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REVIEW PAPER

"May Contain" Allergen Statements: Facilitating or Frustrating Consumers?

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Abstract As a result of mandatory labelling legislation, major food allergens that commonly cause allergic reactions are declared on packaging. The usage of precautionary allergen labelling (PAL) on packaging is not regulated in all countries, and the food industry uses various forms of "may contain" labelling which firstly is often inconsistent and secondly over time may diminish the value of such advisory statements. Hence, the aims of this paper are to review the current industry usage of PAL and to provide recommendations on future use that are of value to academics, policy makers, food industry, and consumers. A case study example is used to illustrate the likely costs and benefits of improving the current PAL status by considering a "peanut-free" product and calculation using the Voluntary Incidental Trace Allergen Labelling (VITAL) calculator. Governance such as addressing the inconsistent usage of PALs, promoting the harmonization of language used in PALs, and improving PAL status to quantified PAL statements would be helpful in communicating risks to consumers, so they can make informed choices when purchasing food products.

Keywords Allergens · Eliciting dose · Precautionary allergen labelling (PAL) · Quantified PAL

Introduction

Food allergy, as a condition, results in an adverse immune response to proteins in foods that can be immunoglobulin E (IgE)-mediated, non-IgE-mediated, or a combination of both (Kulis et al. 2015; Sicherer and Sampson 2010). The immune response can trigger a number of symptoms involving the skin, digestive, respiratory, and cardiovascular systems (Boyce et al. 2010). Some of the most common food allergens are highly prevalent in the USA such as fish,

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eggs, milk, peanuts, shellfish, soy, tree nuts, and wheat (Boyce et al. 2010; Branum and Lukacs 2009), whilst sesame (Dano et al. 2015), lupine (Jappe and Vieths 2010), mustard (Sirvent et al. 2012), and celery (Fuchs et al. 2012) have been identified as major allergenic food sources in European countries. Shellfish is the most common food allergen from Asia (Lee et al. 2013; Shek et al. 2010; Wu et al. 2012) whilst egg and cow's milk allergies are most prevalent among young children and infants in Asia too (Chen et al. 2011; Lee et al. 2013; Wu et al. 2012). Estimates for the total number of consumers affected by food allergies range from 1–2% adults and 5–8% children in westernized countries (Gupta et al. 2011; Patel et al. 2011; Tang and Hsiao 2016). The above studies are examples of common allergens occurring in specific countries as a result of geographic and dietary variations.

As there is no preventive medical treatment for food allergies and in extreme cases such allergies can result in symptoms such as anaphylactic shock, in order to avoid allergic reactions, strict avoidance of the allergenic food is the only mechanism available to sensitive individuals (Burks et al. 2012). In order to protect consumers, regulations are in place across the world, e.g., the Food Allergen Labelling and Consumer Protection Act of 2004 (US FDA 2016), EU Regulation No. 1169/ (2011), GB 7718-2011 The General Rules for the Labelling of Prepackaged Food (CIRS 2014; USDA Gain Report 2011), and Standard 1.2.3—Mandatory Warning and Advisory Statements and Declarations (FSANZ 2014). These regulations state that the foods that cause the most common allergenic reactions need to have their presence identified on food product labels, where the description of the product alone will not give an indication, e.g., milk labelled as milk, nuts labelled as nuts (Table 1).

In EU Regulation No. 1169/2011, 14 food allergens are listed as requiring mandatory labelling. However, legislation does not consider the wider need for warnings with regard to traces of allergenic material that at some point in the food supply chain may cross-contaminate and form an inclusion in what otherwise is considered in the legislation context as a non-allergenic food product. This argument was first highlighted more than a decade ago by Anandan and Sheikh (2005) and Said and Weiner (2004) leading to food manufacturers using an "alibi" or precautionary allergen labelling (PAL) on their packaging via statements such as "may contain" where there is a potential for cross-contamination (Luber et al. 2015). The aim of this paper is to review the development and use of PAL, then consider the proliferation of various types of PAL descriptors. This in turn will provide recommendations for the development of a quantified PAL approach based on threshold doses and risk assessment and management that then act as a guide for the food industry and practitioners in assessing the need to provide "may contain" labelling. The structure of the paper will firstly examine the literature and then build on this through reviewing the role of PAL in preventing accidental exposure to allergens and the techniques to undertake quantitative mechanisms of risk assessment in order to inform the use of PAL followed by an estimation using cost–benefit analysis. A case study example is used to illustrate the cost and the benefit where a quantified PAL approach is conducted.

Food Allergen Labelling Regulations

There is an innate degree of uncertainty with regard to the actual risk of allergenic cross-contamination and lack of information on the threshold levels above which allergenic

Table 1 Regulatory requirements for allergen labelling by country (adapted from AG nd; EC 2011; FARRP nd; FDA 2013; Gendel 2012; Health Canada n.d.; Manning and Soon 2016)

Food type	EU	USA	Canada	Australia/New Zealand
Cereals with gluten	Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof. Note that wheat is included in the description.	Wheat	Cereals with gluten including wheat	Cereals containing gluten and their products, namely, wheat, rye, barley, oats, and spelt and their hybridized strains other than where these substances are present in beer and spirits standardized in Standards 2.7.2 and 2.7.5, respectively
Crustacean shellfish	Crustaceans and products thereof	Crustacean shellfish (e.g., crab, lobster, or shrimp)	Seafood (fish, crustaceans, shellfish)	Crustaceans and their products
Fish	Fish and products thereof	Fish (e.g., bass, flounder, or cod)		Fish and fish products, except for isinglass derived from swim bladders and used as a clarifying agent in beer and wine
Egg	Eggs and products thereof	Egg	Eggs	Egg and egg products
Peanuts	Peanuts and products thereof	Peanuts	Peanuts	Peanuts and peanut products
Soybeans	Soybeans and products thereof	Soybeans	Soy	Soybeans and soybean products
Milk	Milk and products thereof (including lactose)	Milk	Milk	Milk and milk products
Tree nuts	Tree nuts (see the "Introduction" section) and products thereof	Tree nuts (e.g., almonds, pecans, or walnuts)	Tree nuts (almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts)	Tree nuts and tree nut products other than coconut from the fruit of the palm *Cocos nucifera*
Sulphites	Sulphur dioxide and sulphites at concentrations of ≥10 mg/kg or 10 mg/l expressed as SO_2	≥10 mg/kg[b]	Directly added or ≥10 mg/kg	Added sulphites in concentrations of 10 mg/kg or more
Mustard	Mustard and products thereof		Mustard	
Sesame	Sesame seeds and products thereof		Sesame seeds	Sesame seeds and sesame seed products
Celery	Celery and products thereof			
Lupin	Lupin and products thereof			
Molluscan shellfish	Molluscs and products thereof			Molluscs
Wheat				
Buckwheat				
Bee pollen/propolis				Bee pollen

Table 1 (continued)

Food type	EU	USA	Canada	Australia/New Zealand
Royal jelly				Royal jelly
Peach				
Pork				
Tomato				

Food type	Hong Kong	China	Japan[a]	Korea	Mexico, Chile, and Argentina	Venezuela, Nicaragua, Cuba, Costa Rica, and Colombia
Cereals with gluten	X				X (not wheat)	X
Crustacean shellfish	X	X	X (crab, shrimp, prawn)	X (crab, shrimp, prawn)	X	X
Fish	X	X		X (mackerel)	X	X
Egg	X	X	X	X	X	X
Peanuts	X	X	X	X	X	X
Soybeans	X	X		X	X	X
Milk	X	X	X	X	X	X
Tree nuts	X					X
Sulphites	≥10 mg/kg				≥10 mg/kg	≥10 mg/kg
Mustard						
Sesame						
Celery						
Lupin						
Molluscan shellfish						
Wheat		X	X	X		
Buckwheat			X	X		
Bee pollen/propolis						
Royal jelly						
Peach				X		
Pork				X		
Tomato				X		

X mandatory labelling is required

[a] Voluntary labelling recommended for 20 other foods

[b] Additional legislation

reactions in sensitive individuals are triggered (Ford et al. 2010). This has prompted the food manufacturing sector to introduce PAL (Allen et al. 2014). Voluntary PAL is often undertaken by the food industry to warn of the potential for cross-contamination (and cross-contact) such as in the instance of shared manufacturing equipment and/or facilities. In a number of countries, this approach is not formalized and the prevalence of multiple types of PAL statements remains high (Zurzolo et al. 2012) which is potentially unhelpful to consumers (Turner et al. 2016). Indeed, it has been suggested that the use of PAL is an intentional strategy to mitigate multiple levels of risk (on the spectrum from low to high) and thus is used to cover the manufacturers' back and/or to protect supply chain actors against product liability claims (Pape 2009).

Based on the UK "FreeFrom" survey conducted among FreeFrom's 5000 newsletter subscribers, 45% of consumers were totally confused about the "may contain" labelling; a further 36% believed that the product would actually contain the allergens in the warning, whilst 19% did not pay attention to the labelling at all (Berriedale-Johnson 2015). There are currently four scenarios of using PAL:

- Scenario 1: PAL-labelled food products that have a genuine risk of causing allergic reactions
- Scenario 2: Products where there is no serious allergenic risk involved, but manufacturers may feel obliged to ensure that labels carry the warning to cover even the potential of a minor risk
- Scenario 3: Products that would not carry PAL because there is no risk of allergenic contamination, but there is concern that consumers would be confused when they cannot find PAL on a product, so as a result, it is included
- Scenario 4: Products where manufacturers are actually unaware of the actual need for PAL

Therefore, initiatives that can make PAL more meaningful will be valuable to all actors in the supply chain, especially manufacturers and consumers. In order to provide an overview of the economic details and cost–benefit of quantified PAL, this study utilizes a theoretical example of a food product manufactured on a production site that also uses other food allergens (Manning and Soon 2016). The worked example includes the estimated price of the genuine food product in a small–medium company and the cost of purchasing allergen test kits. The actual and approximate costs of raw materials and test kits were considered.

