

VIEWPOINT

Consensus of stakeholders on precautionary allergen labelling: A report from the Centre for Food and Allergy Research

Giovanni A Zurzolo,^{1,2} Jennifer J Koplin,¹ Anne-Louise Ponsonby,^{1,3} Vicki McWilliam,¹ Shyamali Dharmage,⁴ Ralf G Heine,^{1,3,5} Mimi LK Tang,^{1,3,5} Susan Prescott,⁶ Dianne E Campbell,⁷ Richard Loh,⁸ Kristina Rueter,^{6,8} Merryn Netting,^{9,10} Katie Frith,¹¹ Wendy Norton,¹² Maria Said,¹² Michael Gold,¹³ N Alicec Lee,¹⁴ Michael Mathai,² Maximilian deCourten² and Katrina J Allen^{2,3,4,5}

¹Murdoch Children's Research Institute, Centre for Food and Allergy Research, ²Centre for Chronic Disease, College of Health and Biomedicine, Victoria University, ³Department of Paediatrics and ⁴Melbourne School of Population and Global Health, University of Melbourne, ⁵Department of Allergy and Immunology, Royal Children's Hospital, Melbourne, Victoria ⁶School of Paediatrics and Child Health, University of Western Australia, ⁸Princess Margaret Hospital for Children, Perth, Western Australia, ⁷The Children's Hospital at Westmead, ¹¹Department of Immunology and Infectious Diseases, Sydney Children's Hospital, ¹²Allergy and Anaphylaxis, ¹⁴ARC Training Centre for Advanced Technologies in Food Manufacture, The University of New South Wales, Sydney, New South Wales, ⁹Women's and Children's Health Research Institute and ¹⁰Discipline of Paediatrics, School of Medicine, The University of Adelaide, Adelaide, South Australia, Australia

Introduction

The prevalence of food allergy in Australia has been reported to be as high as 10% in infants¹ with food allergies being one of the first manifestations of allergic disease and one that significantly impacts on general health perception, the child's involvement in family activities and the emotional distress experienced by parents.² To date, there is no cure in routine clinical use for food allergy: management of food allergy consists of the removal of the allergen from the diet and the provision of an action plan to manage accidental exposure to the food protein.³ The food-allergic consumer relies on clear, concise information on food labels to make an informed and safe choice when purchasing foods for themselves or their family.

Precautionary allergen labelling (PAL) consists of statements on food products (such as 'may contain traces of x'). These advise the food-allergic consumer that cross contact may have occurred during the manufacturing process. When cross contact occurs, it often does so within the processing plant through shared equipment or during product storage and distribution stages. Allergen cross contact management and risk review processes have been developed by the food industry to maximise food safety management and communication for the allergic consumer. This type of labelling is voluntary for the food industry and is not standardised, which means that many different wordings for PAL statements can be used.⁴ European and US studies have found that an increasing number of consumers with food allergy are ignoring PAL statements. This is possibly due to their increased usage causing familiarity and complacency in consumers regardless of the important information that they contain. In addition, the studies suggest that food-allergic consumers are risk-taking by either ignoring PAL

statements on food packaging or assuming that the degree of risk depends on the wording of the label.^{5,6}

This is also true in Australia where there is increasing evidence that food-allergic consumers are not always heeding PAL statements⁴ and that health professionals are confused and sceptical about their value.⁷ We have shown that consumers grade the level of perceived risk based on the wording of the precautionary statements. Consumers demonstrate complacency with PAL by disregarding some forms of advisory labelling because they incorrectly assume that statements such as 'shared facility' and 'may contain' indicate different levels of risk. We have found that many statements are now being disregarded by parents of food-allergic children with up to 65% ignoring PAL irrespective of whether their child has had a previous anaphylactic reaction.⁸ In addition, 35% of supermarket products in the study did not contain a PAL statement, and it is unclear whether these products were free from allergen and safe or had simply not undergone a risk assessment and were therefore unlabelled (Fig. 1a,b).

