ALLERGEN SURVEY

NSW GOVERNMENT
Department of Primary Industries
Food Authority

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Introduction

Food allergy

Food allergies are on the increase. Food allergies are a result of the immune system reacting abnormally to a particular component of food, usually a protein. The body produces antibodies against the food protein which causes the release of histamine and other chemicals causing an allergic reaction. An allergic reaction can include a range of symptoms including rashes, vomiting, diarrhoea, swelling of the throat and in severe cases, anaphylaxis. Anaphylaxis is a potentially life threatening allergic reaction that requires immediate medical attention. Symptoms include difficulty breathing, swelling of the tongue and throat, difficulty talking and dizziness.

The most common types of food allergens in Australia are: crustaceans, eggs, fish, milk, peanuts, sesame seeds, soybeans, tree nuts, wheat and lupin (Food Standards Australia New Zealand, 2017). In Australia, 1 in 20 children and 1 in 50 adults have a food allergy (National Allergy Strategy, 2017)

Food Intolerance

Food intolerance is the body's inability to digest a particular component in the food. It does not involve the immune system and is therefore not defined as a food allergy. Food intolerances are more common than allergies. Symptoms of food intolerances can include stomach pain, diarrhoea, hives and general malaise. Common causes of food intolerances include lactose, milk, gluten and food additives.

Coeliac disease

Coeliac disease is not an allergy or intolerance but an auto-immune disease where gluten causes inflammation and damage to the lining of the small intestine. Damage is caused by white blood cells and not by antibodies. The damage adversely affects the ability of the small intestine to absorb nutrients which may result in fatigue, bloating, cramps and diarrhoea. If left untreated, the disease-related malnutrition can lead to chronic poor health (Coeliac Australia, 2015).

Gluten is a protein found in wheat, oats, barley and rye. Wheat flour and gluten are commonly used in foodstuffs to improve product texture, moisture retention and flavour. Gluten can be found in a variety of products including pasta, bread, chips and others.

Coeliac Australia reports that approximately 1 in 70 Australians are affected by coeliac disease with many in the population unaware they may be suffering from the condition. The main risk management strategy for people with coeliac disease is to avoid foods containing gluten.

Food allergy prevalence

Prevalence of food allergy appears to be on the increase (Rinaldi, Harnack, Oberg, Schreiner, Sauver & Travis, 2012; Eckers et al., 2015; Nwaru et al, 2014; Tang & Mullins, 2017; Branum & Lukacs, 2009). A 2013 report published by the Australian Society of Clinical Immunology and Allergy (ASCIA) estimated that food induced anaphylaxis doubled in the last ten years (ASCIA, 2013). Approximately 10% of infants under the age of one have an immediate food allergy which drops to 4-8% under five years and then to 2% of adults (ASCIA, 2013). Different ethnic groups appear to have different allergy prevalence and sensitisation (Buka et al, 2015; Kool, Chandra & Fitzharris, 2016; Joseph et al, 2016; Koplin et al, 2015; Wegienka, Johnson, Zoratti & Havstad, 2013). Food allergy prevalence appears to be relatively low in Asian countries compared to Australia and European countries. Although south Asia has a higher prevalence of more unusual allergies compared to other countries (Arakali, Green & Dinakar, 2017). Internationally, the prevalence varies; Canada's prevalence is 6-8% in children under three years of age and 2.5% of adults (Ben-Shoshan et al, 2010). In Brazil, the estimated prevalence is 0.61% in children 4-59

months of age (Goncalves et al, 2016), in the UK the estimated prevalence is 2.6% for children under two years of age and Israel's prevalence is 1.2% for children under two years of age (Geller-Bernstein & Etzioni, 2013). Gender also affects prevalence with females more like to have a food allergy (Pali-Scholl, 2017; Kool, Chandra & Fitzharris, 2016; Just et al, 2016).

It is important to note the difference between self-diagnosed and medically diagnosed allergies. Self-diagnosis leads to a higher prevalence than medically diagnosed (Goncalves et al, 2016; Ben-shoshan et al, 2010; Kotz, Simpson, & Sheikh, 2011; Venter et al, 2016).

Threshold levels

Threshold levels for allergic reactions vary significantly between allergic individuals, and what may cause an adverse reaction in one consumer may not cause an adverse reaction in another. An individual's threshold level can be determined through a double blind placebo-controlled oral food challenge; however this is generally not often conducted.

Blom et al., 2012 suggested the following levels that would affect 5% of the allergic children population:

- 1.6 mg peanut
- 1.1 mg cows milk
- 1.5 mg egg
- 0.29 mg hazelnut
- 7.4 mg cashew

Blankestin et al., (2016) calculated the reference dose for walnut to be 3.1mg for 5% of the allergic population. A 2006 paper by the American Food and Drug Administration (FDA) threshold working group discusses in detail how different processing affects allergenicity and summarised the available published lowest observed adverse effect level of (LOAELs) for food allergens (Table 1) (FDA, 2006). Ballmer-Weber et al (2015) determined threshold doses for 10% of the allergic population for hazelnut, peanut, and celery, ranging from 1.6 to 10.1 mg of protein, 27.3 mg of fish protein and a much higher dose of 2.5 g shrimp protein. Threshold levels may be affected by other cofactors, however further research is still required in this area. These cofactors include:

- exercise (Beaudouin et al., 2006; Cardona et al., 2012; Hanakawa, Tohyama, Shirakata, Murakami, & Hasimoto, 1998; Porcel et al., 2006; Versluis et al., 2016; Wolbing, Fisher, Koberle, Kaesler, & Biedermann, 2013)
- alcohol (Cardona et al., 2012; Versluis et al., 2016; Vidal et al., 2009; Wolbing, Fisher, Koberle, Kaesler, & Biedermann, 2013;)
- wellbeing (Trikha et al., 2013; Versluis et al., 2016; Wolbing, Fisher, Koberle, Kaesler, & Biedermann, 2013)
- medication (Cardona et al., 2012; Pali-Scholl et al., 2008; Versluis et al., 2016; Wolbing, Fisher, Koberle, Kaesler, & Biedermann, 2013).
- gut microflora (Berin & Sampson, 2013; del Giudice, Salvatore, Maiello, & Brunese, 2010; Frossard, Steidler, & Eigenmann, 2007; Tsai, Cheng, & Pan, 2012;)
- processing (Beslar, Steinhart, & Paschke, 2001; Meinlschmidt et al., 2017; Sathe, Teuber, & Roux, 2005; Thomas et al., 2007; Rahaman, Vasiljevic & Ramchandran, 2016)
- fat content of ingested food (Mackie et al., 2012)

VITAL ® Program

The VITAL® Program (Voluntary Incidental Trace Allergen Labelling) is a risk-based tool designed by the Australian and New Zealand Allergen Bureau (www.allergenbureau.net) for food manufacturers to assist in food labelling of allergens. The VITAL scientific panel (VSEP) used clinical data points and statistical modelling to set action levels (Table 1) (Taylor et al., 2014). VITAL® aims to standardise allergen risk assessment process for the food industry to determine if a precautionary statement is required. Manufacturers enter production data into the VITAL calculator to determine if a '*may be present*' statement is required.