Legislation often considers the use of PAL to be an adequate and appropriate safety measure (Pape 2009). In the UK, advisory labelling takes the form of "may contain (an allergen)," "made on equipment that also processes (an allergen)," or "made in a factory that also handles (an allergen)" to warn consumers of potential cross-contamination risks (FSA 2015). Labelling rules contained within the European Directives 2003/89/EC and 2006/142/EC required comprehensive ingredient listing information. This regulation was built upon by the implementation of the Food Information for Consumers Regulation (FIR) (EU) No. 1169/2011 that became legislation in the UK in December 2014. Article 36 in the EU Regulation No. 1169/2011 covers the general requirements that voluntary food information must meet the following:

- It shall not mislead the consumer.
- It shall not be ambiguous or confusing for the consumer.
- It shall, where appropriate, be based on relevant scientific data.

According to Article 36.3a of the FIR legislation, the European Commission shall adopt the above measures when implementing voluntary "may contain" labelling, i.e., information on the possible and unintentional presence in food of substances or products causing allergies or intolerances (EU Regulation No. 1169/2011 2011). Similarly, the US Food and Drug Administration (FDA 2006) and Health Canada (2012) advise that PAL must be truthful, not misleading, non-ambiguous, and not to be used as a substitute for implementing operational prerequisite programmes such as Good Manufacturing Practices (GMPs). Japan does not allow "may contain" labelling and reported that if such labelling was recognized at the regulatory level, then some manufacturers may choose to escape liability as provided in the Product Liability Act (Ministry of Health, Labour and Welfare n.d.). International legislative requirements for PAL have been synthesized as part of this research (Table 2), and examples of common PAL statements that are found on labels are collated (Table 3).

Based on Table 2, it is noted that Japan, Switzerland, and South Africa also regulate "may contain" labelling. In Switzerland, only ingredients that have not been added voluntarily and exceeded 10 mg/100 g gluten in cereals or 1 g/kg or litre for other allergens must be declared (Federal Department Affairs 2005). PAL labelling is prohibited in Argentina (Argentina Food Code 2010) whilst South Africa requires documented risk assessment and steps taken to avoid allergen cross-contamination (Department of Health, Government of South Africa 2010). Although there is limited evidence on why certain countries have chosen to regulate or not to regulate PAL, different countries do have different allergen and precautionary labelling requirements due to the variable prevalence of such allergens and also different dietary preferences (Hattersley and Ward 2014). Japan is a notable exception. In Japan, 10 μg protein/g food is used as the threshold to monitor the labelling. This level is considered as the minimum for controlling the contamination of allergic ingredients using a detection method (e.g., enzyme-linked immunosorbent assay [ELISA]) for routine and industrial analyses (Akiyama et al. 2011). The authors hope that the case study example in the latter section of this paper will not only provide food manufacturers and consumers with a better understanding of the PAL system but also underline for regulators the option to adopt risk-based approaches in PAL.

Role of PAL in Accidental Exposures to Allergens

Consumers assume that a product does not contain an allergen if an allergy advice box is absent from the labelling (Barnett et al. 2011a). Gluten-free (GF)-labelled foods, with statements such as "produced in a facility that also processes wheat" or "made on equipment shared with wheat," also confuse consumers (Sharma et al. 2015). Up to 90% of food products bearing peanut advisory statements did not contain any protein that can cause an allergic reaction (Hefle et al. 2007). Ong (2008) argued that this use of PAL can frustrate and restrict consumers' food choice and may lead to health issues due to nutrient imbalance. Further, at times, allergenic individuals may choose to ignore PAL and take risks with food products bearing PAL statements. Hefle et al. (2007) reported that consumers were more likely to heed PAL in 2003 (85%) compared to 2006 (75%). It could be asserted that the proliferation of PAL statements across multiple food items could have resulted in "label fatigue" among consumers and may increase the tendency for people to disregard advisory labelling (Robertson et al. 2013) or revert to unhealthy choices (Thorndike et al. 2014). Studies found that in the sample group, 6.3% (Sheth et al. 2008) and 8.3% (n = 695) (Sheth et al. 2010) of allergic individuals

Table 2 Legislative requirements for precautionary allergen labelling

Countries	"May contain" statements		Additional recommendations	References
	Voluntary?	Regulated		
Australia and New Zealand	Yes	No	Food containing the bee product royal jelly is required to have a warning statement; application of the Voluntary Incidental Trace Allergen Labelling (VITAL)—a risk-based approach to guide advisory labelling	Allen et al. (2014); Food Standards Australia New Zealand (2015a, b)
Canada	Yes	No	Recommended only one precautionary statement—"may contain [allergen]"	Health Canada (2012)
Codex	No	No	Section 4.2.2 When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed	FAO/WHO Food Standards (1985)
EU	Yes	No	PAL should only be made after a thorough risk assessment has been performed (despite all reasonable measures conducted by the food industry) and consideration of real risk to food allergic consumers	EU Food Information for Consumers Regulation No. 1169/2011 Technical Guidance
Japan	Forbidden	Forbidden	Action limit for labelling—10 mg/kg; however, providing the food allergen information to the consumer is allowed (as marginal alert). Examples of calling for attention are the following: contamination through the use of a common production line, i.e., "the plant manufacturing this product produces products containing [allergen]"; or contamination through the method of gathering ingredients, i.e., "whitebait used in this product is gathered in a fishing method where crabs [specify allergen] may be intermingled"	Akiyama et al. (2011)
South Africa	Yes	Yes	PAL shall only be utilized after steps have been taken to assess and manage the risk of allergen and documented and are not used to circumvent the implementation of GMPs	Department of Health (2010)
Switzerland	Forbidden	Forbidden	Action limit for labelling—1 g/kg	Allen et al. (2014)
US FALCPA (Food Allergen Labelling and Consumer Protection Act) 2004	Yes	No		US FDA (2006)

Table 3 Precautionary allergen labelling (PAL) with examples of different wording used

PAL with different wordings	Examples of advisory labelling of prepacked processed foods
May contain, contains, free-related labelling	May contain traces of wheat and barley due to farming practices
	Contains: milk, wheat, gluten. This product contains no nuts. However, we cannot guarantee the ingredients used are nut-free
	Contains wheat, gluten. Manufactured in a nut-free environment.
	Nut-free, dairy-free, gluten-free, egg-free
	Contains milk. Dietary advice: suitable for vegetarians. Gluten-free
	Contains milk, soy. Recipe contains cashew nuts. May contain traces of other nuts
Production, packaging, factory, premises, manufacturing method-related advisory labelling	Made in premises which produce nut products
	Contains wheat, milk. Produced on a line handling soy and in a factory handling egg, hazelnut but on a different line
	Packed on a production line that also packs nuts, seed, and cereals that contain gluten. Therefore cannot be guaranteed nut-, seed- or gluten-free
	Contains milk, wheat, gluten, soy. Recipe: No nuts. Ingredients: Cannot guarantee nut-free. Factory: Product made in nut-free area, but nuts used elsewhere
	Contains eggs, wheat, oats, gluten. Not suitable for cow's milk and sesame allergy sufferers due to manufacturing methods used
	Contains soy, milk. May contain nuts, cereals. This product contains milk due to the unavoidable cross-contamination from milk chocolate made on the same manufacturing line.
	Contains: milk. Recipe: No nuts. Ingredients: Cannot guarantee nut-free. Factory: Before being prepared for manufacture of this product, the equipment was previously used to make products containing nuts. Product may contain traces of soy.
	Contains milk and soy products. May contain traces of hazelnuts, almonds, and peanuts due to shared equipment.
	Contains milk and soy. Not suitable for nut or wheat gluten allergy sufferers due to manufacturing methods.
	This recipe contains gluten, egg, fish, and milk. We made it in a busy working kitchen so it may also contain traces of nuts and sesame.
	Food fact: This product may contain traces of nuts and seeds. Allergen advice: Contains egg, gluten, milk, and soy. Manufactured on a site that also handles celery, fish, molluscs, mustard, nuts, peanuts, and sulphites.
	Contains wheat, gluten, and barley. Produced in a factory which handles milk powder. Not suitable for people with nut allergy.
	This product is manufactured in a factory which uses sesame seeds, lentils, wheat, and nuts. Therefore, this product may contain trace allergens. This product contains peanuts.
	Our packing house handles nuts and seeds
	May contain traces of soy. Manufactured under controlled conditions in our own factory in which no nuts are ever used.
	Contains dairy. May contain nut traces. Vegetarian. Free from gluten, soy, GM, colouring, and preservatives. Made in a factory where peanuts and sesame seeds are used.
	Allergy advice: Contains eggs and milk. Produced in a factory that handles wheat, gluten, soy, nuts (cashew), sesame, and mustard. Mycoprotein is high in protein and fibre. This may cause intolerance in some people.
Other advisory labelling	Any allergies? I contain celery. I have been known to hang around near nuts, peanuts, and sesame seeds and I may contain them as well.
	Do not munch if you are allergic to soy beans and sesame seeds.