An important step in improving PAL statements was the initiation of the Voluntary Incidental Trace Allergen Labelling (VITALTM), which was developed and implemented in 2007 and is managed by the Allergen Bureau.⁹ VITALTM is a risk assessment tool that allows manufacturers to determine whether a food product should carry a PAL statement based upon action levels (fixed concentrations of allergens likely to be found in the product). Action levels are based on individuals eliciting the thresholds. These have been defined as Eliciting Dose 01 or ED01 (likely to cause a reaction in 1% of the allergic population) and Eliciting Dose 05 or ED05 (likely to cause a reaction in 5% of the allergic population). VITALTM action levels are based on ED01.¹⁰ If a product falls above a defined action level, then this particular product carries a PAL statement, which is the only statement that can be used with the VITALTM 'may be present' statement. If the product falls lower than the action level, it does not require a PAL statement. VITALTM action levels are based on scientific evidence from reference doses. They are also based on the statistical dose-distribution modelling of individual thresholds to ascertain reaction amongst food-allergic patients. These findings are sourced from clinical oral food

Correspondence: Prof Katrina Allen, Centre of Food and Allergy Research, Murdoch Children's Research Institute, Royal Children's Hospital, Parkville, Vic. 3052, Australia. Fax: +61 39936 6585; email: katie.allen@rch.org.au

Conflict of interest: None declared.

Accepted for publication 22 February 2016.

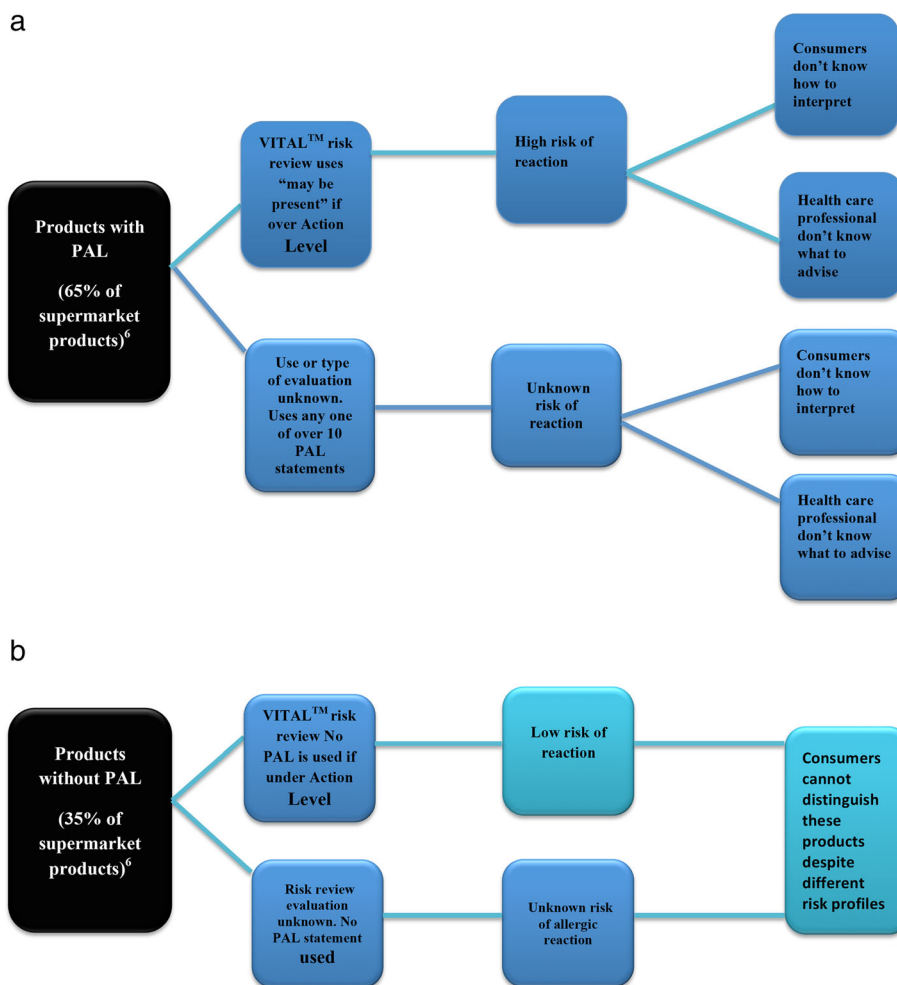


Fig. 1 (a) Cross-contact evaluation, appearance and implications of products with precautionary allergen labelling (PAL) statements modified from Zurzolo *et al.* (2013) Perceptions of precautionary labelling amongst parents of children with food allergy and anaphylaxis.⁶ (b) Cross-contact evaluation, appearance and implications of products without PAL statements modified from Zurzolo *et al.* (2013) Perceptions of precautionary labelling amongst parents of children with food allergy and anaphylaxis.⁶