Table 1: Threshold levels for eleven food allergens

Food	Summary of published LOAEL (mg protein) for food Allergens (FDA, 2006)	Reference Dose (mg)
egg	0.13 – 1	0.03
peanut	0.25 – 10	0.2
milk	0.36 – 3.6	0.1
tree nuts	0.02 – 7.5	0.1
soy	88 – 522	1
fish	1 – 100	0.1
Wheat		1
Mustard		0.05
lupin		4
sesame		0.2
crustacean		10

Labelling requirements

Australia and New Zealand

To ensure people with allergies, intolerances and Coeliac disease can buy food with confidence, *Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declaration*, clause 4 of the Australia New Zealand Food Standards Code (the Code) requires a declaration of the presence of ten different ingredients and their products (Food Standards Australia New Zealand, 2017). These allergens are wheat, crustacea, egg, fish, milk, peanuts, sesame, soybeans, tree nuts (excluding coconut) and lupin. Sulphites also have to be declared on all packaged products. Declaration is made through the ingredient list.

International

Different countries have different legislation regarding the labelling of allergens. The number of mandatory allergens that require labelling ranges from eight to fourteen allergens, depending on the prevalence of those allergies in that particular country. Most countries appear to require labelling for at least eight of the major allergens.

- Codex – Codex Standard 1-1985 General standard for the Labelling of pre-packaged food section 4.2.1.4 states that the following nine allergens shall always be declared: gluten, crustaceans, egg, fish, peanuts, soybeans, milk, tree nuts and sulphites.
- Europe – The EU food information for Consumers Regulation No 1169/2011 requires food businesses to provide allergy information on food sold unpackaged (in writing or orally) for fourteen allergens. These fourteen allergens are: gluten, crustaceans, egg, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide, lupin, and molluscs. There are certain exemptions that may be applied.
- Canada – Health Canada is responsible for labelling regulation in Canada under the Food and Drugs Act and they require mandatory labelling for tree nuts, sesame seeds, wheat, eggs, milk, soybeans, mustard, fish, crustaceans, shellfish and sulphur dioxide.
- USA – The FDA's Food Allergen Labelling and Consumer Protection Act of 2004 (Public Law 108-282, Title II) states that milk, egg, fish, crustaceans, tree nuts, wheat, peanuts and soybeans are major food allergens and must be labelled. The type of fish, tree nut or crustacean must be specified. This does not address the issue of '*may contain*' statements with the exception that any statement must not be misleading.
- Northern Ireland – Food Information Regulations (Northern Ireland) 2014 states that fourteen mandatory allergens and their derivatives need to be labelled.
- South Africa – Regulation R146/2014 lists the allergens that must be labelled: gluten, milk, egg, soy, peanuts, tree nuts, shellfish, crustaceans and major cereals. (http://safoods.mrc.ac.za/labelling.htm)
- Hong Kong – The Food and Drugs (Composition and Labelling) Regulation 2, Schedule 3: Marking and Labelling of pre-packaged foods clause 4E states that gluten, egg, fish, peanuts, soybeans, milk, tree nuts and sulphite must be labelled. (http://www.cfs.gov.hk/english/food_leg/food_leg_cl.html#5)
- China requires gluten, egg, milk, peanut, tree nuts, soy, crustaceans and fish to be labelled (http://www.ccilc.pt/sites/default/files/general_rules_for_the_labeling_of_prepackaged_foods_gb7718-2011.pdf)

Recalls and incidents

Unlabelled allergens (intentional or unintentional) are the most common reason for food recalls both nationally and internationally. In Australia, the number of recalls is increasing most likely due to an increase in allergy awareness by both manufacturers and consumers (Figure 1). Dairy, peanuts and eggs are the top three undeclared allergens (Figure 2). There are many well documented cases of severe reactions to food that contain undeclared allergens. A common recall is undeclared milk in non-dairy alternative products such as coconut water and sorbets.

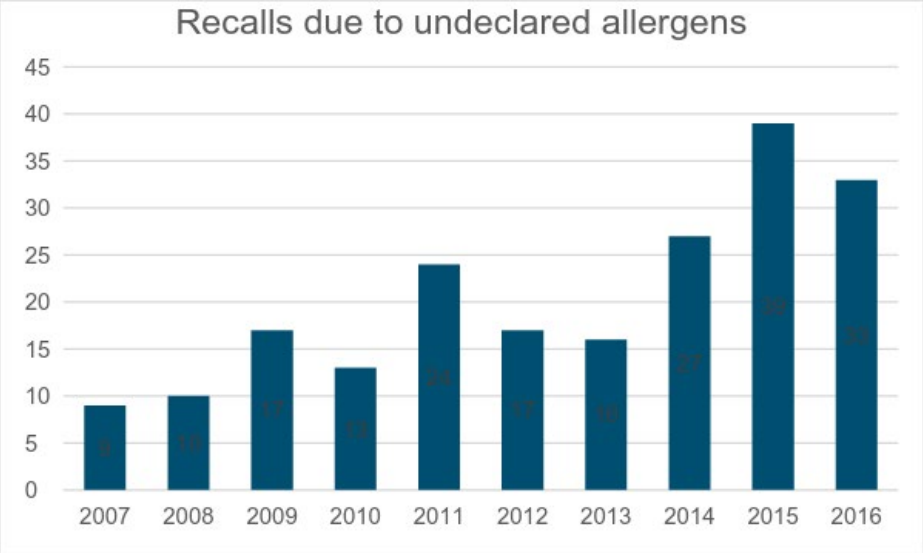

Figure 1: Number of food recalls in Australia coordinated by FSANZ each year, due to undeclared allergens, between 1 January 2007 and 31 December 2016. (Food Standards Australia New Zealand)

