Symbols may also accompany these statements.(2.)

The legislation allows ‘room’ for variation and therefore subjectivity of interpretation. Statements such as ‘Made in Australia from local and imported ingredients’ do not provide sufficient information as to the amount of imported ingredients in the product, nor is it compulsory to identify the percentage in the ingredients list. In addition, Australian food importers, manufacturers, distributors, or retailers, who label or re-label food products ‘Australian Made’ or ‘Made in Australia’ may have only combined the ingredients and packaged them in Australia and claim that this constitutes ‘Made in Australia’ or ‘Australian Made’ is misleading. There are compliance requirements regarding misleading or false statements.

Recently, Country of Origin food labelling has become a political priority in Australia, given the Hepatitis A outbreak from mixed berries imported from China. Subsequent community and media outrage over the lack of food labelling clarity has ‘forced the hand’ of politicians to consider the introduction of more informative Country of Origin food labels.

In recent years Australian importation of foods from countries such as China has dramatically increased, doubling between 2002-2012.(3.) The amount of food recalls has also increased over this time period. There were 586 recalls, an average of 59 recalls per year, between 1 January 2005 and 31 December 2014.(4.)

FoodRecallAus™ food recall app assists consumers in rapid notification of packaged foods that have been recalled due to country of origin issues such as imported contaminated foods.

References:

1. www.foodstandards.gov.au/code/Pages/default.aspx and www.comlaw.gov.au (01.03.16)

2. www.accc.gov.au/consumers/groceries/country-of-origin (07.07.15)
3. Commonwealth of Australia (2014), Imported Food Inspection Data Report, July – December 2013, Department of Agriculture. Retrieved www.agriculture.gov.au/import/food/inspection-compliance/inspection-data (02.06.15).
4. www.foodstandards.gov.au/industry/foodrecalls/recallstats/Pages/default.aspx (07.07.15)

Undeclared Food Allergens

http://www.foodrecallaus.com.au/undeclared-food-allergens.html

The Food Standards Australia and New Zealand (FSANZ) Food Standards Code, Standard 1.2.3 provides legislative requirements for food declarations including warning statements, advisory statements, and declarations.

The Food Standards Code, Standard 1.2.3 - 4 states the following regarding mandatory food declarations(1.):

(1) For the labelling provisions, if any of the following foods or substances is present in a food for sale in a manner listed in subsection (2), a declaration that the food or substance is present is required:

(a) added sulphites in concentrations of 10 mg/kg or more;

(b) any of the following foods, or products of those foods:

*(i) cereals containing *gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits;*

(ii) crustacea;

(iii) egg;

(iv) fish, except for isinglass derived from swim bladders and used as a clarifying agent in beer or wine;

(v) milk;

(vi) peanuts;

(vii) soybeans;

(viii) sesame seeds;

(ix) tree nuts, other than coconut from the fruit of the palm Cocos nucifera.

(2) For subsection (1), the food or substance may be present as:

*(a) an ingredient or as an ingredient of a *compound ingredient; or*

*(b) a substance *used as a food additive, or an ingredient or component of*

such a substance; or

*(c) a substance or food *used as a processing aid, or an ingredient or component of such a substance or food.*

Refer to the Food Standards Code, Standard 1.2.3 - 4 for more information.
FSANZ statistics reveal that in 2014 most food recalls were due to undeclared allergens.(2.)

The FoodRecallAus app provides immediate push notifications directly from FSANZ via RSS feed so that app users are kept up-to-date with the latest food recall notifications. This is extremely important for those who suffer from food allergies and are concerned about packaged food products that may be recalled due to undeclared food allergen on the food label.

References:
1. http://www.foodstandards.gov.au/code/Pages/default.aspx (03/03/16)
2. http://www.foodstandards.gov.au/industry/foodrecalls/recallstats/Pages/default.aspx (01/03/16)

Food Recalls

http://www.foodrecallaus.com.au/food-recalls.html

FoodRecallAus has incorporated two food recall sections into the app - 'Food Recalls' and 'Quick Recall'.

This first section, 'Food Recalls', is derived directly from the Food Standards Australia and New Zealand (FSANZ) food recall website pages. Food Recall Notifications are not altered in any way and include colour images of the product(s) where provided.

The second section, 'Quick Recall', is an RSS feed derived from www.foodstandards.gov.au, which delivers food recall notification updates. These appear as brief food recall summaries on the FoodRecallAus app and generally include the title of the food, the date of the food recall, and a brief description of the reason for the food recall.

Both food recall notification sections of FoodRecallAus app are useful to consumers,

because some consumers prefer the fast reference option 'Quick Recall' provides, while others prefer the greater detail provided by full Food Recall Notifications.

