

An International First: Stakeholder Consensus Statement for Food Allergen Management in Packaged Foods and Food Service for Australia and New Zealand



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Food-allergic consumers encounter inadequate, confusing, and ambiguous allergen information for packaged and unpackaged foods. Key Australian and New Zealand allergy organizations convened multiple forums to facilitate discussions among consumers, food manufacturers, food retailers, regulatory bodies, researchers, and health professionals to develop a unified approach to improving food allergen management. The following stakeholder consensus statement provides a foundation for advocacy for improved food allergen management and safety.

It is the responsibility of consumers to:

1. declare their food allergies and read food labels (including ingredient lists and allergen declaration statements), and
2. ultimately make their own judgment about the foods they choose to consume.

We consider that to enable consumers to make informed decisions about their safety,

It is the responsibility of packaged food manufacturers to:

1. follow robust allergen management practices including quantitative risk assessment, and

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The Centre for Food and Allergy Research is funded by National Health and Medical Research Council of Australia Centre for Research Excellence GNT1134812. J.J. Koplin is supported by National Health and Medical Research Council of Australia Fellowship GNT1158699.

Conflicts of interest: W. Freeman is a voluntary member of the National Allergy Strategy Steering Committee. C.J. Hornung contributed to this work through employment as the CFAR Coordinator. J. Lacis-Lee is a voluntary board director for the Allergen Bureau. K.P. Perrett received a Melbourne Children's Clinician-Scientist Fellowship; received payments to her institution from the National Health and Medical Research Council of Australia (NHMRC) Investigator fellowship, Australia, NHMRC CTCS grant, EW Thrasher grant, United Kingdom, Allergy and Immunology Foundation of Australia, National Institutes of Health National Institute of Allergy and Infectious Diseases, United States, DBV Technologies, and Novartis; received consulting fees (paid to her institution) from Aravax; received support for attending meetings/travel (paid to her

institution) from MedImmune; participated in a data safety and monitoring board/advisory board (voluntary): Concussion Essentials and Allergy Pal (chair, scientific advisory board). V.L. McWilliam received MCRI, Australia Theme Funding Grants 2021 and 2019 (research salary support); Allergy and Immunology Foundation of Australia project funding; EW Thrasher Grant project funding; received payment of speaker honoraria from Nutricia, Nestlé Health Sciences, and Abbott; and had a leadership or fiduciary role in the AusEE scientific advisory board (voluntary). C. Gray received support from the Allergen Bureau, International Flavours and Fragrances NZLtd, New Zealand, and Danisco NZLtd; received support for attending meetings/travel from DuPont NZLtd, United States; and had a leadership or fiduciary role in the Allergen Bureau Board of Directors. J. Smith had a leadership or fiduciary role as the CEO of the Australasian Society of Clinical Immunology and Allergy. M.J. Netting received NHMRC Early Career Fellowship APP1156518; Grants or contracts from the Nestlé Nutrition Institute; and payment or honoraria from the Nestlé Nutrition Institute (speaker honoraria). D.E. Campbell received grants or contracts from the NHMRC, Australia (project funding to the institution); received consulting fees from the Allergen Advisory board (paid to herself) and from the Westmead Fertility Centre Governance Committee (paid to the institution); received payment or honoraria from Nestlé Health Sciences (paid to the institution); received support for attending meetings from the NSW Ministry of Health, Australia and DBV Technologies; participated in a data safety monitoring board: St Vincent's Hospital Sydney CAR T cell DSBM (voluntary); received stock or stock options from DBV Technologies (stock options); and is a part-time employee of DBV Technologies. K. Grinter declares a leadership or fiduciary role as Allergen Bureau director (voluntary). The rest of the authors declare that they have no relevant conflicts of interest.

Received for publication December 12, 2021; revised March 14, 2022; accepted for publication March 23, 2022.

Available online April 2, 2022.

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<https://doi.org/10.1016/j.jaip.2022.03.018>

2. use clear, consistent labeling to inform consumers about that food's allergen content, including the possible presence of unintended allergens.

It is the responsibility of food service establishments and providers to:

- 1. follow robust allergen management practices, and**
 - 2. ensure that staff understand and can inform consumers about the allergen content of the food they provide, including the possible presence of unintended allergens.**
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INTRODUCTION

Australia has a high prevalence of IgE-mediated food allergy, affecting approximately 10% of infants,¹ 4.5% of children aged 4 to 14 years,^{2,3} and 2% to 4% of adults.⁴ With no cure currently available, the cornerstone of food allergy management involves education, complete allergen avoidance, a written personal emergency plan, and, when indicated, provision of an adrenaline (epinephrine) injector. To prevent known allergen exposure, food-allergic consumers and their carers must be vigilant and informed. They rely on clear and accurate information about the allergenic ingredients of packaged foods; yet, undeclared food allergens are the leading cause of food recalls in Australia, mostly owing to packaging and labeling errors.⁵ Consumers also rely on accurate information about potentially allergenic ingredients in unpackaged foods and food eaten in food service settings. However, the accuracy of information available to food-allergic consumers remains inconsistent, and accidental exposures to allergens in packaged food and food eaten away from home are common⁶⁻⁹ and potentially life-threatening.