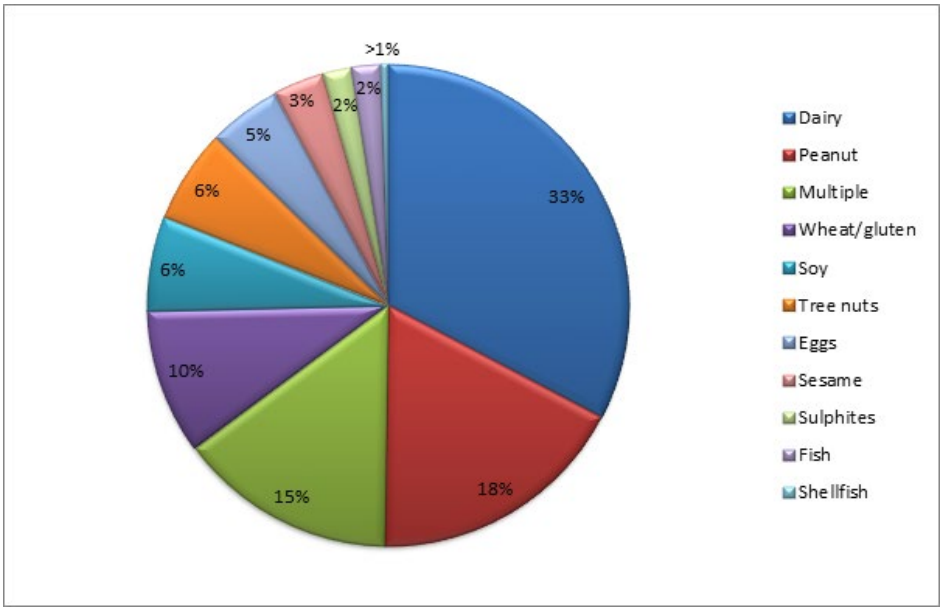

Figure 2: Breakdown of food recalls by allergen, as a proportion of all undeclared allergen recalls during the period 1 January 2007 to 31 December 2016. (Food Standards Australia New Zealand)

Aim

This project aimed to:

- determine the prevalence of undeclared allergens in a variety of packaged and unpackaged food mainly targeting foods with 'free from' statements, and
- examine the different allergen labelling formats and language used by manufacturers.

Method

Samples were purchased at random from supermarkets, greengrocers, cafes and other retail outlets between January 2016 and February 2017 in the greater Sydney area. Samples consisted of a variety of food categories and included 'allergen-free' samples, samples with '*may contain*' statements and samples that made no reference to any allergens. Samples were photographed and all information was recorded in an excel spreadsheet including the ingredient list, allergen and warning statements.

Samples purchased unpackaged from retail establishments only included those with a free claim.

Samples were transported under temperature control to DTS FACTA in Queensland for testing. Testing was conducted using ELISA systems.

Results

520 samples were purchased and tested for a variety of allergens based on their labels and sample type. Sample numbers and results are in Table 2. Please note that an individual sample may have been tested for multiple allergens.

Seventy-nine samples (15.4%) tested positive for allergens that were not listed in the ingredient list (but may have had a precautionary '*may contain*' statement).

Twenty-three were unpackaged samples from retail outlets such as cafes and restaurants. These samples contained the declared '*free from*' allergen at levels ranging from 7.1 ppm to greater than 8,000 ppm.

Fifty-six were packaged samples:

- twelve had a '*free claim*' for the detected allergen (ranging from 9.2 to 9,600 ppm)
- twelve had no statement about the detected allergen (ranging from 17 to 9,100 ppm)
- twenty-three made a precautionary '*may contain*' or equivalent statement about the detected allergen (ranging from 3.9 to 9,100 ppm).

Forty-one had levels of undeclared allergen over 100 ppm. Thirty-three of these were dark chocolate or samples that used dark chocolate as an ingredient that contained undeclared dairy.

Table 2: Sample numbers and analytical results (for allergens tested)

Category	Number of samples	Samples with a '*free-from*' statement			'*may contain*' statement only	No allergen statement	Samples positive for undeclared* allergens	Breakdown of labelling of positive samples#		
		Total	'*free from*' only	Plus '*may contain*' statement^				No statement	'*may contain*' or equivalent statement	Free-from statement
Baby food	19	16	12	4	2	1	0	0	0	0
Bars	30	29	8	21	1	0	3 (10.0%)	0	0	3
Biscuits and cake	25	25	10	15	0	0	3 (12.0%)	0	1	2
Bread	21	21	13	8	0	0	1 (4.8%)	0	0	1
Cereals, muesli and grains	32	26	13	14	3	2	0	0	0	0
Chocolate	67	33	9	24	28	6	27 (40.3%)	3	17 (milk)	1 (gluten), 6 (dairy)
Confectionery	10	6	3	3	1	3	2 (20.0%)	2	0	0
Dried fruit	17	2	2	0	5	10	0	0	0	0
Flour – one ingredient	51	32	22	10	6	13	7 (13.7%)	2	1	4 (gluten)
Sauce, stocks, dips and spreads	31	26	23	3	0	5	1 (3.2%)	1	0	0
Non-dairy alternatives	40	37	30	5	2	3	1 (4.8%)	0	0	1
Pasta and noodles	16	16	11	5	0	0	0	0	0	0
Premix – several ingredients	39	32	21	11	4	3	9 (23.1%)	4	3	2
Processed meat	17	17	15	2	0	0	0	0	0	0
Ready meals and soups	19	17	9	8	0	2	0	0	0	0
Retail (unpackaged)	72	72	72	0	0		23 (31.9%)	-	-	23
Savoury snacks	14	12	8	4	0	2	2 (14.3%)	0	1	1
Total	**520**	**421**	**281**	**137**	**52**	**50**	**79 (15.2%)**	**12**	**23**	**44**

*Undeclared – not listed in ingredient list ^ '*may contain*' for a different allergen to the free from claim
labelling of allergen detected

Retail samples

Seventy-two unpackaged samples were purchased from cafes and bakeries from across the greater Sydney area. These samples were all labelled gluten free and nine were also labelled dairy free. Samples included muffins, slices and cakes. No other information was collected about these samples.

Nineteen (26.4%) samples contained detectable gluten at levels ranging from 7.1 ppm to greater than 8,000 ppm (Figure 3). Six samples contained gluten over 100 ppm which would have resulted in a public recall if the samples were sold packaged. Nine samples contained gluten between 20 ppm and 99 ppm and the remaining two samples contained less than 20 ppm of gluten. Two samples contained greater than 8,000 ppm of gluten and it is likely that mislabelling may have occurred at some point during handling.

Four samples labelled '*dairy free*' contained dairy at 9 ppm, 150 ppm, 1,700 ppm and 1,800 ppm (the sample with 1,700 ppm contained chocolate as an ingredient).

It is clear that more work is required in this area to educate retailers as well as the manufacturers that supply these outlets on the manufacture, transportation, storage and display of these products to prevent cross contamination.