Food Recall Reasons

http://www.foodrecallaus.com.au/recall-reasons.html

Food Recalls fall into the following categories, according to Food Standards Australia and New Zealand:

- Labelling
- Undeclared allergen
- Tampering
- Microbial contamination
- Chemical/other contaminants
- Biotoxin
- Foreign matter
- Other

Food recalls are performed to action the removal of food that may pose a consumer safety risk to customers from retail sale, distribution and consumption.

There are two types of food recalls:

- Trade Level
- Consumer Level

A Trade Level recall is the recovery of food from distribution that has not yet been sold to customers. This may include distribution to facilities such as hospital and aged care facility kitchens for example. It may also include manufacturers, wholesalers, and distributors.

A Consumer Level recall is the recovery of food from consumer possession e.g. retail sales.

Development of FSANZ and the Food Standards Code Australia and New Zealand have a mutual recognition agreement in place to recognise the Food Standards Code. Australia and

New Zealand mutual recognition agreement of the Food Standards Code began with the establishment of a System for the Development of Joint Food Standards treaty, this was followed by the Trans-Tasman Mutual Recognition Agreement.

Food Standards Australia and New Zealand (FSANZ) is an independent statutory agency that develops the food standards but does not perform enforcement activities. Australian States and Territories possess food legislation to govern the regulation and enforcement of food safety. Such legislation is in the form of Food Acts and subordinate legislation.

The Food Standards Code is legislated across Australia and New Zealand. Although Australia includes a few extra provisions not mandated in New Zealand, such as country of origin labelling, for example. The Food Standards Code has been legislated into State and Territory Food Acts. For example, Compliance with the Food Standards Code in Queensland (QLD) Food Act 2006, section 39 - (1),(2),(3),(4); in New South Wales (NSW), for example, NSW Food Act 2003, section 21 - (1),(2),(3),(4),(5).

Food Recall in the Food Standards Code
The Food Standards Code, standard 3.2.2 section 12 describes legal obligations of food businesses with regard to food recalls. It states:

"Food Recall – A food business engaged in the wholesale supply, manufacture or importation of food must –
(a) have in place a system to ensure the recall of unsafe food;
(b) set out this system in a written document and make this document available to an authorised officer upon request; and
(c) comply with this system when recalling unsafe food."

NOTE: Food subject to a recall is 'food for disposal' and therefore, standard 3.2.2, section 11 applies, which states:

"Food Disposal –
(1) A food business must ensure that food for disposal is held and kept separate until – (a) destroyed or otherwise used or disposed of so that it cannot be used for human consumption;
(b) return to its supplier;
(c) further processed in a way that ensures its safety and sustainability; or

(d) ascertained to be safe and suitable.

(2) In subclause (1), 'food for disposal' means food that -
(a) is subject to a recall;
(b) has been returned;
(c) is not safe or suitable; or
(d) is reasonably suspected of not being safe or suitable.

(3) A food business must clearly identify any food that is held and kept separate in accordance with subclause (1) as returned food, recalled food, or food that is or may not be safe or suitable, as the case may be."

The Food Standards Code can be found at www.foodstandards.gov.au

Food Watch (News)

http://www.foodrecallaus.com.au/food-watch.html

'Food Watch News' is a collection of Australian food news stories. These are adaptations of news stories in the current media.

FoodRecallAus has incorporated a 'Food Watch News' section. This section is an RSS news feed derived from www.ausfoodnews.com.au, which delivers news updates related to food safety, food industry, and food policy. Permission has been obtained from www.ausfoodnews.com.au for use of RSS feeds derived from its website to operate on FoodRecallAus app. FoodRecallAus app has no affiliation with, or between, or endorsement or sponsorship of FN Media and Australian Food News.

'Food Watch News' updates are a complementary add-on to the FoodRecallAus app as they empower consumers by providing timely food news information enabling consumers to make relevant food purchase choices.

Often food recall information is portrayed in the news media in a broader light than food recall notifications and progress further than simply a food recall notification. For example, a food borne pathogen outbreak from a particular recalled packaged food may progress to Public Health notifications, media stories, political engagement, and pressure from consumer groups. Furthermore, not all foods in the marketplace are represented by food recalls. Food

Recall Notifications are specific to non-exempt (Food Standards Code) packaged foods for retail sale and do not represent primary production (produce). For example, predatory fish for sale in a retail fish and chips store may have ciguatera toxins that may cause health problems if consumed. This example would not be captured in a FSANZ food recall. Hence, 'Food Watch News' updates supplement food recall notifications in informing food safety.