Table 3 (continued)

PAL with different wordings	Examples of advisory labelling of prepacked processed foods
	Contains nuts and peanuts. In our bakery, we use soy, cow's milk, and sesame seeds. We cannot be absolutely sure they will not find their way into this bar.
	Some chocolates contain nuts and soya, but all chocolates contain milk and traces of nuts and soya.
	Contains: hazelnuts, almonds, milk, soy. May contain: other nuts. Some chocolates contain nuts. All chocolates may contain parts of or traces of nuts.
	Allergy advice: See list of ingredients

Adapted from FSA 2014

who ignored PAL went on to have a resultant allergic reaction to the material that was present in the product through cross-contamination. Further, the variations in precautionary labels used to inform consumers of the scenarios faced within manufacturing and the necessary steps taken to minimize risk mean that the wording can be perceived and possibly graded by consumers as identifying different levels of risk, and this influences buying decisions (Verrill and Choinière 2009). This suggests that customers will, individually or on behalf of others, apply a quantitative assessment to what is a qualitative statement and on that basis exhibit risk-taking behaviour. The main function of PAL is to warn allergic individuals of the potential risk if they were to consume a given product. However, PAL acts like a double-edged sword as on the one hand, it is trying to protect consumers but on the other, consumers can choose either to ignore the warning due to label fatigue or to bypass all foods of that type because of historic allergic reactions to foods after consuming PAL products in the past. The use of perception or inference by consumers is a reductionist way of navigating a given set of often complex issues or challenges. This is often because consumers lack access to, or the understanding to interpret, complex statistics (Slovic et al. 1981), so instead, they use cues from past experience or observation in their decision-making. A heuristic can be described as an approach, or technique, that is used by individuals to solve problems, make judgements, and form decisions. Thus, in order to consider, deliberate, and come to a decision on a given problem, a decision-making approach can be used by consumers when they apply an assessment to what is often just a qualitative statement by manufacturers and on that basis exhibit what would be seen by some as risk-taking behaviour.

The challenge is further nuanced by the fact that in some countries, legislation is approached in terms of product liability, e.g., in the USA and Canada, when in others, such as in Europe, the precautionary principle informs the application of the regulation. Although in Europe, in order to actually demonstrate adherence to GMPs, the food industry needs to implement appropriate monitoring and verification activities, so the food industry is required to exercise reasonable precautions and demonstrate due diligence. It is within that context that the use of PAL should be substantiated by a documented formal risk assessment. Whilst qualitative approaches to monitoring and verification may include observation and assessment of work practices for compliance with the formalized documented allergen control systems, a quantitative approach would test the intrinsic nature of the product produced and whether a protein capable of producing an allergenic reaction in individuals that are sensitive is actually present. Thus, whether through market drivers such as either shareholder requirements for

business managers to mitigate the potential risk associated with their dividend payments, as an ethical or moral requirement to provide safe food for all consumers, or as a regulatory need to provide safe food, managers are required to take up more responsibility to accurately measure the amount of allergenic material in their products. Bearing in mind not only the existence of numerous small and medium food companies that operate in a wider supply chain or network controlled by multinational corporations (MNCs) but also the cost of quantitatively detecting and measuring proteinaceous material that can cause an allergenic reaction in some individuals, this quantitative approach to risk mitigation would have serious financial implications for these small companies if the need for improved allergen control became a prerequisite to supply. This is explored in further detail in the cost–benefit analysis of a chia seed and raisin bar product later in this paper.

It is noted in the literature that consumers with a recognized food allergy are more likely to purchase products with "shared facilities" than "shared equipment" labelling (Hefle et al. 2007). However, when considering "shared equipment" and "may contain" labelling, consumers were more likely to purchase from the former label (Hefle et al. 2007). Consumers most commonly avoid "not suitable for [allergen] allergy sufferers" followed by "may contain" labelling (Sheth et al. 2008) (Fig. 1). Ong (2008) also reported that susceptible consumers are not only prevented from consuming food that declare allergens but also have to avoid food products with such advisory labelling. Based on previous experience, consumers use their own strategies, i.e., heuristics in dealing with PAL products (Barnett et al. 2011b). Peters et al. (2004) argue that whilst in a business setting, risk and benefit are often positively correlated, i.e., the greater the risk the greater the return, conversely, they are negatively correlated in the minds of the public, suggesting that an affect heuristic plays a role in risk assessment, i.e., a combination of what people think and what they feel rather than analytical decision-making.

The severity of subsequent allergenic reactions cannot be predicted from symptoms reported during initial reactions (Crevel et al. 2014; Pumphrey 2004; Vander Leek et al. 2000). Extrinsic factors such as medical and drug history or exercise may enhance the absorption of allergenic protein. Thus, with the current system of PAL, the extrapolation or creation of personal risk hierarchies by consumers from assessing qualitative statements and converting them to risk-based decisions is flawed (Fig. 1). As part of this work, a review of relevant literature around the detection of allergens in PAL-designated products shows that in many studies, the actual proportion of products that contained the allergen was low, but for some sensitive individuals, these products still present a clear risk (Table 4).

FreeFrom proposed an independent, validated certification known as "Allergen Safe" for manufacturers whose allergen controls and management meet FSA guidelines (Berriedale-Johnson 2015). Allergen Safe strives to create awareness among allergic consumers or customers who opt for a free-from diet so they can purchase with confidence, reduce their risk of allergic reactions to food, and increase their food choices. Manufacturers also have the added benefit of new business in the "free-from" sector and also a decrease in fear of prosecution. However, manufacturers must be able to demonstrate that this approach contains an effective validation step and then ongoing process and product verification to ensure that standards are maintained. Remington et al. (2013) proposed the use of a probabilistic risk assessment tool to determine if the usage of advisory labelling is actually appropriate. As consumers are paying lesser attention to advisory labels, due often to the proliferation of PALs and based on consumers' prior experiences (Hefle et al. 2007; Sherlock et al. 2014), a more precise or quantified PAL would instead provide consumers with informed choices to guide them whilst purchasing allergen-free-labelled or PAL products. However, quantified

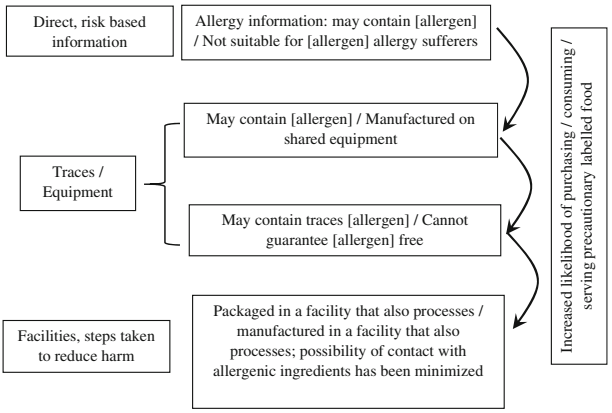

Fig. 1 Variations of wordings and the likelihood of purchasing/consuming/serving food with precautionary labelling that can cause a hierarchy of decision-making by consumers (Hefle et al. 2007; Noimark et al. 2009; Sheth et al. 2008; Verrill and Choinière 2009)

Table 4 Detection of allergen in PAL food products

Products that are labelled with advisory statements	Percentage of samples where allergens were detected (number of positive samples/total samples)	Reference
Milk (including various milk-based products, e.g., chocolate)	10.2 (6/59)	Ford et al. (2010)
Milk	42 (34/81)	Crotty and Taylor (2010)
Peanuts	7.3 (13/179)	Hefle et al. (2007)
	4.5 (5/112)	Ford et al. (2010)
	5.3 (2/38)	Robertson et al. (2013)
	8.6 (16/186)	Remington et al. (2013)
	7 (5/75)	FSAI (2011)
	17.6 (96/544)[a]	Pele et al. (2007)
Eggs	1.8 (1/57)	Ford et al. (2010)
	6 (1/18)	FSAI (2011)
Gluten	43.4 (23/53)	Sharma et al. (2015)
Soy	3 (1/30)	FSAI (2011)
Hazelnut	14.2 (75/526)[b]	Pele et al. (2007)

[a] Based on positive dipstick or positive ELISA test; percentage of positive samples excluding food products not declaring peanut on the label

[b] Based on positive dipstick or positive ELISA test; percentage of positive samples excluding food products not declaring hazelnut on the label

PAL should be coupled with training and risk communication among manufacturers, retailers, food services, and consumers.

Quantitative Risk Assessment to Predict Allergenic Reactions

Probabilistic risk assessment is one of the most promising approaches for use by risk managers (Madsen et al. 2009) to both evaluate population at risk and also serve as a guide for PAL. This type of assessment has been particularly useful in assessing public health threat from undeclared allergens in food (Spanjersberg et al. 2010). Examination of products by quantitative testing can include using an ELISA test to detect and quantify levels of allergenic ingredients in foods. One such approach for the examining and monitoring of allergen-labelled products is used in Japan (Akiyama et al. 2014; Ministry of Health, Labour and Welfare n.d.). Food containing 10 μg protein/g food or more will give a positive result using ELISA techniques. In Japan, having established such presence using analytical tests, this is then followed up by an investigation of manufacturing records such as raw material lists and process records. If manufacturing records were unclear, then further confirmatory tests such as using the Western blot method for egg and milk products or the polymerase chain reaction (PCR) method for wheat, buckwheat, or peanut can confirm the presence of allergenic material (Akiyama et al. 2011). After thorough verification of the procedures associated with product labelling, the allergy labelling decision tree (Fig. 2) is used to assist risk managers and the wider food industry to confirm and make sure that the type of allergen labelling is correct. The use of decision trees such as in Figure 2 should inform food manufacturers as to the correct labelling for their products, i.e., whether to use mandatory, caution, recommended, prohibited, or unnecessary labelling.