challenges. Actual quantification of VITAL™ action levels is not required but some companies implementing a VITAL type system do analytical testing to confirm that allergen levels are not higher than their calculations and predicted level of safety. Yet under the current VITAL™ system, if a risk assessment is done and a PAL not indicated, then there is no current mechanism by which that is communicated to the public. Note that we have previously provided a detailed description of VITAL™: its strengths and its limitations.^{4,11}

In November 2014, the Centre for Food and Allergy Research (CFAR), a National Health and Medical Research Council-funded Centre of Research Excellence in Paediatric Food Allergy, organised a roundtable discussion, which included major stakeholders with an interest in PAL. These stakeholders included researchers, government representatives, health and industry professionals and consumers (Fig. 2).

The aims of the roundtable were to

- Understand the role of various stakeholders in relation to PAL
- Analyse the current approach to PAL in Australia

- Identify opportunities to improve choice and outcomes for the food-allergic consumer
- Inform the future work of the various stakeholders, including the Centre for Food and Allergy Research

An external facilitator led the roundtable discussion, and presentations were delivered by each sector represented. The attendees were then divided into groups to undertake a strengths, weaknesses, opportunities and threats (SWOT) analysis of the SWOT of the PAL statements. The workshop then concluded with a group discussion regarding recommendations for PAL.

Summary of Presentations

It was generally agreed that PAL statements needed to be clearly visible, simple to understand, reliable and safe. Importantly, they needed to clearly indicate identified risk levels. A motion was raised to incorporate into the labelling an element that would identify safe foods for allergy affected individuals. This was termed

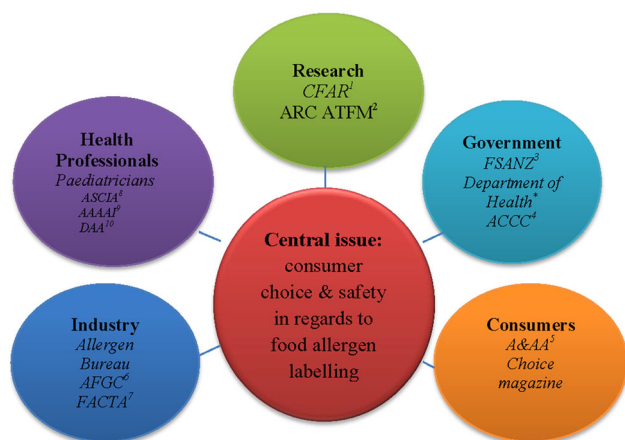


Fig. 2 Groups represented at the Centre for Food and Allergy Research roundtable on precautionary allergen labelling, November 14, 2014.

‘permissive labelling’. The meeting concluded with a roundtable discussion of the SWOT in regards to PAL.

The health professionals’ perspective

The background and purpose of PAL statements on pre-packaged manufactured goods is widely misunderstood by health professionals. A survey of more than 160 health professionals (predominantly specialist paediatric allergists) across Australia, New Zealand and the UK indicates that 33% of health professionals incorrectly believe PAL is currently mandated by the government and 84% incorrectly believe the most common reason PAL is used is to minimise litigation. It also indicated that 57% of health professionals had not previously heard of VITALTM.⁷

The consumer perspective

The discussion highlighted that the majority of consumers experience confusion with regard to PAL statements. This has led to consumer representatives calling for consistency. It was suggested that PAL be standardised, an action that would occur if the VITALTM process was made mandatory. This is an important step as there is evidence to suggest that current labelling is resulting in consumers taking unnecessary risks when purchasing foods or unnecessarily limiting their diets.⁸ The diversity of the ethnic background, education and literacy levels of the food-allergic consumer adds to the challenge of this process. One of the other major challenges of VITALTM and PAL (in its current form in Australia) is that foods that have been through a risk assessment process are not labelled as such. Therefore, the consumer has no way of knowing whether a food that does not bear a PAL statement has been tested and deemed safe or whether it has been through a risk assessment process at all (Fig. 1a,b).