Web blog

The following web blog was posted on several websites and social media outlets including NutritionBuff and Science Meets Business.

2015 – Australia's Year of Food Safety Woe:

Spurs Country of Origin Labelling & Food Recall App

It all started in early 2015 with the nationally publicised frozen mixed berry scare, resulting in 34 cases of hepatitis A, linked to consumption of the imported berries (1). Most of the berries were imported from China and the media were quick to point out China's less stringent food safety regulations and practices. The packaged berries were subject to an urgent food recall. In the last two years the majority of food recalls were due to undeclared allergen, with microbial contamination following closely behind (2).

To make matters worse, the ambiguous Country of Origin Labelling (CoOL) of packaged foods with statements such as: "packed in Australia from imported fruit" or "made from local and imported ingredients", caused a media and public furore. As a consequence, the Australian Federal Government hurried to introduce better CoOL laws. Instead of non-informative CoOL statements, Government consultations culminated in combinations of graphical and statement concepts that distinguish the proportion of Australian ingredients (3). These laws come into force in 2016.

As the news of the mixed berry scare broke, A/Prof Andreas Lopata (a food safety expert from James Cook University and my PhD mentor) contacted me and suggested we develop a food recall notification app! I thought little of it until the next day when I researched if such an app exists. To my surprise, no dedicated food recall notification app existed in Australia, unlike the USA, Canada, and the UK. So, for the next 5 months I set out to develop the FoodRecallAus app – Australia's only dedicated food recall notification app. I succeeded and

also produced a companion website: www.FoodRecallAus.com.au. Since the app's debut many media interviews have ensued and the app has been credited with national endorsement by Environmental Health Australia (EHA) – Australia's peak body representing Environmental Health Officers (food safety compliance and enforcement inspectors and regulators).

Toward the middle of the year, tropical North Queensland had succumb to one of the largest single cluster outbreaks of ciguatera intoxication in Australia's living memory. At least 17 cases were affected in Townsville from consumption of Spanish Mackerel (4). Ciguatoxin originates from dinoflagellate algae and subsequent bio-accumulates in predatory reef fish. There is no rapid diagnostic test available to test the fish for ciguatoxin, and freezing or cooking does not destroy the toxin. Unusual symptoms present in people who consume the toxic fish, such as reverse temperature sensation. We attempt to capture these types of food borne outbreaks, which are unfortunately not subject to food recalls, by incorporating in our FoodRecallAus app the 'Food Watch News' section, which is constantly updated from www.ausfoodnews.com.au.

In the later half of the year from August through to November 2015 the Department of Agriculture & Water Resources, who are responsible for imported foods, were directed to test every imported coconut milk product for undeclared allergen. There was a spike in food recalls due to the compulsory testing of coconut milk products containing undeclared allergens from milk, with at least 19 imported coconut milk products had to be recalled. The reason for the increased surveillance of imported coconut products was as a consequence of the death of a 10 year old boy in 2013 from undeclared dairy allergens in a can of coconut juice (5). There was unfortunately a substantial delay between the death of the child and testing of all coconut imports, and in September a 9 year old child had an anaphylactic shock, according to Allergy and Anaphylaxis Australia.

Food Standards Australia & New Zealand (FSANZ) reveals that the year 2014 had the highest ever number of food recalls recorded for a single year with 76 food recalls (2). We anticipate that 2015 FSANZ food recall statistics will show a similarly high or even higher number of food recalls.

The FoodRecallAus app is available from both the GooglePlay and iTunes stores. For more information go to www.FoodRecallAus.com.au

By: Michael Sheridan

References:

1. http://www.foodstandards.gov.au/consumer/safety/Pages/Frozen-berries-recall-.aspx (29.12.2015)

2. http://www.foodstandards.gov.au/industry/foodrecalls/recallstats/Pages/default.aspx (30.12.2015)

3. http://www.industry.gov.au/industry/IndustrySectors/FoodManufacturingIndustry/Documents/Country-of-Origin-Labelling-Colmar-Brunton-Market-Research-2015.pdf (29.12.2015)

4. http://www.townsvillebulletin.com.au/news/stricken-by-fish-poisoning/story-fnjfzs4b-1226855439893 (29.12.2015)

5. http://www.smh.com.au/national/health/child-aged-10-dies-after-drinking-coconut-milk-as-importer-admits-label-charges-20150925-gjvakb.html (30.12.2015)

Appendix D. FoodRecallAus App Data

Table 14: FoodRecallAus app download duration of analysis.