A probabilistic model can be used to predict the likelihood of an allergic reaction based on an estimation of the proportion of allergic population, the proportion of that consuming the food, the amount consumed, the likelihood of the food containing an allergen, and if it is present, its actual concentration compared with the lowest observed eliciting dose (LOED) for the given allergen (Kruizinga et al. 2008; Spanjersberg et al. 2007). By comparing the LOEDs and the consumption of the allergen, the probability of an allergic reaction can be predicted (Kruizinga et al. 2008; Spanjersberg et al. 2007) (Fig. 3).

The minimal eliciting dose (ED) refers to the lowest dose that can trigger an objective reaction in a controlled clinical challenge (Luccioli and Kwegyir-Afful 2014; Taylor et al. 2010). The understanding of ED for individuals will improve consumers' quality of life and assist them in making more informed choices whilst purchasing food products (Luccioli and Kwegyir-Afful 2014). Three parametric models (log logistic, log normal, and Weibull) were applied to derive the estimates of ED_1 (for peanut and cow's milk) and both ED_1 and ED_5 (for egg and hazelnut) whilst the 95% lower confidence interval of the ED_5 was estimated for soybean, wheat, sesame seed, lupine, mustard, cashew, and shrimp. See Allen et al. (2014) and Taylor et al. (2014) for further elaboration on how the reference doses were derived. Studies have estimated threshold doses that are derived from the ED to trigger a reaction in 1% (ED_{01}), 5% (ED_{05}), or 10% (ED_{10}) of the population such as the reference doses established by the Voluntary Incidental Trace Allergen Labelling (VITAL) expert panel group for 11 major food allergens as listed in Table 5. Wider frustrations over PAL triggered the formation of the Allergen Bureau of Australia and New Zealand (ABA) which later released the Labelling VITAL programme (Fleming et al. 2010). The VITAL programme has established reference

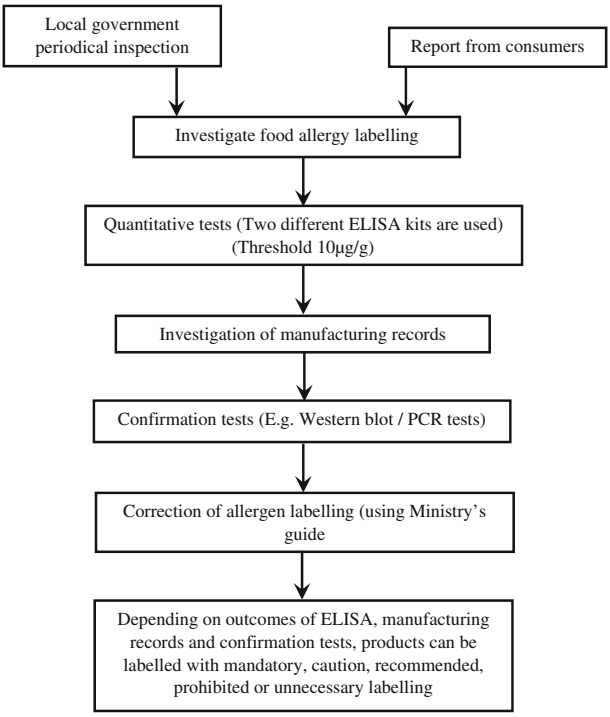

Fig. 2 Ministry's guide to the inspecting and monitoring of allergy labelling system in Japan (Adapted from Akiyama et al. 2011; Ministry of Health, Labor and Welfare n.d.)

doses that can guide the application of precautionary labelling, ensuring that the PALs are appropriate and relevant to the actual level of risk faced by allergic consumers. If the ingestion of a food may result in a higher dose of allergenic food protein intake than the reference dose, then precautionary labelling is recommended. However, the dose of the allergenic food protein is dependent on the amount of food consumed and the concentration of the allergenic protein (Taylor et al. 2014). The reference doses proposed by VITAL are a positive step forward for the food industry. However, due to the variation in a given consumer's threshold dose,

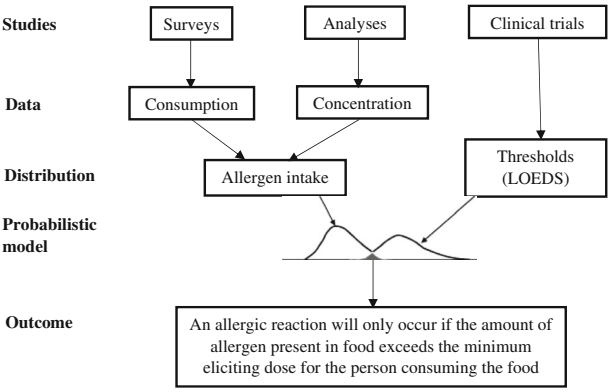

Fig. 3 Probabilistic approach in food allergen risk assessment (Crevel 2010; Kruizinga et al. 2008; Spanjersberg et al. 2007)

Table 5 Eliciting dose (ED) (mg protein unless stated as whole) of various food allergens that triggered reaction in 1%, 5%, and 10% of the population

Products	Eliciting dose (mg protein)	Number of subjects	References
Hazelnut	ED_{10} = 8.5	132	Ballmer-Weber et al. 2015
Peanut	ED_{10} = 2.8	135	
Celeriac	ED_{10} = 1.6	64	
Fish	ED_{10} = 27.3	50	
Shrimp	ED_{10} = 2.5 g	55	
Peanuts	ED_{05} = 5.2 mg of whole peanut	Combined data set of 450 peanut-allergic individuals	Taylor et al. 2010
Peanuts	ED_{05} = 6 mg of whole peanut/1.5 mg of peanut protein	375	Zurzolo et al. 2013
Peanut	Proposed ED_{01} = 0.2	$n > 200$	Allen et al. 2014
Milk	Proposed ED_{01} = 0.1	$n > 200$	
Egg	Proposed ED_{01} = 0.03	$n > 200$	
Hazelnut	Proposed ED_{01} = 0.1	$n > 200$	
Sesame seed	ED_{05} ranges from 1.2 to 4.0	35	Dano et al. 2015
	ED_{10} ranges from 4.2 to 6.2	35	
Cashew nut	ED_{1} = 1.30 ED_{5} = 7.41 ED_{10} = 16.0 ED_{50} = 120	31	Blom et al. 2013 (EDs based on bjective symptoms; study population consisted of children)
Hen's egg	ED_{1} = 1.30 ED_{5} = 7.41 ED_{10} = 16.0 ED_{50} = 120	53	
Peanut	ED_{1} = 0.07 ED_{5} = 1.51 ED_{10} = 5.82 ED_{50} = 199	135	
Cow's milk	ED_{1} = 0.05 ED_{5} = 1.07 ED_{10} = 4.24 ED_{50} = 156	93	
Hazelnut	ED_{1} = 0.01 ED_{5} = 0.29	28	

Table 5 (continued)

Products	Eliciting dose (mg protein)	Number of subjects	References
	ED_{10} = 1.38 ED_{50} = 80.6		
Egg	ED_{10} = 42.9-mg whole egg	487	Eller et al. 2012 (EDs based on objective symptoms of 405 challenges; study population ages range from 0.5 to 73.5 years)
Hazelnut	ED_{10} = 133.8-mg whole hazelnut	487	
Roasted peanut	ED_{10} = 106.5-mg roasted peanut	487	
Milk	ED_{10} = 2.9 ml milk	487	
Peanut	ED_5 = 5.08 ED_{10} = 10.8 ED_{50} = 291	362 (combined adults and children)	Klemans et al. 2015 (EDs based on objective symptoms)
	ED_5 = 6.38 ED_{10} = 18.6 ED_{50} = 303	262 children	
	ED_5 = 2.86 ED_{10} = 13.7 ED_{50} = 821	100 adults	
Soybean	ED_1 = 37.2 Reference dose (Based on ED_1 or 95% lower confidence interval of ED_5)	22	Ballmer-Weber et al. 2007 (ED based on objective symptoms)
Peanut	0.2 (ED_1)	Based on statistical dose distribution models	Allen et al. 2014; Taylor et al. 2014 (Reference dose for ED_5 are within the lower 95% CI)
Cow's milk	0.1 (ED_1)		
Egg	0.03 (Both ED_1 and lower 95% CI of ED_5)		
Hazelnut	0.1 (Both ED_1 and lower 95% CI of ED_5)		
Soy	1.0 (ED_5)		
Wheat	1.0 (ED_5)		
Cashew	Provisional 2.0 (ED_5)		
Mustard	0.05 (ED_5)		
Lupin	4.0 (ED_5)		
Sesame seed	0.2 (ED_5)		
Shrimp	10 (ED_5)		

proposing a single reference dose remains the biggest challenge. This can be seen from the individual studies proposing different ED values for multiple allergenic foods (Table 5). The establishment of reference doses by public health authorities is crucial to quantifying PAL statements.