Industry and Food Standards Australia New Zealand perspective

From the food manufacturing perspective, VITALTM is a science-based allergen risk review tool and programme that is both

consistent and effective. However, it has not been adopted universally by the industry. In order to expand the reach of VITALTM, it was suggested that risk review, risk communication, certification investigation and VITALTM Online be areas of focus for the future.

The precautionary allergen labelling of foods: A roundtable discussion of strengths, weaknesses, opportunities and threats

The results of the SWOT analysis undertaken by the roundtable group indicate that PAL is widely used and VITALTM has a global audience (Table 1). Some of the identified weaknesses included that stakeholders (health professionals and the industry) find it confusing and that consumers cannot identify the safety levels of the products. Suggestions to improve PAL included permissive labelling, the standardisation of labels and the education of stakeholders and consumers to help distinguish safer products. The additional cost to industry and the inconsistency of opinion amongst experts regarding the threshold were identified as threats to improving PAL (Table 1).

The precautionary allergen labelling of foods: The roundtable group discussion/recommendations

The main themes that emerged from the group discussion were *the certification of PAL, the need for education, recommendations for CFAR/VITALTM and identified gaps in research* (Table 2).

Certification

In order to certify PAL, the group recommended a comparison of the prevalence of unlabelled products that have used VITALTM/PAL to those that have not.

Education

It was suggested that an effective education campaign be implemented to inform all stakeholders of the appropriate use of PAL (Table 2).

Gaps in research

The roundtable discussion identified gaps in research and made the following recommendations:

- 1 To assess the knowledge or attitude barrier to the use of VITALTM, the factors influencing the industry’s uptake of it need to be examined.
- 2 To investigate the proportion of products that have been assessed by VITALTM and are perceived as safe, it is necessary to investigate the prevalence of unlabelled products that have used VITALTM/PAL versus those that have not (Fig. 1a,b).
- 3 To assess the safety of food products with no label, there is a need to examine the allergen content of these products as this would help to determine whether or not they have been through a risk assessment process.
- 4 To assess whether the current status quo is resulting in unexpectedly high rates of adverse reactions, there is a need to examine the number of anaphylaxis events due to ingestion of products both with and without PAL (Table 2).

Table 1 Strengths, Weakness, Opportunities and Threats analysis of the Australian PAL system (inclusive of VITAL™)

Strengths	Weaknesses	Opportunities	Threats
PAL is widely used	All stakeholders find PAL to be confusing and inconsistent	All stakeholders believe that labelling can be improved by implementing standards and then education	VITAL reference dose may be incorrect
VITAL™ is acknowledged internationally	No label on products that have been assessed to be safe	Standardisation of labels	Additional cost to the industry
PAL raises awareness of allergens	Consumers cannot distinguish between the most and least safe food products	The development and adoption of VITAL reference dose to industry	Legal threat if consumer has a reaction
Manages the food safety risk and communicates the risk to the consumer	PAL is voluntary and less likely to be adopted by smaller companies	Introduce permissive labelling	Inconsistency of opinion amongst all experts

PAL, precautionary allergen labelling; VITAL, Voluntary Incidental Trace Allergen Labelling.

Table 2 Conclusion from the working group discussion and gaps in research identified that need to be address

Certification of PAL	Education	Recommendations CFAR/VITAL™ and gaps in research
Percentage of unlabelled products that have gone through VITAL™ compared to those that have not	Create an education campaign to inform stakeholders	Investigate the prevalence of unlabelled products that have used VITAL™/PAL versus those that have not
Understand the links between anaphylaxis cases with and without PAL	Inform all stakeholders regarding the appropriate use of PAL	Examine the allergen content of these products
Industry survey on the perception and use of VITAL™	Allergy & Anaphylaxis Australia to connect with state enforcement agencies	Examine factors that influence industry's uptake of VITAL™
Products to be VITALised with a label	Message to get across all sectors	Examine the number of anaphylaxis events due to ingestion of products with and without PAL by developing a system of reporting that would allow such an outcome to be determined

CFAR, Centre for Food and Allergy Research; PAL, precautionary allergen labelling; VITAL, Voluntary Incidental Trace Allergen Labelling.