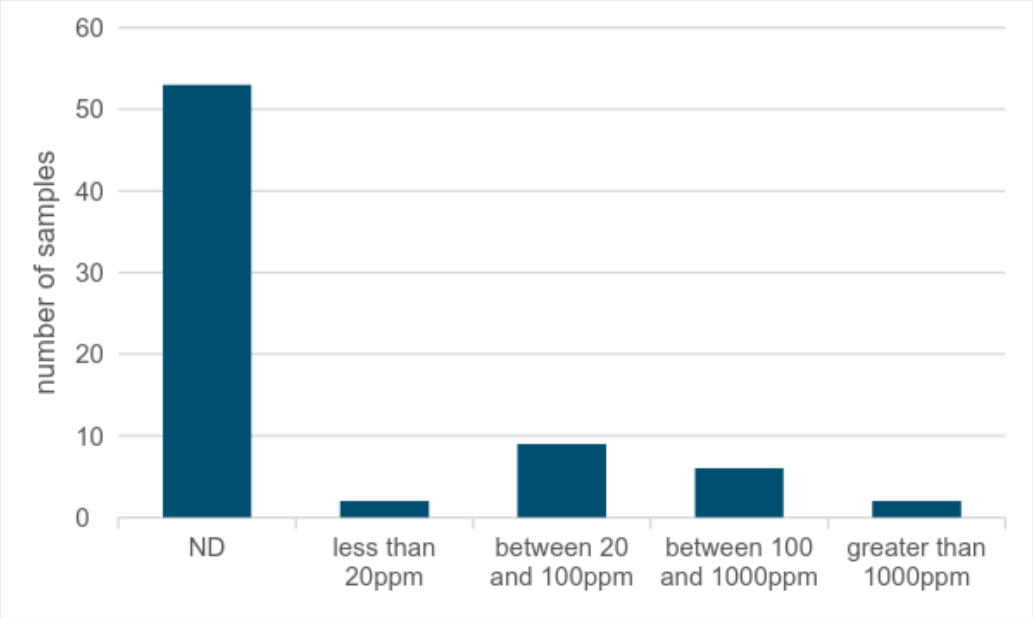

Figure 3: Gluten detected in gluten free unpackaged samples

Packaged samples

A total of 448 packaged samples were tested for a range of different allergens depending on their labels. Three fifths were made or packed in Australia and two fifths were imported from thirty-seven countries. Of the 56 samples positive for unlabelled allergens, country of origin was recorded for 55 of these:

- nineteen listed made in Australia
- six were made in Australia from local and imported ingredients
- four were made in Australia from imported and local
- one was imported from New Zealand
- twenty-six were fully imported from thirteen countries

Dairy

A total of 189 packaged samples were tested for dairy (total milk). The majority of them (n=125) were labelled as dairy free. This included nine samples that implied dairy free by using phrases such as '*without milk*', '*no added dairy*', '*made in a dairy free factory*', '*no other allergens*' or '*vegan*'. This category also included two samples labelled dairy free on front of pack which also had a '*may contain dairy*' statement on back of pack. Twenty-eight samples had a '*may contain dairy*' statement and a further thirty-six samples made no statement about dairy.

Thirty-five of these samples contained dairy ranging from 3.2 to 9,600 ppm (Table 4). Twenty-five samples that contained undeclared dairy were dark chocolate or samples that contained dark chocolate (discussed below).

Chocolate

Fifty-one samples of dark chocolate were tested for dairy. Seventeen of these were labelled '*dairy free*', four implied they were dairy free by using on front of pack '*vegan*' and '*no added dairy*', twenty-two had a '*may contain dairy*' statement and eight made no reference to dairy in a precautionary statement or ingredient list.

Twenty-five samples (49%) contained dairy ranging from 3.2 to 9,600 ppm (Table 3). Fourteen of these had levels over 1,000 ppm. Four were labelled '*dairy free'*, one implied it was dairy free by using the phrase '*no added dairy*', sixteen stated '*may contain dairy*' and four made no statement.

Table 3: Chocolate results

Claim	No. tested	No. tested positive for dairy
Dairy free	17	4 (23.5%)
Dairy free – implied	4	1 (25.0%)
May contain dairy	22	16 (72.7%)
No statement	8	4 (50%)
Total	**51**	**25 (49.0%)**

The four samples making '*dairy free'* statements that contained dairy were all produced from smaller or boutique manufacturers. The sample that used the phrase '*no added dairy*' on front of pack stated on the back of the label in smaller writing '*may contain milk*'. This sample contained 600 ppm of total milk protein.

Table 4: Dairy results

Sample category	Dairy free[1]		May contain dairy[2]		No statement[3]		Total
	No*	Conc#	No*	Conc#	No*	Conc#	
Baby food	4 (0)	-	-	-	-	-	4 (0)
Bars	15 (0)	-	1 (0)	-	1 (0)	-	17 (0)
Biscuits & cake	8 (1)	9.2		-		-	8 (1)
Bread	5 (0)	-	-	-	1 (0)	-	6 (0)
Cereals, muesli & grains	11 (0)	-	-	-	1 (0)	-	12 (0)
Chocolate	21 (5)	24, 910, 2700, 1800, 600,	22 (16)	3.2, 135, 180, 570, 580, 780, 1000, 1100, 1100, 1400, 1800, 3600, 4100, 4600, 8500, 9100	8 (4)	18, 100, 9100, 9600	51 (25)
Confectionery	2 (0)	-	1 (1)	-	2 (1)	17	5 (2)
Flour – one ingredient	5 (0)	-		-	-	-	5 (0)
Sauce, stocks, dips & spreads	6 (0)	-		-	1 (0)	-	7 (0)
Non-dairy alternatives	19 (1)	120		-	17 (0)	-	36 (0)
Pasta & noodles	2 (0)	-		-	-	-	2 (0)
Premix – several ingredients	17 (2)	12, 280	3 (3)	10, 12, 37	3 (0)	-	23 (5)
Ready meals and soups	8 (0)	-		-	2 (0)	-	10 (0)
Savoury snacks	2 (0)	-	1 (1)	400	-	-	3 (1)
Total	**125 (9)**	**-**	**28 (21)**	**-**	**36 (5)**	**-**	**189 (35)**

* Number of samples tested (number of positive samples)
#concentration in ppm
[1] Samples include samples labelled '*dairy free*', '*milk free*', '*no added dairy*', '*vegan*', '*children with milk allergies can join the fun*', '*made in dairy free environment*', '*low allergy*'
[2] Samples include samples labelled '*not suitable for someone with a milk allergy*', '*may contain dairy*', '*may contain milk*', '*made on processing line that uses milk*', '*produced in a plant processing milk*'
[3] Samples include samples that did not list dairy as an ingredient and made no additional statement about dairy

Egg

Forty-nine packaged samples were tested for egg. Thirty-seven of these were labelled '*egg free*'. The remaining twelve samples made no statement about egg. No egg was detected in any sample tested.

Gluten

A total of 414 packaged samples were tested for gluten.

Of these, 323 samples made a '*gluten free*' claim, two made a '*wheat free*' claim and two stated '*contains gluten*' (but did not list a gluten containing ingredient in the ingredient list). Eighteen made a '*may contain gluten*' statement, four made a '*may contain wheat*' statement and sixty-five made no statement about gluten (or wheat).

Seventeen samples (4.1%) contained gluten at levels ranging from 7.1 to 180 ppm (Table 5, page 14). Nine of these samples made a '*gluten free*' claim and one made a '*wheat free*' claim (without a '*may contain*' gluten statement). One sample, which made no reference to gluten on the label and contained 115 ppm of gluten, listed malt extract on the ingredient list but did not state the source of the malt extract.