Building on VITAL's conception in Australia and New Zealand and similar successful approaches in Japan and Switzerland (both Japan and Switzerland do not permit the usage of "contain labelling"; see Table 2), the European Voluntary Incidental Trace Allergen Labelling (EU-VITAL) was initiated at a Food Allergy meeting in 2010 to improve and harmonize the declaration of food allergens. This approach contains three action levels that can then guide allergen labelling in the EU (Table 6). These action levels vary by product in terms of the threshold of allergenic substance where the action level is determined according to action level 1 (white zone where no advisory labelling is required), action level 2 (blue zone where traces of allergen will be listed), and action level 3 (red zone where allergen will be listed as ingredient). Future research emulating the Australian and New Zealand VITAL systems is suggested as the levels proposed by EU-VITAL were given as concentrations (Table 6) rather than doses (compared to Table 5). For example, allergic consumers react to doses which take into account the concentration of the allergen in the food and the amount of food consumed.

The establishment and validation of threshold doses for major food allergens will help to quantify precautionary labelling. Based on validated threshold doses and determination of residues of food allergen, this will assist the food industries in developing quantitative precautionary labelling (Allen et al. 2014). A quantified precautionary label may be helpful for allergic consumers. In fact, the absence of a precautionary label would indicate that 95–99% (depending on the ED) of the allergic consumers can safely ingest the food. However, it is important that the proposed reference doses do not create unnecessary burden on most food manufacturing industries (Crevel et al. 2014). This gives rise to some conceptual questions such as the following: How do we balance reference doses with quantified PAL? How do we

Table 6 EU-VITAL model threshold values (mg allergenic substance/kg food [ppm] action levels (EU-VITAL n.d.; Kuhn et al. 2010))

Action levels	Labelling	Declaration	
1 (white zone)	Not required	–	
2 (blue zone)	Required	"contains traces of [allergen]"	
3 (red zone)	Required as ingredient	"contains [allergen] as ingredient"	
	Action level		
	1	2	3
Milk	<50	50–500	>500
Egg	<20	20–200	>200
Soy	<25	25–250	>250
Fish	<100	100–1000	>1000
Peanut	<8	8–80	>80
Tree nuts	<10	10–100	>100
Sesame	<10	10–100	>100
Crustaceans	<10	10–100	>100
Gluten	<20	20–100	>100
Celery	<20	20–200	>200
Lupine	<20	20–200	>200
Molluscs	<20	20–200	>200
Mustard	<20	20–200	>200
Sulphur dioxide/sulphites	<10	10–100	>100

ensure that consumers are not further confused with the change from a "blanket approach" of precautionary labelling to a "quantified precautionary labelling"—where, based on the reference or EDs, the quantitative guidance will help to indicate when a product should be labelled with advise and reduce the number of foods with precautionary labelling? Figure 4 captures some of the recommendations that can be put into practise by policy makers, e.g., via adoption of a system similar to VITAL, risk assessors, e.g., via assessments and establishments of reference doses nationally or regionally, food industry, e.g., via continuous due diligence, risk assessment and management to control the risk of allergen cross-contamination at manufacturing plant level, and consumers via communication through an allergen awareness group or social media network on the benefits of quantified PAL labelling. Other strategies that can benefit consumers and food manufacturers are to simplify "may contain" descriptors. Instead of being creative with phrases, food manufacturers should be consistent in using PAL wordings and this would provide a uniformity to risk communication that would benefit consumers. A case study is now explored to consider the cost–benefit analysis of such techniques.

Case Study: Cost–Benefit Analysis of a Food Product with Potential Cross-Contact of Allergens

VITAL is a risk assessment tool and an online calculator that determines the level of allergens that may be present in the food product, provides clear guidance for industries, and quantifies PAL labelling. Users can conduct a free online trial or sign up for annual access to VITAL. Assuming a small–medium manufacturer with 10–50 full-time equivalent employees, the VITAL Online yearly plan costs AUS$ 990 (about US$ 750) for non-Allergen Bureau members (Allergen Bureau 2017a). Information on recipe and raw material allergen status and cross-contact allergens and whether these are in particulate or dispersible form should be provided. Based on the information on allergen handling and how much could contaminate a

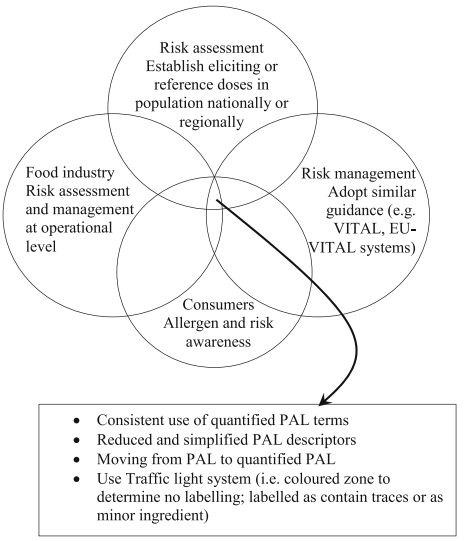

Fig. 4 Strategies to address inconsistent usage of PALs

batch, VITAL produces a "labelling outcome" about the presence of allergen due to intentional inclusion or cross-contact (Allergen Bureau 2017b).

The following case study illustrates the example of a small–medium company (company XYZ) that manufactures peanut, raisin, and milk chocolate confectionary bars and is planning to manufacture chia seed and raisin bars using the same production line (Table 7). In order to simplify the example, it has been assumed that the raisins have not been preserved with sulphur dioxide. The milk chocolate is in a form where milk protein is not easily dissociated in order to cause a milk-specific issue and the milk chocolate does not contain soy lecithin. Further, as peanuts are used in the manufacturing plant for the original product, there is a risk of cross-contamination. Peanut is selected as the allergen example here as it has the highest prevalence among food-allergic individuals (Gupta et al. 2011) and can result in severe and fatal reactions. Additionally, peanut as an ingredient can cause contamination as a result of particulate contamination. The cost of manufacture per kilogram and ingredient cost per serving (100 g) are shown (Table 7). The cost of producing the chia seed bar (500 kg) and purchasing of peanut protein test kits is $2555.84 (i.e., $0.511/100 g). The gross cost of determining allergen cross-contact would be $0.011 per batch.

The labelling outcomes for action levels 1 and 2 and the intentionally added allergen would be colour coded, and guidance is provided on how to label the ingredient. For cereals containing gluten, since this is intentionally added, this allergen is required to be declared in the ingredient list. Milk at action level 1 represents protein from cross-contact allergen in the final product and is not present at amounts greater than the reference dose. The cross-contact allergen is not present at a significant amount, and a precautionary statement is not required. Meanwhile, for peanuts which were detected in the final product and are present at an amount ≥0.2 of the reference dose, this cross-contact allergen is present in a significant amount and a precautionary cross-contact statement for this allergen is required (Allergen Bureau 2016). The VITAL risk assessment is an excellent guide to help food manufacturers and to provide quantitative PAL labelling. An example of a summary of the labelling outcomes for the chia seed and raisin bars is shown in Table 8.

Whilst reviewing Table 8, one could estimate the costs–benefits of allergen labelling to both the manufacturers and consumers. With regard to consumers, the quantified PAL on the chia seed and raisin bars will inform and differentiate between the potentials for the presence of peanut. Taking into consideration that 8% of children are affected by food allergies (Gupta et al. 2011), thus, in the USA, 6 million children, out of a total of 74 million children in 2017 (ChildStats.gov, n.d), could be affected by a change to PAL labelling. Gupta et al. (2013) found that family members spend 27% of the indirect costs (costs borne by family) to purchase "allergen-free" food. A more quantitative approach to PAL would widen the food choices of consumers and provide them with informed choices. Reduced incidence of allergic reactions would also decrease the burden on healthcare services and the loss of productivity due to, in the case of adults affected or adult carers of children who are affected, time taken off work. Higher medical and indirect costs for families with food-allergic members have been noted in previous research as a result of lost productivity and inability to carry out household and domestic tasks (Fox et al. 2013; Voordouw et al. 2010).

The approach described in this paper is of value when compared to the use of qualitative PAL as an allergen control measure. Allergen management protocols can be introduced as part of a wider GMP programme, especially the use of time separation. In this approach, food manufacturers process their products according to a given schedule, e.g., products that

Table 7 Case study example of production of new chia seed bar and estimated costs

Current confectionary bar produced by company XYZ (adapted from Manning and Soon 2016)		New confectionary bar to be produced by company XYZ (adapted from Manning and Soon 2016)	Cost per 1 kg ($)	Ingredient cost per 100-g bar ($)
Peanuts and raisin milk choco-top bar	➔	Chia seeds and raisins choco-top bar		
Chopped peanuts (*Arachis hypogaea*)		Chia seeds (*Salvia hispanica*)	3.00	0.30
Wheat flour (*Triticum aestivum*)		Wheat flour[a]	0.20	0.01
Raisins (*Vitis vinifera*)		Raisins	0.30	0.03
Milk chocolate topping		Chocolate topping (without milk)	1.50	0.15
		Packaging	0.01 per piece	0.01
		Total costs of raw materials		0.50
		Total pieces produced and cost		5000 units (based on the gross estimate of 500 -kg raw materials) × $0.50 = $2500
		Costs of allergen test kits[b]		
		Lateral flow device swabs for peanuts	9.70 per swab × duplicate tests	19.40
		Lateral flow device swabs for milk	9.70 per swab × duplicate tests	19.40
		ELISA test kit for peanut	4.26 per determination (per well) × duplicate tests	8.52
		ELISA test kit for milk	4.26 perdetermination (per well) × duplicate tests	8.52
		Total costs of testing per batch		55.84
		Total cost of production and testing		2555.84
				0.511 per 100 g