From and including: Thursday, 7 May 2015
To and including: Monday, 17 July 2017
Result: 803 days
It is 803 days from the start date to the end date, end date included
Or 2 years, 2 months, 11 days including the end date
Alternative time units
803 days can be converted to one of these units:
69,379,200 seconds
1,156,320 minutes
19,272 hours
803 days
114 weeks and 5 days
220.00% of a common year (365 days)

4.8 Raw data analysed for app downloads versus variables.

Table 15: FoodRecallAus app download raw data correlated to food recalls, and variables.

Downloads	DATE	Recall Number	DATE of RECALL	TYPE of RECALL	Reason	MEDIA (TV News Aust National)	Affiliates, Publication
0	06-May-11	1	06-May-11	Stone Baked Sourdough garlic	metal		
0	13-May-11	1	13-May-11	JimJam Salsa	allergen		
1	19-May-11						
1	20-May-11						
0	21-May-11	1	21-May-11	William's Eggs	cracked eggs		
1	23-May-11						
2	24-May-11						
4	25-May-11						
6	26-May-11						
4	27-May-11						
2	28-May-11						
3	31-May-11						
2	01-Jun-11						
0	03-Jun-11	1	03-Jun-11	Woolworths Chicken & Vegetable Pies			
2	09-Jun-11						
1	10-Jun-11						
1	12-Jun-11						
1	14-Jun-11						
2	15-Jun-11						
1	18-Jun-11	2	18-Jun-11	Ebuta Dairy Goats Milk, Bakewell Party Pies	microbial, metal		
12	21-Jun-11						

2	22-Jun-11						
1	25-Jun-11						
1	26-Jun-11						
1	27-Jun-11						
1	28-Jun-11						
1	14-Jul-11						
0	28-Jul-11	1	28-Jul-11	Crumbed Pork Schnitzel	allergen		
0	29-Jul-11	2	29-Jul-11	Buchi Kombucha 500ml, Phoenix branded 330ml cola	alcohol, glass		
1	10-Aug-11						
0	20-Aug-11	1	20-Aug-11	Cottage Cheese Farm Goats Fetta	microbial		
1	27-Aug-11						
0	28-Aug-11	1	28-Aug-11	Coco Joy Pure Coconut Milk	allergen		
0	02-Sep-11	1	02-Sep-11	JL King and Co Gourmet Salads Fried Rice	microbial		
1	07-Sep-11						
1	16-Sep-11						
0	17-Sep-11	1	17-Sep-11	V-Fresh Coconut Milk Drink, Orthodox Coconut Palm Coconut Juice	allergen		
0	18-Sep-11	1	18-Sep-11	Mandala Chai products	allergen		
0	22-Sep-11	1	22-Sep-11	Coconut Juice, Dooley's Ice Cream	allergen		
1	23-Sep-11	1	23-Sep-11	Emma Instant Coconut Milk Powder	allergen		
1	24-Sep-11						
2	25-Sep-11						
1	27-Sep-11						

1	28-Sep-11						
0	29-Sep-11	1	29-Sep-11	Bioflex and Bulk Nutrients Pure Supplements	allergen		
0	30-Sep-11	1	30-Sep-11	Orthodox Coconut Palm and Sasaya Coconut Milk	allergen		
1	05-Oct-11						
2	06-Oct-11						
1	07-Oct-11						
2	08-Oct-11						
1	11-Oct-11						
1	15-Oct-11	1	15-Oct-11	Ayres Rock Instant Coconut Milk Powder	allergen		
0	16-Oct-11	1	16-Oct-11	Nakula Organic Coconut Cream	allergen		
1	19-Oct-11						
1	20-Oct-11						
0	21-Oct-11	1	21-Oct-11	Chaokoh Young Coconut Juice with Jelly	allergen		ABC Radio interview
2	22-Oct-11	1	22-Oct-11	Foco Roasted Coconut Juice, Vitasoy Coconut Soy Drink			
1	26-Oct-11	2	26-Oct-11	Fresh Frozen Young Coconut Juice, Coconut Peach Drink	allergen, allergen		
4	27-Oct-11	1	27-Oct-11	Thai Coco Coconut Juice	allergen		
2	28-Oct-11	1	28-Oct-11	Golden Choice Young Coconut Juice with Pulp	allergen		
0	29-Oct-11	3	29-Oct-11	Mikko Ready Mix Coconut Milk Powder 150g, Cocomi Bio Organic Coconut Milk Powder, First Quality Free Range Eggs 700g	allergen, allergen, cracked eggs		