Accurate and reliable PAL statements on pre-packaged manufactured foods are essential for allergic consumers to make informed and safer choices about the foods that they purchase. There are many inconsistencies in the current PAL system that lead to confusion amongst consumers and health professionals alike. A useful PAL system should be clear and concise and it should enhance food choice capacity for the food-allergic community.

Certification of precautionary allergen labelling/Voluntary Incidental Trace Allergen Labelling and gaps in research

It was strongly agreed that in order to implement certification processes for precautionary allergen labelling, the identified gaps in research would need to be addressed (Table 2). By addressing these gaps, it would be possible to alert consumers that the VITAL™ process is a form of labelling that is different (and potentially safer) than other forms of PAL. Furthermore, it would distinguish the products with no labelling that have been through a risk assessment process such as VITAL™ (and are thus safe) from unlabelled

products that have had no such assessment (and that are potentially unsafe). Examining the allergen content of these products is important in order to evaluate the effectiveness of VITAL™ in preventing allergic reactions in consumers.

As the industry's uptake of VITAL™ has been slow, it is essential that we try to understand any limitations that it has with the process. As per our current knowledge, there has been no investigation into the number of anaphylaxis events because of ingestion of products with or without PAL statements on packaging. Filling this gap in research will help us to understand the prevalence of these events.

Education

It was agreed that it would be beneficial to provide education to consumers and health professionals regarding the current labelling system. This would help to reduce the confusion and inconsistency in consumers' daily shopping practices and in health professionals' recommendations to food-allergic consumers. A cohesive

education programme would be essential if and when certification of PAL/VITALTM occurred.

The discussion around PAL has become topical in Australia and in other developed countries with high prevalence of food allergy. Apart from CFAR, other groups have held workshops on the topic of PAL. Recently Dunn Galvin *et al.* (2015) aimed to summarise the perspectives of key stakeholders in regards to PAL. The authors suggested that a useful PAL system should reflect actual risk and that its use should indicate the possible, unintended presence of an allergen at or above any proposed action level.¹²

Additionally Madsen *et al.* (2011) conducted a workshop in the UK that involved key stakeholders in food allergen labelling. The workshop's main objective was different to ours as it focused on defining a tolerable level of risk in food allergy. This study concluded that threshold levels are useful in moving VITALTM forward.¹³ In comparison, the European Parliament and the European Federation for Allergy and Airways Diseases Patients Associations organised a workshop with a wide variety of stakeholders to discuss food allergen labelling. The recommendation from this workshop was that PAL was ineffective and should be eliminated in the near future.¹⁴

While our workshop did not reach the same conclusions, all stakeholders agreed that the most effective way to advance appropriate allergen management risk review and labelling was to act on agreed outcomes. It was strongly agreed that in order to obtain certification of the application of the VITALTM principles and programme, the identified gaps in research would need addressing. Closing the knowledge gaps identified in the roundtable discussion will strengthen the call for government agencies to endorse the VITALTM process and aid the standardisation of PAL by the food industry.

Conclusion

Precautionary allergen labelling (PAL) is the main communication tool available to indicate safety levels for food-allergic consumers with regard to potential allergens present in pre-packaged foods. VITALTM is a valuable innovation, and the consensus achieved at the roundtable discussion has the potential to assist in its increased uptake by the industry. Gaps in the literature were identified, which, once addressed, will assist in extending the VITALTM programme to improve its utility. There is potential for the certification of PAL as well as the development of a permissive labelling indication. Improved education is also required to ensure that practitioners and organisations supporting food-allergic patients are providing consistent information regarding the foods that are safe for them to consume.