Given these gaps in practice, mandatory labeling of common food allergens (peanuts, tree nuts, milk, eggs, sesame, fish, crustaceans, soy, and cereals containing gluten) was first introduced in Australia and New Zealand in 2002 by Food Standards Australia New Zealand (FSANZ) via the Food Standards Code (FSC),¹⁰ with lupin added in 2017. Similar legislation was introduced by the European Commission and the US Congress in 2003 to 2004.^{11,12} Whereas most countries that regulate food allergen labeling mandate declaration of the eight common food allergens outlined by the Codex Alimentarius Commission in 1999,^{13,14} there are significant regional differences in additional food allergens that must be declared depending on local food allergy prevalence.^{14,15} Regulation (or its absence) in relation to the format, terminology, and location of allergen declarations also differs widely.^{14,15} In 2021, FSANZ introduced new regulations and changes to the FSC,¹⁰ providing clarification regarding wheat, tree nut, and mollusc allergens and mandating the specific terminology, format, and location of allergen information on food packaging. This new legislation aims to make allergen information on packaging consistent and clearer for consumers and brings Australian regulations in line with other countries that regulate the location, format, and terminology of allergen labeling.

Precautionary allergen labeling (PAL) statements such as “may contain allergen x” relate to the potential presence of unintended allergens in a product through cross-contamination, also referred to as cross-contact by the food industry.¹⁴ This can occur during agricultural practices, from an ingredient received from a supplier, manufacturing, or packaging processes. Few countries in the world regulate or prohibit PAL statements, and those that do

take different approaches.¹⁵ As is the case in many countries, PAL statements in Australia and New Zealand are unregulated and inconsistently worded, and consumers cannot discern whether robust risk assessment processes have been followed by manufacturers when a PAL statement is present or absent.

Voluntary Incidental Trace Allergen Labelling (VITAL)¹⁶ is an important initiative developed by the food industry to improve PAL. Led by the Allergen Bureau, VITAL was introduced in 2007 and updated in 2019 to VITAL 3.0.¹⁷ It is a scientific risk assessment developed for food manufacturers to assess the impact of cross-contamination and provide appropriate food allergen labeling. VITAL aims to minimize allergen cross-contamination during the manufacture of the product, improving food safety for consumers and consumer communication with meaningful PAL statements.¹⁶

Eating from food service settings poses additional risks for food-allergic consumers, which has a negative impact on quality of life by increasing anxiety related to eating away from home, decreasing family socialization and limiting independence in adolescents.¹⁸ Of 22 food-related anaphylaxis deaths in Australia (1997-2013), 15 occurred while eating outside the home and two occurred at home after the consumption of restaurant meals.⁸ In Australia, 11 coronial enquiries were undertaken between 2002 and 2019¹⁹ into deaths resulting from anaphylaxis after eating food in hospitals, at school, at recreational camps, or in restaurants and cafés, as well as from pre-packaged purchased food. The Australia New Zealand FSC requires food that is sold without a label to have allergen information displayed in connection with the food or provided to the purchaser upon request.¹⁰

This project aimed to establish a consensus statement among a broad range of stakeholders, for food allergen management in the food manufacturing and food service industries in Australia and New Zealand, with the view to improving food allergen management practices, food safety, and information for food-allergic consumers.

METHODS

Between 2014 and 2020, the Centre for Food and Allergy Research (CFAR), in partnership with the Allergen Bureau, Allergy and Anaphylaxis Australia (A&AA), the National Allergy Strategy (NAS), and the Australasian Society of Clinical Immunology and Allergy (ASCIA) (Table 1), convened two stakeholder roundtable symposia. The second symposium (2019), held at the Third Food Allergen Management Symposium (FAMS) focused on food allergen management in the food industry, with subsequent videoconference and e-mail stakeholder discussions. This collaboration aimed to develop an Australian and New Zealand stakeholder consensus statement for food allergen management in food labeling and food service to assist (1) future efforts to improve food allergen management in the food industry, (2) facilitate communication in the food manufacturing and food service industries, and (3) improve consumer and health professional practices and ultimately improve food safety for consumers. Figure 1 shows the process of development of the consensus statement.