1	01-Nov-11						
1	02-Nov-11						
1	03-Nov-11						
1	04-Nov-11	1	04-Nov-11	Nutty Bruce Organic Coconut Milk	allergen		
1	09-Nov-11	1	09-Nov-11	Lupins	biotoxin		
0	10-Nov-11	1	10-Nov-11	Northside Fine Foods Ham off the bone	microbial		
1	11-Nov-11						
1	12-Nov-11	1	12-Nov-11	Thai Gormet Panang Curry Paste	allergen		
1	13-Nov-11	1	13-Nov-11	La Natural Young Coconut Juice	allergan		
2	14-Nov-11						
3	15-Nov-11						
1	19-Nov-11	1	19-Nov-11	Original Ginger Marmalade	glass		
1	22-Nov-11						
1	23-Nov-11						
2	24-Nov-11	1	24-Nov-11	Celebrate Health Superfoods Flaxseed with Coco and Berries	allergen		
2	25-Nov-11	1	25-Nov-11	No Udder Coconut Yoghurt	allergen		
15	26-Nov-11						
10	27-Nov-11						
1	28-Nov-11						
1	29-Nov-11						
1	02-Dec-11	1	02-Dec-11	Carlton Dry Beer	glass		
1	03-Dec-11						
1	05-Dec-11						

1	07-Dec-11	1	07-Dec-11	Gourmet Organic Herbs Ground Coriander	microbial		
1	08-Dec-11						
0	10-Dec-11						Science Meets Business
1	11-Dec-11						
1	24-Dec-11						
2	26-Dec-11						
1	03-Jan-12						
1	04-Jan-12						
1	06-Jan-12						
0	11-Jan-12	1	11-Jan-12	Beta Wholesale Pine Nuts	allergen		
0	12-Jan-12	1	12-Jan-12	Inghams Quick Cook Chicken Meatballs	date		
0	16-Jan-12	1	16-Jan-12	Garlic Bread	plastic	News	
0	18-Jan-12	1	18-Jan-12	Latina Fresh Creamy Chicken Pesto	allergen		
0	19-Jan-12	1	19-Jan-12	Aldi Bakers Life Bakehouse White Rolls 6 pack	allergen		
0	21-Jan-12	1	21-Jan-12	Ovaston Organics Eggs	dirty eggs		
0	24-Jan-12	1	24-Jan-12	Easy Cut Shoulder Ham	microbial		
0	25-Jan-12	1	25-Jan-12	Coles Hilo and Full Cream milk 1L	microbial		
1	26-Jan-12	1	26-Jan-12	Farmers United Iced Coffee	microbial		
2	28-Jan-12						
4	03-Feb-12	2	03-Feb-12	Pre-packaged salad leaves, Forever Young	microbial, allergen	News	
1	04-Feb-12	1	04-Feb-12	Woolworths Loose Leaf Lettuce	microbial	News	

1	05-Feb-12	1	05-Feb-12	Garden and Life RAW Meal Organic Shakes	microbial		
1	11-Feb-12						
1	18-Feb-12						
1	19-Feb-12						
1	20-Feb-12						
2	25-Feb-12	1	25-Feb-12	I Quit Sugar Superfood Protein Ball	allergen		
3	28-Feb-12						
2	29-Feb-12						
2	02-Mar-12						
1	05-Mar-12						
1	07-Mar-12						
1	08-Mar-12	1	08-Mar-12	Gallo Marinated Fetta	microbial		
2	09-Mar-12	2	09-Mar-12	Street Kitchen Curries, Chung Hing Fresh Tofu and Supa Fresh Tofu	microbial, metal		
0	10-Mar-12	2	10-Mar-12	Just Entrees Australia Pate, Cicada Artisan Chocolate	microbial, allergen		
2	11-Mar-12	2	11-Mar-12	Dark Couvature chocolate 58 percent, Naturally Deliciously Free Moist Choc Mud Cake Mix	allergen, allergen		
1	15-Mar-12						
0	17-Mar-12	4	17-Mar-12	Spring Bay Mussels, Pitango Butter Chicken Curry, Well and Good Cake and Muffin Mix, Coles Simply Gluten Free Vanilla Cupcake Mix	Biotoxin, allergen, allergen, allergen		
1	19-Mar-12						

1	20-Mar-12							
0	23-Mar-12	1	23-Mar-12	Imperial Grain Brown Rice Microwave Cups	Microbial			
1	24-Mar-12							
1	26-Mar-12							
1	27-Mar-12							
1	28-Mar-12							
2	29-Mar-12							
4	30-Mar-12							
2	31-Mar-12							
3	03-Apr-12							
1	04-Apr-12							
2	09-Apr-12							
1	10-Apr-12							
2	17-Apr-12							
1	19-Apr-12							
1	21-Apr-12							
1	23-Apr-12							
1	28-Apr-12							
1	29-Apr-12							
2	02-May-12	1	02-May-12	Coles Chicken Breast Tenders	allergen			
0	03-May-12	1	03-May-12	Streets Blue Ribbon Ice Cream Tubs	plastic	News		
2	08-May-12							
0	10-May-12	1	10-May-12	Perfect Sweet Chocolate Bake Mix	allergen			