Internationally, levels under 20 ppm are often classified as gluten free. Excluding samples with less than 20 ppm gluten, the percentage of samples with undeclared gluten is 2.7%.

Table 5: Gluten results

Sample category	Gluten free		Wheat free		May contain gluten		May contain wheat		Contains gluten^		No statement		Total
	No*	Conc#	No*	Conc#	No*	Conc#	No*	Conc#	No*	Conc#	No*	Conc#	
Baby food	12 (0)	-	-	-	-	-	-	-	-	-	2 (0)	-	14 (0)
Bars	29 (1)	19	-	-	-	-	-	-	-	-	1 (0)	-	30 (1)
Biscuits & cake	25 (1)	21	-	-	-	-	-	-	-	-	-	-	25 (1)
Bread	21 (1)	180	-	-	-	-	-	-	-	-	-	-	21 (1)
Cereals, muesli and grains	24 (0)	-	-	-	2 (0)	-		-	-	-	2 (0)	-	28 (0)
Chocolate	30 (1)	7.1	-	-	9 (0)	-	3 (0)	-	-	-	22 (0)	-	64 (1)
Confectionery	6 (0)	-	-	-	-	-	-	-	-	-	4 (0)	-	10 (0)
Dried fruit	2 (0)	-	-	-	-	-	-	-	1 (0)	-	-	-	3 (0)
Flour – one ingredient	32 (4)	9.6, 20 33, 100	-	-	5 (0)	-	-	-	1 (1)	71	13 (2)	32, 140	51 (7)
Sauce, stocks, dips & spreads	26 (0)	-	-	-	-	-	-	-	-	-	5 (0)	-	31 (0)
Non-dairy alternatives	28 (0)	-	-	-	-	-	-	-	-	-	6 (0)	-	34 (0)
Pasta & noodles	15 (0)	-	1 (0)	-	-	-	-	-	-	-	-	-	16 (0)
Premix – several ingredients	30 (1)	12	-	-	2 (1)	9.3	1 (0)	-	-	-	6 (3)	33, 46, 115	39 (5)
Processed meat	17 (0)	-	-	-	-	-	-	-	-	-	-	-	17 (0)
Ready meals and soups	15 (0)	-	-	-	-	-	-	-	-	-	2 (0)	-	17 (0)
Savoury snacks	11 (0)	-	1 (1)	15	-	-	-	-	-	-	2 (0)	-	14 (1)
Total	**323 (9)**		**2 (1)**		**18 (1)**		**4 (0)**		**2 (1)**		**65 (5)**		**414 (17)**

* Number of samples tested (number of positive samples) ^ with no gluten containing ingredient

#concentration in ppm

Peanuts

A total of 153 packaged samples were tested for peanut. Allergen labelling for peanuts was quite varied. Allergen labelling often used the generic term '*nuts*' which does not differentiate between peanuts and tree nuts. Fifty-seven samples were labelled '*peanut free*' using different statements such as '*nut free*', '*peanut free*', '*no allergens*' or '*peanut free factory*'. Forty-one had a '*may contain peanuts*' or '*may contain nuts*' statement, twelve had '*may contain tree nuts*', thirty-nine made no statement about any type of nuts and four listed tree nuts in the ingredient list but had no statement about peanuts. One sample (0.65%) contained peanut at 25 ppm (Table 6). This was an imported sauce, which made no statement about nuts and was subsequently recalled. No other sample contained detectable level of peanut protein.

Table 6: Peanut results

Sample category	Peanut free[1]		May contain peanuts[2]		No statement[3]		Total
	No*	Conc#	No*	Conc#	No*	Conc#	
Baby food	5 (0)	-	-	-	-	-	5 (0)
Bars	5 (0)	-	-	-	1 (0)	-	6 (0)
Biscuits & cake	5 (0)	-	1 (0)	-	1 (0)	-	7 (0)
Bread	3 (0)	-	-	-	2 (0)	-	5 (0)
Cereals, muesli and grains	9 (0)	-	5 (0)	-	6 (0)	-	20 (0)
Chocolate	5 (0)	-	25 (0)	-	17 (0)	-	47 (0)
Confectionery	1 (0)	-	2 (0)	-	2 (0)	-	5 (0)
Dried fruit	-	-	5 (0)	-	12 (0)	-	17 (0)
Flour – one ingredient	5 (0)	-	-	-	-	-	5 (0)
Sauce, stocks, dips & spreads	3 (0)	-	-	-	3 (1)	25	6 (1)
Non-dairy alternatives	2 (0)	-	2 (0)	-	2 (0)	-	6 (0)
Pasta & noodles	1 (0)	-	-	-	-	-	1 (0)
Premix – several ingredients	9(0)	-	1 (0)	-	6 (0)	-	16 (0)
Ready meals and soups	4 (0)	-	-	-	2 (0)	-	6 (0)
Savoury snacks	-	-	-	-	1 (0)	-	1 (0)
Total	**57 (0)**		**41 (0)**		**55 (1)**		**153 (1)**

* Number of samples tested
# Concentration in ppm
[1] Samples include those labelled '*Peanut free*', '*No allergens*', '*No peanuts are ever used*' '*Made in a nut free environment*', '*Peanut and tree nut free*', '*Peanut and nut free*', '*Nut free*', '*produced in a nut free factory*', '*peanut free, contains almonds*', '*nut free, made in a facility that uses tree nuts*', '*peanut free, may contain tree nuts*', '*made in a facility that uses nuts but is peanut free*'
[2] Samples include samples labelled with no peanut or nut free claim but with '*may contain traces of peanuts and tree nuts*', '*produced in a facility that uses peanuts and tree nuts*', '*may contain peanuts', 'may contain nuts*' or '*contains tree nuts, may contain peanuts*'. Also includes samples with no peanut free claim, contain tree nuts in the ingredient list and have a '*may contain peanut*' statement
[3] Samples included those labelled with no reference to peanuts on the label. This includes samples that contain tree nuts in the ingredient list and do not have a '*may contain peanuts*' statement and samples that make a '*may contain tree nuts*' statement only

Sesame

Twenty-nine samples were tested for sesame. Five samples were labelled '*sesame free*'. Nine samples had a '*may contain*' sesame and fifteen made no statement about sesame. Sesame was detected in one sample at 0.84 ppm (which is below the limit of quantification for the test). This sample had a '*may contain sesame*' statement.

Soy

A total of 185 packaged samples were tested for soy. Fifty-five samples were labelled '*soy free*' including four using '*no allergens*', twenty-five made a '*may contain*' statement and 105 samples made no statement about soy on the labelling.

Two samples (1.1%) contained soy at 13 and 270 ppm (Table 7). One bread sample with a free claim contained soy at 13 ppm and one sample of buckwheat flour which made a '*no allergens*' claim contained soy at 270 ppm.