Phase 1: 2014 PAL roundtable

The first roundtable organized by CFAR in 2014 is described in detail elsewhere.²⁰ That forum focused on PAL and aimed to understand the roles and views of various stakeholders, analyze the

TABLE I. Lead organizations

Centre for Food and Allergy Research (CFAR) is a National Health and Medical Research Council-funded Center of Research Excellence in Pediatric Food Allergy.

Allergen Bureau is the peak industry body representing food industry allergen management in Australia and New Zealand.

Allergy and Anaphylaxis Australia is the peak national consumer support organization for allergy and anaphylaxis in Australia.

National Allergy Strategy is a government-funded partnership between the Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy and Anaphylaxis Australia (A&AA), working in consultation with key stakeholder organizations with a strategic public health approach to allergic disease.

Australasian Society for Clinical Immunology and Allergy (ASCIA) is the peak health professional body for allergy and immunology in Australasia.

approach to PAL in Australia, identify opportunities to improve choice and increase consumer safety, and identify gaps in knowledge to inform research and the future work of stakeholders. Attendees included researchers, representatives from government bodies, health and food industry professionals, and consumers with an interest in food allergen management and PAL. Led by an external facilitator, presentations from each stakeholder sector were followed by an analysis of the strengths, weaknesses, opportunities, and threats relating to PAL, and group discussions regarding recommendations. Stakeholders agreed that the certification of products using a risk assessment process such as VITAL for PAL would better inform and potentially improve food choices for food-allergic consumers, and research gaps were identified.²⁰

Phase 2: 2019 PAL roundtable

The second roundtable organized by CFAR in partnership with A&AA, ASCIA, the Allergen Bureau, NAS, and the FAMS steering committee, entitled “Current and Future Australian Best Practice in Allergen Labelling Roundtable Discussion,” was held in May 2019, facilitated by an external researcher from the Food Allergy Research and Resource Program (University of Nebraska). The objectives of the roundtable were to gather input from stakeholders regarding whether action was needed to make allergen labeling more effective for consumers and to arrive at a stakeholder consensus statement about food allergen labeling. There were more than 70 stakeholder attendees, including scientific and health researchers in food allergy and allergen science; health professionals (pediatricians, allergy specialists, and those from allied health); representatives from CFAR, NAS, and ASCIA; consumers and consumer groups (A&AA and Allergy New Zealand); industry (Allergen Bureau, FAMS, and food manufacturers and retailers); and government and regulatory bodies, including representatives from FSANZ. Participants were informed before the meeting of the roundtable aims. After presentations by researchers, industry, and consumers, attendees participated in an interactive moderated oral discussion forum and interactive polling. Key points were summarized. A consensus statement was drafted during the roundtable discussion for further development in subsequent electronic and virtual discussions.

Phase 3: electronic and virtual discussions

After the second roundtable discussion, a series of videoconference and e-mail discussions held between August 2019 and October 2020 aimed to finalize the consensus statement. Stakeholders in

attendance sought feedback within their organizations or representative bodies after each discussion and reported back to the group. This feedback was used to develop the consensus statement further. Finalized in October 2020, the consensus statement represents a collaboration among CFAR, NAS, A&AA, ASCIA, the Allergen Bureau, and Allergy New Zealand.

Phase 4: international benchmarking

An comparison of international approaches to regulating allergenic ingredients, PAL, and allergens in food service was undertaken by reviewing the relevant scientific and gray literature (which included legal, industry, and government reports and regulatory websites in relation to international food allergen management practices).

RESULTS

Main areas of concern identified by stakeholders were (1) the lack of specific regulations in relation to the mandatory declaration of food allergens on packaging; (2) the lack of standardized robust risk assessment processes for voluntarily applied PAL statements; (3) variable food allergen management practices in the food service sector; and (4) consumer responsibilities. The discussion and viewpoints from the 2019 roundtable are listed in [Tables II and III](#).

Stakeholders agreed that mandatory allergen labeling requirements should specify both the terminology to be used for each allergen and where on the packaging allergens are declared, so that consumers can easily locate this information. Regulatory stakeholders and some industry representatives were not supportive of introducing PAL regulation, in contrast to consumers and other stakeholders, who felt that little would change without regulatory action. Some major retailers raised the issue of poor understanding of labeling requirements among the many small to medium enterprises, including start-ups involved in food manufacturing and importing in Australia. It was suggested that many food businesses would need significant support, resources, and education to comply if PAL statements were regulated, or for a risk-based process such as VITAL to be implemented industry-wide.