1	11-May-12						
0	12-May-12	1	12-May-12	Ardmona Whole Peeled Vine Ripened Tomatoes	injury		
2	13-May-12						
0	17-May-12	1	17-May-12	Yayla and Try Me Yoghurt	microbial		
0	18-May-12	2	18-May-12	Sunshine Sprouts and Star Tu Chinese Bean Sprouts, Cholimex - dried satay chilli	microbial, allergen		
0	19-May-12				microbial		
1	21-May-12						
3	23-May-12						
1	24-May-12						
1	28-May-12						
2	31-May-12						
3	04-Jun-12						
2	07-Jun-12	1	07-Jun-12	Wood Smoked Sicilian Olives	microbial		
0	08-Jun-12	1	08-Jun-12	Forest Gate Organics Mung Bean Sprouts	allergen		
0	09-Jun-12	1	09-Jun-12	Chilli Muruku			
1	14-Jun-12						
0	15-Jun-12	1	15-Jun-12	Eleman Bakery Authentic Lebanese Date Biscuits	allergen		
1	26-Jun-12						
1	28-Jun-12						
0	30-Jun-12	1	30-Jun-12	Hillcrest Chewy Choc Squiggle Musli Bars	allergen		
2	03-Jul-12						

8	07-Jul-12						
1	08-Jul-12	1	08-Jul-12	Simply Cook Chicken Chasseur	allergen		
0	10-Jul-12						Healthy-Kids
2	11-Jul-12	1	11-Jul-12	Baker's Life Hot Dog Rolls 6 pack	metal		Nutrition Buff
9	12-Jul-12						
2	14-Jul-12						
1	15-Jul-12						
2	16-Jul-12						
1	17-Jul-12						
1	18-Jul-12						A&AA
1	19-Jul-12						
1	20-Jul-12						
1	26-Jul-12						
2	27-Jul-12	2	27-Jul-12	Chocklad and Godis products - Ikea chocolate, Health Lab Protein Balls	allergens, allergen		
1	29-Jul-12						
3	31-Jul-12						
1	01-Aug-12						
7	03-Aug-12	1	03-Aug-12	Sweet William Dairy Free Original Chocolate	allergen		
1	04-Aug-12						
1	05-Aug-12						
1	06-Aug-12						
1	07-Aug-12						

1	09-Aug-12						
2	11-Aug-12						
1	13-Aug-12						
2	14-Aug-12						
1	15-Aug-12						
2	16-Aug-12						Food Australia Journal
3	17-Aug-12	1	17-Aug-12	Zehnder Gluten Free Breads	allergen		
3	18-Aug-12	1	18-Aug-12	Dark Chocolate Belgian hot chocolate stirers	allergen		
4	19-Aug-12						
1	20-Aug-12						
4	22-Aug-12						
2	23-Aug-12						
1	25-Aug-12						
1	27-Aug-12						
1	28-Aug-12						
1	29-Aug-12						
1	01-Sep-12	1	01-Sep-12	CocoLuscious Certified Organic coconut milk ice cream	allergen		
5	02-Sep-12				chemical contamination		
1	03-Sep-12						
1	04-Sep-12						
1	07-Sep-12						
1	09-Sep-12						

1	10-Sep-12						
1	11-Sep-12						
3	13-Sep-12	1	13-Sep-12	Stone and Wood Pacific Ale			
1	14-Sep-12						
1	15-Sep-12						
1	18-Sep-12						
5	19-Sep-12	1	19-Sep-12	Coles curried pumpkin and corn burgers	allergen		
5	22-Sep-12	1	22-Sep-12	Linke's Centrral Meat Store Mettwurst and Pepperoni	microbial		
1	23-Sep-12						
1	24-Sep-12						
3	28-Sep-12	1	28-Sep-12	Quality Bakers Australia Bread Rolls	metal		
2	29-Sep-12						
1	01-Oct-12						
1	03-Oct-12						
1	12-Oct-12						
4	13-Oct-12	1	13-Oct-12	Woolworths Singleton Australia pork, lamb, beef mince	metal	News	
3	15-Oct-12						
1	16-Oct-12						
2	17-Oct-12	1	17-Oct-12	Pandaroo Sushi Ginger	glass		
2	18-Oct-12						
1	20-Oct-12						
4	23-Oct-12	1	23-Oct-12	Cloud 9 Farm White Velvet Cheese	E.coli		