[a] This can potentially be substituted with buckwheat flour (*Fagopyrum esculentum*) (buckwheat is not one of the foods requiring allergen labelling in EU) to develop a new chia seed raisin bar with no gluten and peanuts. Similarly, the costs of lateral flow devices and ELISA test kits would be similar

[b] Based on estimated price quotes of commercial test kits

Table 8 Example of VITAL online labelling outcome for chia seed and raisins bar

Substances	Reference dose[a] (mg)	Action level 1	Action level 2	Cross-contact amount[b]		Labelling outcome	Colour coded
				Particulate	Readily dispersible (ppm)		
Cereals containing gluten	1	<5 ppm	≥5 ppm			Intentionally added	Blue
Milk	0.1	<0.5 ppm	≥0.5 ppm		Not detected (below 0.5 ppm)	Action level 1	Green
Peanut	0.2	<1 ppm	≥1 ppm	Yes	Detected (>1 ppm)	Action level 2	Red

[a] Milligram of protein level (protein from allergenic food) below which only the most sensitive individuals (1–5%—this depends on the quality of the data set available) are likely to experience an adverse reaction

[b] This is an assumption. Refer to VITAL guideline for more information. VITAL calculator will provide the level of cross-contact amount based on assumptions, e.g., determination of protein from cross-contact during cleaning assessment or values in hang-up quantity (a point in manufacturing where a material may accumulate instead of flow through freely) (Allergen Bureau 2012)

intentionally contain allergenic material are often processed as the final batch/lot of the day prior to a full clean-down to minimize the potential for cross-contamination into subsequent lots. Alternatively, zoning within manufacturing facilities and adoption of operational prerequisite programmes are undertaken. Introducing segregation protocols within the manufacturing environment is of value, but this can be limited if segregation protocols have not been adopted at previous steps in the supply chain. This is why the use of PAL has become a main preventive measure to minimize the risk of an allergenic reaction by consumers as a result of accidental cross-contamination. Redesigning a manufacturing plant to seek to produce an allergen-free working environment will be costly, often prohibitively so, and still, it would be difficult to label a product as allergen-free. Taylor et al. (2002) asked the question "how clean is clean enough?" and this can be difficult to determine and may be variable by allergen according to the threshold dose. Manufacturers may operate a due diligence system and should a prosecution arise, if they have carried out a thorough risk assessment and hazard analysis critical control point (HACCP) study of potential contamination with unintended allergens, they may have an adequate legal defence in place, but this does not necessarily protect individual consumers that are vulnerable to a given allergen.

Conclusion

Major food allergens that commonly cause allergic reactions are usually declared on packaging as a result of mandatory labelling legislation. This is helpful for consumers when deciding which products to purchase. There are eight common food allergens listed in Codex, but different regions and countries have different regulatory requirements for allergen labelling. This is beneficial and according to local diet and geographical region is protective of a consumer-based population. For example, royal jelly and pollens are considered as food allergens in Australia and New Zealand, whilst buckwheat is required to be labelled in Japan and Korea. However, the increasing global prevalence rates of food allergies and the greater globalization of diets also call for a review of the eight main food allergens as listed in Codex. In addition to the requirements of mandatory labelling of intentionally added food allergens, the usage of PAL on packaging is not regulated in all countries and where it is regulated, there is no equivalence of legislation. As a result, the food industry uses various forms of "may contain" labelling which firstly is often inconsistent and secondly may diminish the value of such advisory statements as a communication tool over time.

There are four main scenarios of using PAL including genuine risk of causing allergic reactions, potential minor risk, no risk of allergenic contamination, and unaware of the requirements for PAL. The emergence of different types of PAL statements may add to consumers' frustration as well. Is there a way to harmonize or make PAL more meaningful to both manufacturers and consumers? Can one emulate Japan, Switzerland, or South Africa in regulating the "may contain" statement? This review calls for further research or a round-table discussion with countries that have chosen to regulate PAL. VITAL is a beneficial programme in Australia and New Zealand in guiding food manufacturers in ensuring the correct usage of PALs. Similarly, Japan provides clear guidelines to inspect and monitor their local food allergen labelling system. Susceptible consumers remain as a top priority in terms of food safety, amidst the wider risk mitigation activities of a network of supply chain actors. Consumers require effective risk communication and should be informed about the nature,

content, and meaning of a given PAL statement. Strategies such as the harmonization of PALs, addressing the inconsistent usage of PALs, and improving PAL status to give a quantified PAL will be helpful to communicate risks to consumers so they can make informed choices when purchasing food products. Appropriate documented risk assessment and conduction of cost–benefit analyses of selected food products can be carried out by food manufacturers. This will potentially widen the food choices of consumers and provide them with informed choices. Food allergy and intolerance is not a new phenomenon, but the way it is managed is constantly evolving especially with considerations of personalized medicine.

References

AG (Australian Government) (n.d.) Australia New Zealand Food Standards Code—Standard 1.2.3—mandatory warning and advisory statements and declarations—F2011C00610. Available at http://www.comlaw.gov.au/details/f2011c00610 [Accessed on 20 August 2015].

Akiyama, H., Imai, T., & Ebisawa, M. (2011). Japan food allergen labelling regulation—history and evaluation. *Advances in Food and Nutrition Research, 62*, 139–171.

Allen, K. J., Remington, B. C., Baumert, J. L., Crevel, R. W. R., Houben, G. F., Brooke-Taylor, S., Kruizinga, A. G., & Taylor, S. L. (2014). Allergen reference doses for precautionary labelling (VITAL 2.0): clinical implications. *Journal of Allergy and Clinical Immunology, 133*(1), 156–164.

Allergen Bureau (2012). Food industry guide to voluntary incidental trace allergen labelling (VITAL) program version 2.0. Available at http://allergenbureau.net/wp-content/uploads/2013/11/VITAL-Guidance-document-15-May-2012.pdf [Accessed on 12 April 2017].

Allergen Bureau (2016). VITAL Online helpful hint—VITAL online demonstration video. Available at http://allergenbureau.net/vital-online-helpful-hint-vital-online-demonstration-video/ [Accessed on 12 April 2017].

Allergen Bureau (2017a). Pricing. Available at https://vital.allergenbureau.net/pricing [Accessed on 12 April 2017].

Allergen Bureau (2017b). VITAL® Online. Available at http://allergenbureau.net/vital/vital-online/ [Accessed on 12 April 2017].

Anandan, C., & Sheikh, A. (2005). European developments in labelling allergenic foods. More still needs to be done. *British Medical Journal, 331*(7526), 1155–1156.

Argentina Food Code (2010). Joint Resolution 57/2010 and 548/2010 Modification. (Translated) Available at http://servicios.infoleg.gob.ar/infolegInternet/anexos/170000-174999/173091/norma.htm [Accessed on 12 April 2017].

Ballmer-Weber, B. K., Holzhauser, T., Scibilia, J., Mittag, D., Zisa, G., Ortolani, C., Oesterballe, M., Poulsen, L. K., Vieths, S., & Bindslev-Jensen, C. (2007). Clinical characteristics of soybean allergy in Europe: a double blind, placebo-controlled food challenge study. *Journal of Allergy and Clinical Immunology, 119*(6), 1489–1496.

Ballmer-Weber, B. K., Fernandez-Rivas, M., Beyer, K., Defernez, M., Sperrin, M., Mackie, A. R., et al. (2015). How much is too much? Threshold dose distributions for 5 food allergens. *Journal of Allergy and Clinical Immunology, 135*(4), 964–971.

Barnett, J., Leftwich, J., Muncer, K., Grimshaw, K., Shepherd, R., Raats, M. M., Gowland, M. H., & Lucas, J. S. (2011a). How do peanut and nut-allergic consumers use information on the packaging to avoid allergens? *Allergy, 66*, 696–978.

Barnett, J., Muncer, K., Leftwich, J., Shepherd, R., Raats, M. M., Gowland, M. H., Grimshaw, K., & Lucas, J. S. (2011b). Using 'may contain' labelling to inform food choice: a qualitative study of nut allergic consumers. *BMC Public Health, 11*, 734.

Berriedale-Johnson, M. (2015). *Allergen safe labelling: launch of accreditation scheme. Foods matter live*. London: ExCel.

Blom, W. M., Vlieg-Boerstra, B. J., Kruizinga, A. G., van der Heide, S. M., Houben, G. F., & Dubois, A. E. J. (2013). Threshold dose distributions for 5 major allergenic foods in children. *Journal of Allergy and Clinical Immunology, 131*(1), 172–179.

Boyce, J. A., Assa'ad, A., Burks, A. W., Jones, S. M., Sampson, H. A., Wood, R. A., et al. (2010). Guidelines for the diagnosis and management of food allergy in the United States. *Journal of Allergy and Clinical Immunology, 126*(6), S1–S58.

Branum, A. M., & Lukacs, S. L. (2009). Food allergy among children in the United States. *Pediatrics, 124*(6), 1549–1555.

Burks, A. W., Tang, M., Sicherer, S., Murano, A., Eigenmann, P. A., Ebisawa, M., et al. (2012). ICON: food allergy. *Journal of Allergy and Clinical Immunology, 129*(4), 906–920.

Chen, J., Hu, Y., Allen, K. J., Ho, M. H. K., & Li, H. (2011). The prevalence of food allergy in infants in Chongqing, China. *Pediatric Allergy and Immunology, 22*(4), 356–360.

ChildStats.gov (n.d.). Child population: number of children (in millions) ages 0–17 in the United States by age, 1950–2015 and projected 2016–2050. Available at https://www.childstats.gov/americaschildren/tables/pop1.asp [Accessed on 12 April 2017].