Overall, participants agreed that a collaborative stakeholder consensus statement would be helpful to drive progress in improving industry practices in relation to PAL statements. Stakeholders recognized the need for consumer education in relation to food choices and eating out, because communication between consumer and food service staff regarding the need for allergen avoidance is important for a safe experience when eating away from home. Stakeholders agreed that including the food service sector and consumer responsibilities in relation to food allergen management was an important addition to the consensus statement to emphasize equal partnership and shared responsibility among consumers, food manufacturers, and food service providers to improve safety for food-allergic consumers. [Figure 2](#) shows the resulting consensus statement.

[Table IV](#) compares international approaches to mandatory allergen labeling, PAL, and allergen management in the food service sector, highlighting the few countries that regulate PAL and for food service.^{14,15,21-24}

DISCUSSION

A regional stakeholder consensus statement for food allergen management was achieved, which was the first of its kind. We

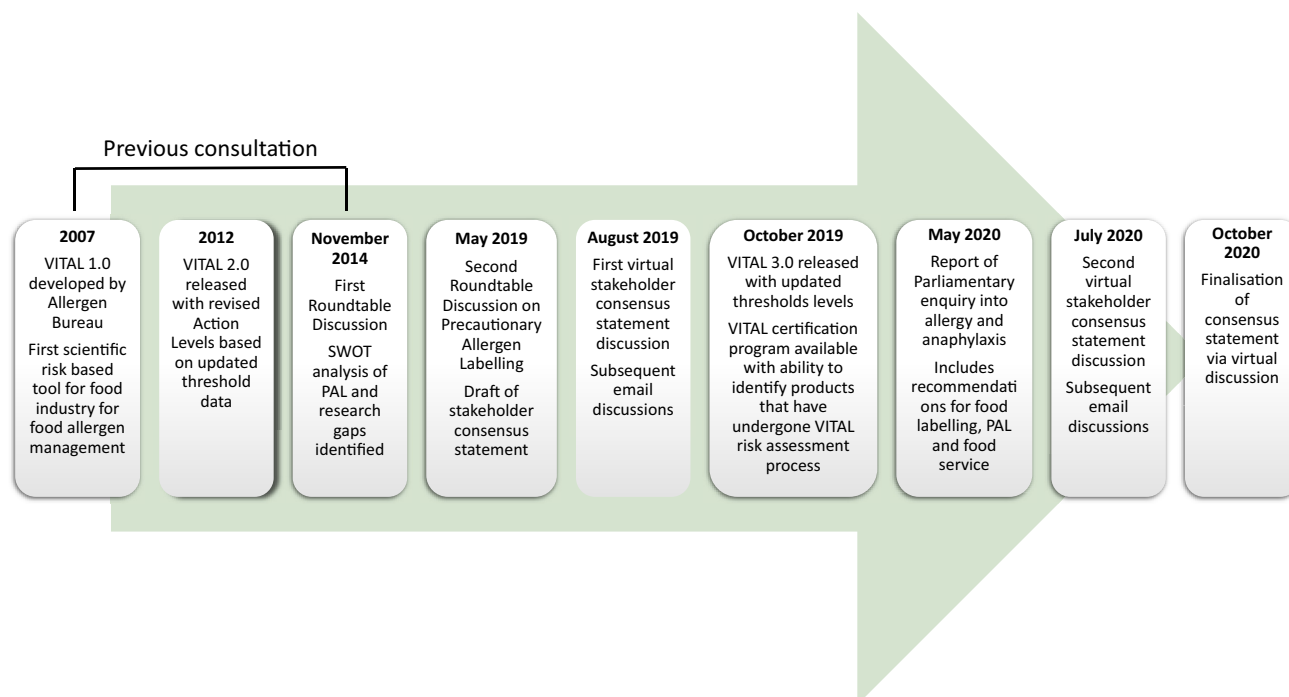


FIGURE 1. Consensus statement development: events and time line. *PAL*, precautionary allergen labeling; *SWOT*, strengths, weaknesses, opportunities, and threats; *VITAL*, Voluntary Incidental Trace Allergen Labelling.

believe this to be an important outcome, and one that can drive improved food allergen management and ultimately provide a pathway for safer choices for food-allergic consumers regionally and internationally. Whereas previous local and international discussions focused only on stakeholder engagement in relation to PAL,^{20,25,26} this stakeholder engagement and the subsequent consensus statement bring together the responsibility of consumers, food manufacturers, and the food service sector. Nevertheless, further work is required to engage the food service sector more broadly.