Table 7: Soy results

Sample category	Soy free [1]		May contain soy[2]		No statement[3]		Total
	No*	Conc#	No*	Conc#	No*	Conc#	
Baby food	1 (0)	-	3 (0)	-	9 (0)	-	13 (0)
Bars	3 (0)	-	3 (0)	-	14 (0)	-	20 (0)
Biscuits and cake	3 (0)	-	1 (0)	-	7 (0)	-	11 (0)
Bread	4 (1)	13	-	-	4 (0)	-	8 (1)
Cereals, muesli and grains	3 (0)	-	-	-		-	3 (0)
Chocolate	10 (0)	-	5 (0)	-	9 (0)	-	14 (0)
Confectionery	-	-	-	-	2 (0)	-	2 (0)
Dried fruit	-	-	1 (0)	-		-	1 (0)
Flour – one ingredient	4 (1)	270	1 (0)	-	3 (0)	-	8 (1)
Sauce, stocks, dips & spreads	-	-	-	-	14 (0)	-	14 (0)
Non-dairy alternatives	13 (0)	-	-	-	17 (0)	-	30 (0)
Pasta and noodles	2 (0)	-	-	-		-	2 (0)
Premix – several ingredients	7 (0)	-	7 (0)	-	15 (0)	-	29 (0)
Processed meat	2 (0)	-	1 (0)	-	5 (0)	-	8 (0)
Ready meals and soups	3 (0)	-	2 (0)	-	3 (0)	-	8 (0)
Savoury snacks	-	-	1 (0)	-	3 (0)	-	
Total	**55 (2)**		**25 (0)**		**105 (0)**		**185 (2)**

* Number of samples tested
# Concentration in ppm
[1] Samples include samples labelled '*Soy free*', '*No direct allergens*', '*No other allergens*' and '*packed in an allergen free room*'
[2] Samples include samples labelled '*May contain soy', Produced in a facility that uses soy' processed on equipment that uses soy'*
[3] Samples include samples labelled with no reference to soy

Tree nuts

Almond

A total of 163 packaged samples were tested for almond.

As with peanuts, the labelling of tree nuts was quite varied. Forty-one samples were labelled '*tree nut free*'. Statements used included '*Nut free*', '*No allergens*', '*Peanut and tree nut free*' and '*made in a nut free environment*. Two samples included in this group had a '*nut free*' claim on the front of pack and a '*made in a facility that uses tree nuts*' statement on the back of pack. No sample specifically mentioned almond.

Fifty-seven were labelled '*may contain tree nuts'*. These statements included '*may contain traces of peanuts and tree nuts*', '*produced in a facility that uses peanuts and tree nuts*', '*May contain traces of hazelnut', 'May contain traces of peanuts and almonds' and 'packaged on equipment that is used to pack nuts'.* This category included three samples that had both a '*peanut free*' claim as well as a '*made in a facility that handles nuts*' statement and one sample that contained macadamias in the ingredient list and had a '*may be present: tree nuts and peanuts*' statement. Only one sample specifically mentioned almond in the '*may contain*' statement.

Sixty-five samples made no statement about tree nuts. This category included four samples that made a '*peanut free*' claim, one sample with a '*may contain peanuts*' statement and one sample that listed cashew in the ingredient list.

Six samples (3.7%) contained almond at levels ranging from 2.7 to 145 ppm (Table 8). Two bars from the same manufacturer with a '*nut free*' claim on front of pack and a '*made in a facility that makes products that contain tree nuts*' contained almond at 2.7 and 12 ppm. These bars are no longer made by the manufacturer. A cake mix with no statement contained 140 ppm almond and after an investigation it was concluded that this was due to cross contamination from another sample that was made on the same line. A biscuit sample with a '*peanut free*' claim and a '*made in a facility that handles nuts*' contained 3.9 ppm almond. The remaining two samples were both chocolate, had '*may contain traces of nuts*' statements and contained almond at 21 and 145 ppm.

Other tree nuts

Nine packaged samples of almond milk were tested for cashew with no detections. Fourteen samples that made a '*nut free*' claim were tested for hazelnut, macadamia and walnut with no detections. Two of these samples were the bars previously mentioned that contained almond at 2.7 and 12 ppm.

Table 8: Almond results

Sample category	Tree nut free[1]		May contain tree nuts[2]		No statement[3]		Total
	No*	Conc#	No*	Conc#	No*	Conc#	
Baby food	4 (0)	-	-	-	1 (0)	-	5 (0)
Bars	4 (2)	2.7, 12	-	-	-	-	4 (2)
Biscuits and cake	2 (0)	-	3 (1)	3.9	2 (0)	-	7 (1)
Bread	2 (0)	-	-	-	-	-	2 (0)
Cereals, muesli and grains	8 (0)	-	6 (0)	-	3 (0)	-	17 (0)
Chocolate	3 (0)	-	34 (2)	145, 21	8 (0)	-	45 (2)
Confectionery	1 (0)	-	2 (0)	-	2 (0)	-	5 (0)
Dried fruit	-	-	4 (0)	-	13 (0)	-	17 (0)
Flour – one ingredient	6 (0)	-	7 (0)	-	10 (0)	-	23 (0)
Sauce, stocks, dips and spreads	3 (0)	-	-	-	3 (0)	-	6 (0)
Non-dairy alternatives	1 (0)	-	-	-	13 (0)	-	14 (0)
Pasta and noodles	1 (0)	-	-	-	-	-	1 (0)
Premix – several ingredients	6 (0)	-	1	-	9 (1)	140	16 (1)
Savoury snacks	-	-	-	-	1 (0)	-	1 (0)
Total	**41 (2)**		**57 (3)**		**65 (1)**		**163 (6)**

* Number of samples tested
# Concentration in ppm
[1] Samples include samples labelled '*Nut free*', '*No allergens*', '*Peanut and tree nut free*', '*made in a nut free environment*' and '*nut free, made in a facility that uses tree nuts*'
[2] Samples include samples with no tree nut free claim and labelled '*may contain traces of peanuts and tree nuts*', '*produced in a facility that uses peanuts and tree nuts*', '*May contain traces of hazelnut', 'May contain traces of peanuts and almonds'*
[3] Samples include samples that make no reference to tree nuts on the label, includes samples that make a '*may contain peanut*' statement

Labelling language

Standard 1.2.3 of the Code requires that all packaged food for sale must list allergens present in the food. At the time of this survey this included nine food allergens. The Code does not dictate the exact wording or format of a precautionary statement – only that it is required and it must be legible.

A total of 448 packaged samples were analysed in this survey. Allergen precautionary statements and formats were recorded for 444 of these samples.

Declaring allergens

- 232 (52.3%) declared no allergens in the ingredient list
- 212 (47.7%) declared allergens in the ingredient list. Of these
  - The allergenic ingredient was bold in seventy-seven (36.3%) samples and not bold in 135 (63.7%) samples
  - 129 (60.8%) contained an additional 'contains' statement to the ingredient list highlighting the presence of an allergenic ingredient and eighty-three (39.2%) did not.
  - Sixty-three (29.7%) had both bolded the allergenic ingredient and had an additional 'contains' statement highlighting the presence of allergenic ingredients.
  - Thirty-nine (18.4%) that contained allergens contained no other allergen statement aside from the ingredient list.