1	25-Oct-12						
1	27-Oct-12	1	27-Oct-12	Granny Macs Dark Chocolate Coffee Beans	allergen		
1	28-Oct-12						
1	29-Oct-12						
1	30-Oct-12						
2	31-Oct-12						
4	01-Nov-12	1	01-Nov-12	Gallo Farms Marinated Cheese	E.coli		
1	02-Nov-12						
3	03-Nov-12						
3	07-Nov-12	1	07-Nov-12	Lite N Easy Traditional Chargrilled Steak	Metal		
1	08-Nov-12						
4	10-Nov-12						
5	16-Nov-12	1	16-Nov-12	Bonvita Rice Milk White Bar	allergen		
3	17-Nov-12	1	17-Nov-12	Paunch lamb stomach	microbes		
1	19-Nov-12						
4	20-Nov-12	1	20-Nov-12	Elfa Bean Sprouts	date		
2	23-Nov-12						
2	29-Nov-12	1	29-Nov-12	Lievito Bakery	allergen		
1	30-Nov-12						
1	06-Dec-12						
1	08-Dec-12						
1	09-Dec-12						
1	12-Dec-12						

3	13-Dec-12	1	13-Dec-12	Lenny and Larry's Complete Cookie Chocolate Chip	allergen		
1	20-Dec-12	1	20-Dec-12	Protein Pancakes	allergen		
2	21-Dec-12						
2	22-Dec-12						
5	27-Dec-12	1	27-Dec-12	Coles Beetroot Dip	allergen		
2	03-Jan-13						
8	04-Jan-13						
3	05-Jan-13	1	05-Jan-13	Birds Eye Golden Crunch Hash Browns	plastic		
1	06-Jan-13						
1	10-Jan-13						
2	12-Jan-13	1	12-Jan-13	The Cider Lab Ciders	allergen		
1	13-Jan-13						
1	15-Jan-13						
4	16-Jan-13	2	16-Jan-13	Picky Picky Peanuts Mexican Salsa Peanuts, Garlic Bread - various	allergen, plastic		
3	17-Jan-13	1	17-Jan-13	Target Cookie Mix in Mason Jars	insects		
2	19-Jan-13						
1	20-Jan-13						
1	22-Jan-13						
2	23-Jan-13						
1	27-Jan-13						
4	30-Jan-13	1	30-Jan-13	Stockmans Eggs	cracked eggs	News	
2	31-Jan-13						

2	01-Feb-13							
2	02-Feb-13							
1	03-Feb-13							
4	04-Feb-13							
2	07-Feb-13	1	07-Feb-13	Maree Wilkinson Products	allergen			
2	09-Feb-13							
1	11-Feb-13							
2	13-Feb-13							
1	14-Feb-13							
1	19-Feb-13							
1	20-Feb-13							
1	22-Feb-13	1	22-Feb-13	Wheat pop Sesame Flavour	allergen			
1	24-Feb-13							
1	25-Feb-13							
4	26-Feb-13							
2	27-Feb-13	1	27-Feb-13	Cottage Cheese Farm Ricotta	E.coli			
2	28-Feb-13							
3	03-Mar-13	1	03-Mar-13	Jinyaunboa Chinese Wonton	allergen			
9	04-Mar-13							
3	05-Mar-13							
2	06-Mar-13	1	06-Mar-13	Chan's Yum Cha at home Seafood Prawn Hargow Dumpling	allergens			
2	07-Mar-13	2	07-Mar-13	Bounce Apple Cinnamon Energy Ball, Food Babies Love	allergen, allergen			

1	08-Mar-13						
1	09-Mar-13						
1	10-Mar-13						
2	11-Mar-13						
2	14-Mar-13						
0	15-Mar-13						RIAMS
0	21-Mar-13	1	21-Mar-13	The Pork Pie Shop Pies	Microbial		
2	22-Mar-13						
4	23-Mar-13	1	23-Mar-13	Yummy Yoghurt Sultanas	allergen		
2	29-Mar-13						
1	30-Mar-13						
1	03-Apr-13	1	03-Apr-13	Organic Finger Foods Baby Biscuits	chocking hazard		
1	04-Apr-13						
1	05-Apr-13						
1	07-Apr-13						
2	08-Apr-13						
2	11-Apr-13						
3	12-Apr-13	1	12-Apr-13	King Island Fresh Milk and Cream	Microbial		
2	14-Apr-13						
2	15-Apr-13						
2	17-Apr-13	1	17-Apr-13	Roberts Confectionery Dark Chocolate Melting Buttons	allergen		
1	18-Apr-13						
1	19-Apr-13	1	19-Apr-13	Coles Honey Soy Chicken Wings	allergen		