CIRS, (Chemical Inspection and Regulation Service) (2014). GB 7718-2011 Food safety national standards for general rules for the labelling of prepackaged food. Available at http://www.cirs-group.com/food/regulations&standards/GB_7718-2011_labelling_prepackaged_food.html [Accessed on 13 May 2016].

Crevel, R. W. R. (2010). Risk assessment for food allergy. In J. I. Boye & S. B. Godefroy (Eds.), *Allergen management in the food industry* (pp. 423–451). Hoboken: Wiley.

Crevel, R. W. R., Baumert, J. L., Luccioli, S., Baka, A., Hattersley, S., Hourihane, J. O., et al. (2014). Translating reference doses into allergen management practice: challenges for stakeholders. *Food and Chemical Toxicology, 67*, 277–287.

Crotty, M. P., & Taylor, S. L. (2010). Risks associated with foods having advisory milk labelling. *Journal of Allergy and Clinical Immunology, 125*(4), 935–937.

Dano, D., Remington, B. C., Astier, C., Baumert, J. L., Kruizinga, A. G., Bihain, B. E., et al. (2015). Sesame allergy threshold dose distribution. *Food and Chemical Toxicology, 83*, 48–53.

Department of Health (2010). Government notice. Foodstuffs, cosmetics and disinfectants act, 1972 (Act 54 of 1972). Regulations relating to the labelling and advertising of foodstuffs. Available at: file://lha-012/pers-J/00075EF2/Downloads/reg0146.pdf [Accessed on 24 May 2016].

Department of Health, Government of South Africa (2010). Regulations relating to the labelling and advertising of foodstuffs. Available at http://www.danone.co.za/upload/R146%20of%201%20March%202010.pdf [Accessed on 12 April 2017].

EC. (2011). Regulation (EU) NO 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. *Official Journal of the European Union, L 304*, 18–63.

Eller, E., Hansen, T. K., & Bindslev-Jensen, C. (2012). Clinical thresholds to egg, hazelnut, milk and peanut: results from a single-center study using standardized challenges. *Annals of Allergy, Asthma and Immunology, 108*(5), 332–336.

EU Regulation No. 1169/2011. Regulation (EU) No. 1169/2011 of the European Parliament and of the council of 25 October 2011. Available at http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32011R1169 [Accessed on 14 November 2015].

EU-VITAL (n.d.). EU-VITAL concept. Available at http://www.eu-vital.org/en/concept.html [Accessed on 14 November 15].

FAO/WHO Food Standards (1985). Codex general standard for the labelling of prepackaged foods. Codex Stan 1–1985 (Rev. 1–1991). Available at http://www.fao.org/docrep/005/y2770e/y2770e02.htm [Accessed on 24 May 2016].

FARRP (Food Allergy Research and Resource Programme) (n.d.), Food allergy research and resource program. Available at http://farrp.unl.edu [Accessed on 20.08.15].

FDA (Food and Drug Administration) (2013), Food Allergen Labelling and Consumer Protection Act (2004) Available at http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106187.htm [Accessed on 20 August 2015].

Federal Department Affairs (2005). Ordinance of the DFI on the labeling and advertising of foodstuffs. (Translated page). Available at https://www.admin.ch/opc/fr/classified-compilation/20050161/index.html [Accessed on 12 April 2017].

Fleming, F., Grinter, K., Leighton, K., Norman, K., Preston, C., & Said, M. (2010). The challenges of precautionary labelling. In J. I. Boye & S. B. Godefroy (Eds.), *Allergen management in the food industry* (pp. 453–472). Hoboken: Wiley.

Ford, L. S., Taylor, S. L. M., Pacenza, R., Niemann, L. M., Lambrecht, D. M., & Sicherer, S. H. (2010). Food allergen advisory labelling and product contamination with egg, milk and peanut. *Journal of Allergy and Clinical Immunology, 126*(2), 384–385.

Fox, M., Mugford, M., Voordouw, J., Cornelisse-Vermaat, J., Antonides, G., de la Hoz Caballer, B., et al. (2013). Health sector costs of self-reported food allergy in Europe: a patient-based cost of illness study. *European Journal of Public Health, 23*(5), 757–762.

FSA (Food Standards Agency) (2014). Survey of allergen advisory labelling and allergen content of UK retail pre-packed processed foods. **Available at** https://www.food.gov.uk/sites/default/files/survey-allergen-labelling-prepacked.pdf [**Accessed** on21 November 15].

FSA (Food Standards Agency) (2015). Food allergen labelling. Available at https://www.food.gov.uk/science/allergy-intolerance/label [Accessed on 04 November 2015].

FSAI (Food Safety Authority Ireland) (2011), Food allergens and labelling survey. Available at: file://lha-012/pers-J/00075EF2/Downloads/FINAL%2028.06.11.pdf [Accessed on 07 November 2015].

FSANZ (Food Standards Australia New Zealand) (2014) Standard 1.2.3 –Mandatory warning and advisory statement and declarations. Available at https://www.legislation.gov.au/Details/F2011C00610 [Accessed on 13 May 16].

FSANZ (Food Standards Australia New Zealand) (2015a). Allergen labelling. Available at http://www.foodstandards.gov.au/consumer/foodallergies/Pages/Allergen-labelling.aspx [Accessed on 24 May 2015].

FSANZ (Food Standards Australia New Zealand) (2015b). Warning and advisory statements. Available at http://www.foodstandards.gov.au/consumer/labelling/advisory/Pages/default.aspx [Accessed on 24 May 2015].

Fuchs, M., Cichna-Marki, M., & Hochegger, R. (2012). Development and validation of a novel real-time PCR method for the detection of celery (*Apium graveolens*) in food. *Food Chemistry, 130*(1), 189–195.

Gendel, S. M. (2012). Comparison of international food allergen labelling regulations. *Regulatory Toxicology and Pharmacology, 63*, 279–285.

Gupta, R. S., Springston, E. E., Warrior, M. R., Smith, B., Kumar, R., Pongracic, J., & Holl, J. L. (2011). The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics, 128*(1), e9–17.

Gupta, R., Holdford, D., Bilaver, L., Dyer, A., Holl, J. L., & Meltzer, D. (2013). The economic impact of childhood food allergy in the United States. *JAMA Pediatrics, 167*(11), 1026–1031.

Hattersley, S., & Ward, R. (2014). Chapter 17. Regulatory controls for food allergens. In C. Madsen, R. Crevel, C. Mills, & S. Taylor (Eds.), *Risk management for food allergy* (pp. 273–289). San Diego: Academic Press.

Health Canada (n.d.), Food allergen labelling. Available at https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/allergen-labelling.html[Accessed on 25.09.17].

Health Canada (2012). The use of food allergen precautionary statements on prepackaged foods. Available at http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/precaution_label-etiquette-eng.php [Accessed on 14 Noveber 2015].

Hefle, S. L., Furlong, T. J., Niemann, L., Lemon-Mule, H., Sicherer, S., & Taylor, S. L. (2007). Consumer attitudes and risks associated with packaged foods having advisory labelling regarding the presence of peanuts. *Journal of Allergy and Clinical Immunology, 120*(1), 171–176.

Jappe, U., & Vieths, S. (2010). Lupine, a source of new as well as hidden food allergens. *Molecular Nutrition and Food Research, 54*(1), 113–126.

Klemans, R. J. B., Blom, W. M., van Erp, F. C., Masthoff, L. J. N., Rubingh, C. M., van der Ent, C. K., et al. (2015). Objective eliciting doses of peanut-allergic adults and children can be combined for risk assessment purposes. *Clinical and Experimental Allergy, 45*(7), 1237–1244.

Kruizinga, A. G., Briggs, D., Crevel, R. W. R., Knulst, A. C., van den Bosch, L. M. C., & Houben, G. F. (2008). Probabilistic risk assessment model for allergens in food: sensitivity analysis of the minimum eliciting dose and food consumption. *Food and Chemical Toxicology, 46*(5), 1437–1443.

Kuhn, M., Waldherr, F., & Lorenzen, E. (2010). EU-VITAL Initiative for harmonized action levels for the declaration of food allergens. Symposium on Frontiers in Food Allergen Risk Assessment, Nice, France, 20–22 October. Available from: http://www.ilsi.org/Europe/Documents/Food%20Allergy%20Symposium/Poster_Lorenzen.pdf [Accessed on 14 November 2015].

Kulis, M., Wright, B. L., Jones, S. M., & Burks, A. W. (2015). Diagnosis, management and investigational therapies for food allergies. *Gastroenterology, 148*(6), 1132–1142.

Lee, A. J., Thalayasingam, M., & Lee, B. W. (2013). Food allergy in Asia: how does it compare? *Asia Pacific Allergy, 3*(1), 3–14.

Luber, F., Demmel, A., Pankofer, K., Busch, U., & Engel, K.-H. (2015). Simultaneous quantification of the food allergens soy bean, celery, white mustard and brown mustard via combination of tetraplex real-time PCR and standard addition. *Food Control, 47*, 246–253.

Luccioli, S., & Kwegyir-Afful, E. K. (2014). Benefits of understanding allergen thresholds. *Journal of Allergy and Clinical Immunology, 134*(2), 399–400.

Madsen, C. B., Hattersley, S., Buck, J., Gendel, S. M., Houben, G. F., Hourihane, J. O. et al. (2009). Approaches to risk assessment in food allergy: report from a workshop "developing a framework for assessing the risk from allergenic foods". *Food and Chemical Toxicology, 47*, 480–489.