Workshop Participants

Tamar Heath, Robin Sherlock, Kirsten Grinter, Fiona Fleming, Tony Beaver, Christel Leemhuis, Jenny Hazelton, Barry Fields, Laurena McBride, Andrew Davies, Bruce Nelan, Milena Canil, Fiona Jones, Paul A Goldsmith, Catrina McStay, Tracy Ward, Joanne Cammans, Tenille Fort, Luke McMahon, Katinka Day,

Saman Buddhadasa, Dean Clarke, James Roberts, Christa Lingham, Alice Lee, Wendy Norton, Maria Said, Dianne Campbell, Shyamali Dharmage, Katie Frith, Mike Gold, Ralf Heine, Jennifer Koplin, Mary Panjari, David Martino, Noor Suaini, Caroline Lodge, Richard Loh, Vicki McWilliam, Merryn Netting, Anne-Louise Ponsonby, Susan Prescott, Mimi Tang, Dean Tey, Sally Voukelatos, Giovanni Zurzolo and Katrina Allen.

Acknowledgement

This work is supported by the NHMRC Centre for Research Excellence (ID 1041420): Centre for Food and Allergy Research.

References

- Allen KJ, Hill DJ, Heine RG. 4. Food allergy in childhood. *Med. J. Aust.* 2006; **185**: 394–400.
- Altschul AS, Scherrer DL, Muñoz-Furlong A, Sicherer SH. Manufacturing and labeling issues for commercial products: Relevance to food allergy. *J. Allergy Clin. Immunol.* 2001; **108**: 468.
- Osborne NJ, Koplin JJ, Martin PE *et al.* Prevalence of challenge-proven IgE-mediated food allergy using population-based sampling and predetermined challenge criteria in infants. *J. Allergy Clin. Immunol.* 2011; **127**: 668–76.e2.
- Zurzolo GA, Mathai ML, Koplin JJ, Allen KJ. Precautionary allergen labelling following new labelling practice in Australia. *J. Paediatr. Child Health* 2013; **49**: E306–10.
- Hefle SL, Furlong TJ, Niemann L, Lemon-Mule H, Sicherer S, Taylor SL. Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. *J. Allergy Clin. Immunol.* 2007; **120**: 171–6.
- Noimark L, Gardner J, Warner JO. Parents' attitudes when purchasing products for children with nut allergy: A UK perspective. *Pediatr. Allergy Immunol.* 2009; **20**: 500–4.
- Campbell D. Knowledge, practice and views on precautionary allergen labelling for the management of patients with IgE mediated food allergy—a survey of Australasian and UK Healthcare Professionals. *J. Allergy Clin. Immunol. Pract.* 2016; **4**: 165–7.
- Zurzolo GA, Koplin JJ, Mathai ML, Tang MK, Allen KJ. Perceptions of precautionary labelling among parents of children with food allergy and anaphylaxis. *Med. J. Aust.* 2013; **198**: 621–3.
- Allergen Bureau. VITAL. Available from: <http://www.allergenbureau.net/vital/vital-qaas> [accessed 7 July 2015].
- Taylor SL, Moneret-Vautrin DA, Crevel RWR *et al.* Threshold dose for peanut: Risk characterization based upon diagnostic oral challenge of a series of 286 peanut-allergic individuals. *Food Chem. Toxicol.* 2010; **48**: 814–9.
- Allen KJ, Remington BC, Baumert JL *et al.* Allergen reference doses for precautionary labeling (VITAL 2.0): Clinical implications. *J. Allergy Clin. Immunol.* 2014; **133**: 156–64.
- DunnGalvin A, Chan CH, Crevel R *et al.* Precautionary allergen labelling: Perspectives from key stakeholder groups. *Allergy* 2015; **70**: 1039–51.
- Madsen CB, Hattersley S, Allen KJ *et al.* Can we define a tolerable level of risk in food allergy? Report from a EuroPrevall/UK Food Standards Agency workshop. *Clin. Exp. Allergy* 2012; **42**: 30–7.
- European Federation of Allergy Airway Diseases Patients Associations Food Allergy Working Group. Report on the EFA "Contains/May Contain – Food Allergen Labelling" Event. Zurich: European Academy of Allergy and Clinical Immunology. Available from: <http://www.efanet.org/presentations/2012> [accessed 7 July 2015].