2	20-Apr-13	1	20-Apr-13	Floridia Grated Parmesan Cheese	allergen		
2	21-Apr-13						
1	22-Apr-13						
1	23-Apr-13						
1	27-Apr-13						
1	29-Apr-13						
1	03-May-13						
1	04-May-13						
5	06-May-13						
0	07-May-13						Promo Video
1	10-May-13	1	10-May-13	Lotus Wing Baby Whiting	allergens		
1	12-May-13	1	12-May-13	CP Authentic Asian Prawn Wonton Ramen with Green Choy Sum	plastic		
1	14-May-13						
2	18-May-13						
2	22-May-13						
1	24-May-13						
1	29-May-13	1	29-May-13	Mures Hot Smoked Salmon	microbial		
2	30-May-13						
3	01-Jun-13	1	01-Jun-13	Creative Gourmet Frozen Mixed Berries 300g	viral	News	
1	02-Jun-13						
1	03-Jun-13						
3	05-Jun-13						

1	07-Jun-13						
1	08-Jun-13	1	08-Jun-13	JHC Thai Coconut Rolls	allergen		
2	11-Jun-13						
1	13-Jun-13						
2	15-Jun-13						
1	19-Jun-13						
2	20-Jun-13	1	20-Jun-13	Hershey's Cookies 'n' Crème Chocolate block 113g	allergens		
3	22-Jun-13	1	22-Jun-13	Hershey's chocolate products	allergens		
2	23-Jun-13						
1	24-Jun-13						
1	25-Jun-13						
1	26-Jun-13						
1	28-Jun-13						
1	01-Jul-13						
1	07-Jul-13						
1	09-Jul-13						
1	11-Jul-13						
1	14-Jul-13						
596	16-Jul-13	129 recalls		products	63 allergen	7	8

Table 16: Generalised Linear Regression Modelling analysis for undeclared food allergen recalls for app downloads over time.

```
. spearman down_rate length_in_days, stats(rho p) pw matrix
(obs=51)
```

Key
rho
Sig. level

	down_r~e	length~s
down_rate	1.0000	
length_in_~s	-0.4620 0.0006	1.0000

```
Generalized linear models                         No. of obs      =         51
Optimization     : ML                             Residual df     =         47
                                                  Scale parameter =   1.274707
Deviance         =  59.91121655                   (1/df) Deviance =   1.274707
Pearson          =  59.91121655                   (1/df) Pearson  =   1.274707

Variance function: V(u) = 1                       [Gaussian]
Link function    : g(u) = u                       [Identity]

                                                  AIC             =   3.155778
Log likelihood   = -76.47233699                   BIC             =  -124.8846
```

down_rate	OIM Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
length_in_days	-.0825398	.0278144	-2.97	0.003	-.137055	-.0280246
year_2016_17	.0538818	.4002804	0.13	0.893	-.7306535	.838417
year_2017	.3038667	.3746761	0.81	0.417	-.4304849	1.038218
_cons	1.729286	.3266752	5.29	0.000	1.089015	2.369558

Table 17: Generalised Linear Regression Modelling analysis for non-undeclared food allergen recall reasons for app downloads.

```
. spearman down_rate length_in_days, stats(rho p) pw matrix
(obs=varies)
```

Key
rho
Sig. level

	down_r~e	length~s
down_rate	1.0000	
length_in_~s	-0.5601 0.0001	1.0000

```
Generalized linear models                         No. of obs      =         43
Optimization     : ML                             Residual df     =         38
                                                  Scale parameter =   .410391
Deviance         =  15.59485711                   (1/df) Deviance =   .410391
Pearson          =  15.59485711                   (1/df) Pearson  =   .410391

Variance function: V(u) = 1                       [Gaussian]
Link function    : g(u) = u                       [Identity]

                                                  AIC             =  2.056176
Log likelihood   = -39.20778997                   BIC             = -127.3307
```

down_rate	OIM Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
length_in_days	-.0251685	.0105076	-2.40	0.017	-.0457632	-.0045739
media	.631555	.2946184	2.14	0.032	.0541135	1.208996
year_2016_17	.4222198	.2431165	1.74	0.082	-.0542798	.8987194
year_2017	-.1976677	.24492	-0.81	0.420	-.6777022	.2823667
_cons	.872901	.2296285	3.80	0.000	.4228374	1.322965

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