Manning, L., & Soon, J. M. (2016). An alternative allergen risk management approach. *Critical Reviews in Food Science and Nutrition*. https://dx.doi.org/10.1080/10408398.2016.1185085.

Ministry of Health, Labour and Welfare (n.d.). FAQs on labelling system for foods containing allergens. Standards and evaluation division, Department of Food Sanitation, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare. Available at: http://www.caa.go.jp/foods/pdf/syokuhin13.pdf [Accessed on 16 November 2015].

Noimark, L., Gardner, J., & Warner, J. O. (2009). Parents' attitudes when purchasing products for children with nut allergy: a UK perspective. *Pediatric Allergy and Immunology, 20*, 500–504.

Ong, P. Y. (2008). Are allergy advisory statements helpful to patients with food allergy? *Journal of Allergy and Clinical Immunology, 121*(2), 536–537.

Pape, S. B. (2009). "May contain" labelling: Adequate consumer warning or unnecessarily defensive manufacturer behaviour? *Journal of Consumer Policy, 32*, 165–188.

Patel, D. A., Holdford, D. A., Edwards, E., & Carroll, N. V. (2011). Estimating the economic burden of food-induced allergic reactions and anaphylaxis in the United States. *Journal of Allergy and Clinical Immunology, 128*(1), 110–115.

Pele, M., Brohee, M., Anklam, E., & Van Hengel, A. J. (2007). Peanut and hazelnut traces in cookies and chocolates: relationship between analytical results and declaration of food allergens on product labels. *Food Additives and Contaminants, 24*(12), 1334–1344.

Peters, E. M., Burraston, B., & Mertz, C. K. (2004). An emotion-based model of risk perception and stigma susceptibility: cognitive appraisals of emotion, affective reactivity, worldviews, and risk perceptions in the generation of technological stigma. *Risk Analysis, 24*(5), 1349–1367.

Pumphrey, R. (2004). Anaphylaxis: can we tell who is at risk of a fatal reaction? *Current Opinion in Allergy and Clinical Immunology, 4*(4), 285–290.

Remington, B. C., Baumert, J. L., Marx, D. B., & Taylor, S. L. (2013). Quantitative risk assessment of foods containing peanut advisory labelling. *Food and Chemical Toxicology, 62*, 179–187.

Robertson, O. N., Hourihane, J. O.'. B., Remington, B. C., Baumert, J. L., & Taylor, S. L. (2013). Survey of peanut levels in selected Irish food products bearing peanut allergen advisory labels. *Food Additives and Contaminants: Part A, 30*(9), 1467–1472.

Said, M., & Weiner, J. M. (2004). "May contain traces of…": hidden food allergens in Australia. More accurate food labelling would assist consumers and the food industry alike. *Medical Journal of Australia, 181*(4), 183–184.

Sharma, G. M., Pereira, M., & Williams, K. M. (2015). Gluten detection in foods available in the United States—a market survey. *Food Chemistry, 169*, 120–126.

Shek, L. P.-C., Cabrera-Morales, E. A., Soh, S. E., Gerez, I., Ng, P. Z., Yi, F. C., et al. (2010). A population-based questionnaire survey on the prevalence of peanut, tree nut, and shellfish allergy in 2 Asian populations. *Journal of Allergy and Clinical Immunology, 126*(2), 324–331.

Sherlock, R., Taylor, S. L., Pfaff, S., Grinter, K., & Crevel, R. W. R. (2014). Chapter 16. May contain—to use or not to use? In C. Madesn, R. Crevel, C. Mills, & S. Taylor (Eds.), *Risk management for food allergy* (pp. 261–272). San Diego: Academic Press.

Sheth, S. S., Waserman, S., Kagan, R., Alizadehfar, R., Primeau, M., et al. (2008). Improving food labelling for the allergic consumer. *Journal of Allergy and Clinical Immunology, 121*(2), S183.

Sheth, S. S., Waserman, S., Kagan, R., Alizadehfar, R., Primeau, M.-N., Elliot, S., et al. (2010). Role of food labels in accidental exposures in food-allergic individuals in Canada. *Annals of Allergy, Asthma & Immunology, 104*(1), 60–65.

Sicherer, S. H., & Sampson, A. (2010). Food allergy. *Journal of Allergy and Clinical Immunology, 125*, S116–S125.

Sirvent, S., Akotenou, M., Cuesta-Herranz, J., Vereda, A., Rodriguez, R., Villalba, M., & Palomares, O. (2012). The 11S globulin sin a 2 from yellow mustard seeds shows IgE cross-reactivity with homologous counterparts from tree nuts and peanut. *Clinical and Transnational Allergy, 2*, 23.

Slovic, P., Fischhoff, B., Lichtenstein, S. and Roe, F.J.C., (1981). Perceived risk: psychological factors and social implications [and discussion]. In *Proceedings of the Royal Society of London A: Mathematical, Physical and Engineering Sciences* (Vol. 376, No. 1764, pp. 17–34). The Royal Society.

Spanjersberg, M. Q. I., Kruizinga, A. G., Rennen, M. A. J., & Houben, G. F. (2007). Risk assessment and food allergy: the probabilistic model applied to allergens. *Food and Chemical Toxicology, 45*(1), 49–54.

Spanjersberg, M. Q. I., Knulst, A. C., Kruizinga, A. G., Van Duijn, G., & Houben, G. F. (2010). Concentrations of undeclared allergens in food products can reach levels that are relevant for public health. *Food Additives and Contaminants, 27*(2), 169–174.

Tang, M. L. K., & Hsiao, K.-C. (2016). An update on oral immunotherapy for the treatment of food allergy. *Paediatrics and Child Health, 26*(7), 304–309.

Taylor, S. L., Hefle, S. L., Bindslev-Jensen, C., Bock, S. A., Burks, A. W., Christie, L., et al. (2002). Factors affecting the determination of threshold doses for allergenic foods: How much is too much? *Journal of Allergy and Clinical Immunology, 109*(1), 24–30.

Taylor, S. L., Moneret-Vautrin, D. A., Vrevel, R. W. R., Sheffield, D., Morisset, M., Dumont, P., Remington, B. C., & Baumert, J. L. (2010). Threshold dose for peanut: Risk characterization based upon diagnostic oral challenge of a series of 286 peanut-allergic individuals. *Food and Chemical Toxicology, 48*, 814–819.

Taylor, S. L., Baumert, J. L., Kruizinga, A. G., Remington, B. C., Crevel, R. W. R., Brooke-Taylor S. et al. (2014). Establishment of reference doses for residues of allergenic foods: Report of the VITAL expert panel. *Food and Chemical Toxicology, 63*, 9–17.

Thorndike, A. N., Riis, J., Sonnenberg, L. M., & Levy, D. E. (2014). Traffic-light labels and choice architecture: Promoting healthy food choices. *American Journal of Preventive Medicine, 46*(2), 143–149.

Turner, P. J., Allen, K. J., Mehr, S., & Campbell, D. E. (2016). Knowledge, practice, and views on precautionary allergen labelling for the management of patients with IgE-mediated food allergy—a survey of Australasian and UK health care professionals. *The Journal of Allergy and Clinical Immunology: In Practice, 4*(1), 165–167.

US FDA, (United States Food and Drug Administration) (2006). Food Allergen Labelling and Consumer Protection Act of 2004 (Public Law 108–282, Title II). Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm [Accessed on 13 May 2016].

US FDA, United States Food and Drug Administration (2016). Guidance for industry: Questions and answers regarding food allergens, including the food allergen labelling and consumer protection of 2004 (Edition 4); Final guidance. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059116.htm [Accessed on 14 November 2015].

US Gain Report (2011). General rules for the labelling of prepackaged foods. GAIN Report CH110030. Available at: http://www.ccilc.pt/sites/default/files/general_rules_for_the_labelling_of_prepackaged_foods_gb7718-2011.pdf [Accessed on 13 May 2016].

Vander Leek, T. K., Liu, A. H., Stefanski, K., Blacker, B., & Bock, S. A. (2000). The natural history of peanut allergy in young children and its association with serum peanut-specific IgE. *Journal of Pediatrics, 137*(6), 749–755.

Verrill, L., & Choinière, C. J. (2009). Are food allergen advisory statements really warnings? Variation in consumer preferences and consumption decisions. *Journal of Food Products Marketing, 15*(2), 139–151.

Voordouw, J., Fox, M., Cornelisse-Vermaat, J., Antonides, G., Mugford, M., & Frewer, L. (2010). Household costs associated with food allergy: an exploratory study. *British Food Journal, 112*(11), 1205–1215.

Wu, T.-C., Tsai, T.-C., Huang, C.-F., Chang, F.-Y., Lin, C.-C., Huang, I.-F., et al. (2012). Prevalence of food allergy in Taiwan: a questionnaire-based survey. *Internal Medicine Journal, 42*(12), 1310–1315.

Zurzolo, G. A., Mathai, M. L., Koplin, J. J., & Allen, K. J. (2012). Hidden allergens in foods and implications for labelling and clinical care of food allergic patients. *Current Allergy and Asthma Reports, 12*(4), 292–296.

Zurzolo, G. A., Allen, K. J., Taylor, S. L., Shreffler, W. g., Baumert, J. L., Tang, M. L. K., et al. (2013). Peanut allergen threshold study (PATS): Validation of eliciting doses using a novel single-dose challenge protocol. *Allergy, Asthma & Clinical Immunology, 9*, 35.