Additional '*contains*' statements are not mandatory in the Code. Listing an allergen in the ingredient list is considered a declaration. Additional precautionary '*contains*' statements are used by businesses to highlight to consumers any allergens in the product.

The format of the additional '*contains*' statement was usually under the ingredient list using the words '*contains*' or '*allergy advice*':

- 108 samples used a derivative of '*contains*'
- Ten samples used a derivative of '*allergy advice*' or '*allergens*:'
- Eight samples used a statement to the effect – '*for allergen advice see ingredients in bold/capitals*'
- Three samples used '*warning product contains…*'

May contain

'*May contain*' statements are not mandated by the Code. They are used to provide an indication to consumers of the unintentional allergens that may be present through unavoidable cross contamination in the processing environment, but are not present as an intentional ingredient in the sample.

- 256 (57.7%) did not have a '*may contain*' statement
- 188 (42.3%) had a '*may contain*' allergen statement. The exact wording used was varied. Below are examples of allergen wording used on the labelling of samples in this survey:
  - Forty (21.3%) used a phrase to effect of 'made in a facility/factory that also uses …'
  - Twenty-six (13.8%) used a phrase to effect of 'made on a production line that also uses'
  - Thirteen (6.9%) used a phrase to effect of 'may be present'

- Ninety-seven (51.6%) used a phrase to effect of 'may contain'
- Twelve (6.4%) used a phrase to effect of 'may contain traces'.

Nine samples which did not have a '*may contain*' statement made an additional comment reinforcing the allergy-free samples such as '*manufactured in a nut free environment*' or '*manufactured in an environment which does not use …*', '*no cross contact allergens*' and '*we test for…*'. One sample included '*contains traces of*' in the ingredient list and did not have a '*may contains*' statement. A chocolate sample stated '*not suitable for someone with a milk allergy*'.

Disappointingly two samples from the same manufacturer contained both the statement '*dairy free*' and '*may contain traces of dairy*'. These two samples contained total milk at the levels of 910 and 2,700 ppm. These samples were recalled and the labelling altered.

Making a free claim

The wording used by manufacturers to declare a sample free from an allergen also varied. The most common was a front of pack statement such as *'gluten free*' or '*dairy free*'. Other less direct statements included '*vegan*' (implying dairy free), '*low allergy*', '*no cross contact allergens*', '*no allergens*', '*made in a nut, dairy, gluten and egg free environment*', '*no added dairy*', '*children with milk allergies can join in the fun*', '*no other allergens*' and '*low allergy*', '*no nuts, dairy or gluten is ever used*' and '*we test for gluten, egg, dairy*'. The majority of these secondary statements were on back of pack near the ingredient list.

Statements such as '*no other allergens*' and '*low allergy*' are ambiguous. Samples with both a '*free claim*' and a '*may contain*' statement for the same allergen are misleading and dangerous.

Adherence to VITAL guidelines

VITAL guidelines recommend bolded allergenic ingredients in the ingredient list, a '*contains*' statement and a precautionary '*may be present*' statement depending on final calculations of the VITAL calculator. Applying the VITAL guidelines from the labelling alone to the 444 samples analysed:

- For those samples containing allergens, seven samples from five companies contained allergen labelling in the VITAL format.
- Two samples from two companies which did not contain allergens had a '*may be present'* statement.

Discussion

It is obvious from this survey and published literature that the labelling for intentionally added allergenic ingredients and unintentional allergens (through cross contamination) is diverse. A variety of phrases, formatting and placements on label are used to convey the allergenic status of a product to the consumer. Any intentional allergenic ingredient must be noted in the ingredient list. However, as the Code does not specify how allergenic ingredients must be labelled, these can be in bold, italicised, in capitals or in the same font and style as the other ingredients. Manufacturers are known to include a variety of statements, in conjunction with the ingredient list, to inform consumers on the allergenic status of a product. Again, this is not specified in the Code. This variety of statements, formats and placement can cause confusion for the consumer and may be misleading. For example, the sample labelled '*dairy free*' on front of pack and then contained a '*may contain dairy*' statement in smaller font under the ingredient list on the back of pack is not only confusing for the consumer, but it could have a disastrous consequence for an allergic consumer relying on the front of pack '*dairy free*' statement.

Dairy contamination of dark chocolate is a known problem that the industry is proactively addressing. Due to the manufacturing process, dark chocolate can become contaminated with dairy if a milk chocolate product is manufactured on the same production line. The dairy contamination will also not be homogenous in the batch. Contamination will be higher earlier in the production run and decrease towards the end of the run. In this case, milk is not included in dark chocolate's ingredient list as its presence is not intentional, nor do manufacturers know the level of contamination as it varies throughout the batch and from batch to batch. To avoid such cross contamination '*Dairy free*' dark chocolate must be run on a dedicated dairy free production line. There have been several international surveys of dairy contamination in dark chocolate. An American survey conducted between 2009-2013 found 54% of dark chocolate tested contained milk when milk was not listed in the ingredient list (FDA, 2016). Three quarters of the chocolate tested had a '*may contain*' statement and the FDA concluded that consumers (for dark chocolate only), should read '*may contain*' as '*likely to contain*'. Contamination rates in the FDA survey were similar to the levels seen in this survey and it appears that in Australia a '*may contain milk*' statement on dark chocolate should also be read as '*likely to contain*'. This survey also concluded that there is a fifty percent chance that dark chocolate with no milk precautionary statement is likely to contain milk. A second American survey by the FDA conducted in 2013-14 (Bedford, Yu, Wang, Garber & Jackson, 2017) again found similar results with 56% of samples tested containing milk with the majority over 1,000 ppm concluding that type of precautionary statement did not predict the level (or absence) of milk in dark chocolate.

A Dutch survey, resulting from a consumer suffering a severe allergic reaction to chocolate sprinkles in the Netherlands (a common sandwich filling) found all brands of dark chocolate sprinkles tested, that did not list milk as an ingredient nor have a precautionary statement, contained milk ranging from 2 to 3,547 ppm total milk (Spanjersberg, Knulst, Kruizinga, Van Duijn, & Houben, 2010). This study did a probabilistic risk assessment of what proportion of the allergic population would react to these levels found in the chocolate sprinkles. Using consumption data and adult threshold data from a previous paper they concluded that the sample with the highest contamination would cause a subjective reaction in over 60% of the allergic and an objective reaction in over 12% of males and 9% of females of the allergic population.

Crotty and Taylor (2010) found fourteen of eighteen samples of dark chocolate with a precautionary statement contained milk ranging from 3.7 to 4,800 ppm. Crotty and Taylor also examined the type of precautionary statement and level of milk in 100 samples tested (dark chocolate was one category of many). Thirty-four samples in total contained undeclared milk. Those with a '*may contain*' statement were more likely to contain milk than those with a '*shared facility*' or shared '*equipment statement*'. It also appeared that products from a smaller company were more

likely to contain milk residues. No relationship between level of milk contamination or precautionary statement type was evident. The study conducted by Crotty and Taylor (2010) was a small study and did not conclude that consumers with milk allergies should avoid dark chocolate.

Other published surveys have also found food categories with more pertinent precautionary statements. Examples include:

- An Australian survey of food samples that carried a precautionary label in 2008 and which was repeated in 2011 found muesli bars were more likely to be contaminated with peanuts (but at levels below the threshold level that would cause 5% of the allergic population to react) (Zurzolo, et al, 2013b).
- A Thai survey found milk was often undeclared in instant noodles, curry and salad dressing and egg was often undeclared in fishery samples (Surojanametakul et al, 2012).
- A large Italian study found that there was a 4.4% chance that gluten free pasta or flour was contaminated with gluten (0.9% chance this was over 20 ppm) (Losio et al, 2017).
- Khuda et al (2016) found that 25% of bakery samples and 11% of snack samples with no precautionary statement contained soy and 19% of bakery and 9% of snacks with a precautionary statement contained soy.
- Remington, Baumert, Marx & Taylor (2013) found peanut in 8.6% of 186 packaged samples that had a peanut precautionary statement (which was a much higher prevalence compared to the current survey).

Consumer confusion, understanding and preference

Consumers' confusion around precautionary statements is understandable given the variety of statements and formats. Examining the analytical results there appear to be certain food groups where the precautionary statement has more relevance compared to other food groups, e.g. dark chocolate and muesli bar. Ambiguous statements such as '*low allergy*' or '*no cross contact*' do not help the consumer clarify the risk to an allergic consumer from eating that product. Conflicting statements as mentioned previously also cause confusion.

Using the generic term 'nuts' to label both peanuts and tree nuts can be limiting for those with a peanut or tree nut allergy. A product with potential cross contamination from peanuts labelled '*may contain nuts*' would be avoided by consumers with both peanut and tree nut allergy, however if the product was labelled '*may contain peanut*' then those with a tree nut allergy could have confidence that the product is safe for them to consume. The same can also be said for using '*tree nuts*' as opposed to naming the particular nut of concern. For example, a product labelled '*made on equipment that also processes tree nuts*' would mean all consumers with a tree nut allergy would avoid the product. However, labelling the product '*made on equipment that also processes cashews*' would allow those with an allergy to macadamia or almonds for example to have the confidence the product was safe for them to consume. Of the samples tested for almond, only three samples mentioned a specific tree nut. One sample stated '*may contain hazelnut*', one said '*manufactured in a facility where almonds are used*' and one stated '*manufactured in a factory which does not use and tests for the presence of peanuts, almonds, hazelnuts, macadamia and walnut*'.

Using a blanket '*may contain*' statement is also limiting for the consumer. Listing all allergens in a '*may contain'* statement restricts the number of consumers who could consume the product. This also lessens the impact of having a precautionary statement. The more consumers see long precautionary statements, the less consideration they will pay to them. Examining ingredients and processing procedures to determine an accurate precautionary statement is beneficial for both consumers and manufacturers.

Zurzolo, Koplin, Mathai, Tang & Allen (2013a) concluded that avoidance of foods with a precautionary statement differed depending on the wording of the statement, with the precautionary '*may contain*' statements often being ignored. Helfe et al. (2007) concluded that consumers with a food allergy were less likely to heed precautionary labelling than previously and the format of the precautionary statement did not affect the likelihood of finding detectable allergen. Marchisotto et al. (2016) found respondents were more inclined to purchase foods with a '*made in the same facility*' statement as opposed to '*may contain*' or '*made on the same processing line*'. Remington et al, (2013) found that samples tested with a unique precautionary statement or '*shared equipment*' statement were more likely to contain peanut than those with a '*shared facility*' statement. This perceived difference in risk between '*made in the same facility*' and '*made on the same processing line*' & '*may contain*' appears to be supported by published studies but more work is required in this area.

A Canadian survey of labelling preferences found that there were three distinct groups of consumers with distinct preferences on allergen labelling. Consumers wanted standardised precautionary and safety statements, preferred the use of symbols more than statements together with a more definite allergen content statement (Marra et al, 2017). Respondents who consider allergens when purchasing food preferred precautionary statements the least.

Less than 50% of samples in this survey had a precautionary statement with most of those that did using the phrase '*may contain*'. The other two top precautionary statements in this survey were '*made in a facility*' (21.3%) then '*made in a production line*' (13.8%). This was similar to an Australian survey in 2009 by the Allergen Bureau which found 47% of analysed samples included a precautionary statement (Allergen bureau, 2010). Comparing results from the 2009 Allergen Bureau survey to this survey, allergen labelling has changed little in the last eight years. Bolding of allergenic ingredients in the ingredient list has increased slightly from 26% to 32%, however uptake of the VITAL precautionary format guidelines appears to have decreased from 7% to 2%.

Not only are consumers confused about the variety of precautionary statements but there also appears to be poor consumer understanding of the legal requirement of allergen labelling across the globe. Marchisotto et al. (2016) found that almost 30% of respondents in a survey of the allergic community in America and Canada incorrectly thought a precautionary statement was required by law.

Conclusion

There is a wide variety in the language and formatting of allergen precautionary statements in Australia. This diversity can be confusing and at time misleading for the consumer. Because precautionary statements are voluntary, allergic consumers cannot predict the true risk of consuming a product, based solely on the precautionary label. Consumers need to take in product history, known food category issues as well as manufacturer's reputation.

Excluding retail and chocolate samples, the prevalence of undeclared allergens in this survey was low ranging from 'no detections' to 4.1% for the different allergens tested.

Milk contamination of dark chocolate is a known problem which the chocolate industry is proactively addressing. However, clearer labelling is certainly needed on some of these products. With levels of milk contamination in dark chocolate above 10,000 ppm it can be argued that these are no longer trace amounts and the product should have a precautionary label of '*contains*' to reduce ambiguity. Likewise, if contamination levels are this high having '*no added dairy*' or '*dairy free but may contain milk*' is again misleading and potentially dangerous. When businesses use a free claim, this must be verifiable and managed appropriately.

Education in the retail sector is required to ensure the safe transportation, storage and display of these products to reduce the chance of cross contamination. This survey found 32% of unpackaged '*free from*' samples contained the '*free from*' allergen. This prevalence is much too high. The National Allergy Strategy (NAS) launched in 2017 has online training material for the retail sector available at https://foodallergytraining.org.au. The Food Authority will continue to promote this training at its retail food meetings, as well as amongst Environmental Health Officers inspecting this sector and online. An allergen module is included in Food Safety Supervisor certification.

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