The food service sector was included in our statement in response to stakeholder input and to address the frequency of allergic reactions that occur when eating away from home. An Australian survey reported that 80% of respondents (food-allergic adults or parents of food-allergic children) experienced a reaction or were served food containing an ingredient to which they were allergic while eating away from home, and 70% were not confident when eating away from home.²⁷ In Australian adolescents aged 10 to 14 years with self-reported anaphylaxis, 17% of reactions in the prior 12 months occurred in restaurants and 8.6% in schools.⁷ The problem is not unique to Australia: countries around the world, including the United Kingdom, The Netherlands, and the United States report that most cases of food-induced anaphylaxis occur outside the home, and significant numbers occur owing to food eaten in restaurants, takeout outlets, and other catering settings.^{28,29}

The consensus statement recognizes the responsibility of consumers as well as food service staff and management. Consumers should declare food allergies every time they eat out. A recent US study reported that 6.2% of unintentional allergen exposure incidents causing reactions were due to the consumer not informing restaurant staff of the food allergy.^{30,31}

Even when consumers declare the food allergy, studies indicate a concerning lack of knowledge, incorrect beliefs, and inadequate skills relating to food allergen management in food service, in which the staff was unable to identify risk-reducing strategies correctly.^{31,32} Encouragingly, manager knowledge was significantly greater than that of the food service staff, and the staff expressed interest in improving knowledge and undertaking training.^{31,33-35} The consensus statement encourages the food service sector to adopt best practice food allergen management procedures and to ensure adequate staff knowledge and skills to improve safety for food-allergic consumers when eating out.

The consensus statement advocates for the need for clear and consistent food allergen labeling to help consumers make informed choices. At the time of the 2019 roundtable, stakeholders strongly supported the Plain English Allergen Labelling proposal initiated by FSANZ in 2017 and gazetted in February 2021, which aimed to standardize food allergen information on food labels and make allergen information easier for consumers to identify and understand. The FSC now specifies the terminology for allergens, which must be listed in bold font in the ingredients list, as well as in a summary statement located in the same field of view as the statement of ingredients.¹⁰ Although this is a welcome improvement, and some companies already comply with the new legislation, food businesses have 3 years to act in accordance with the new legislation, with a 2-year stock in trade time line, so allergen labeling may remain ambiguous in Australia and New Zealand until 2026. During this transition period, consumers must remain vigilant, checking the entire food packaging for allergen declarations, becoming knowledgeable about the different ingredient names for various food allergens, and being aware of the risk that previous labeling practices poses

TABLE II. Key points from presentations, 2019 roundtable

Topic	Key points from presentations
Global perspective on PAL	Few countries in the world regulate PAL, but most countries have similar issues regarding the voluntary nature of PAL. There is strong international interest in the VITAL program; VITAL 2.0 is recommended in several European countries with discussions on regulation under way. Aiming for zero risk of allergen cross-contamination is unsustainable and unrealistic; therefore, eliciting dose (ED)01 and ED05 are used to protect most consumers. The science underpinning VITAL 3.0 is considered by researchers to be robust and peer-reviewed, with an increasing evidence base for EDs for 14 allergens. Evidence is based on oral food challenge studies that are continually added to the database.
Development of VITAL	VITAL was developed by the Allergen Bureau in recognition of the poor understanding of food allergen management within the food industry. VITAL grew into precautionary allergen labeling out of recognition of the need to address labeling inconsistencies. There is a risk for blanket precautionary labeling if regulation is too difficult for industry to implement.
Issues for consumers	There had been little change from 2014 to 2019; some products had PAL statements and did some not. Consumers cannot trust products with or without PAL resulting from the lack of regulation and robust risk assessment in relation to PAL. Undeclared food allergens remain the leading reason for food recalls in Australia. This indicates that manufacturers and companies importing foods have a poor understanding of allergen labeling and/or goods manufacturing processes. Appropriate food choices therefore remain confusing for consumers. Products that state “free from” are not always well-understood by industry because there are no regulated criteria for a “free from” statement. Some manufacturers may state “free from” if the ingredient is not added, but may not have applied a rigorous process or testing procedure to address cross-contamination. Some families of products may look the same but may have different allergen content. Many products have PAL statements, which limits food choices, and consumers feel criticized for consuming these products when reactions occur. Products with PAL that cause reactions are rarely investigated by regulatory authorities, so it is unknown whether the allergen should have been included as an actual ingredient in the product. The VITAL system has been in place for many years, but there has been poor uptake and (at the time of the roundtable discussion) there was no way to identify which products use VITAL. Therefore, there has been little improvement for consumers. Consumers accept that a zero-risk approach is inappropriate, but they are keen to work with industry to move toward meaningful labeling.

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

to those who have a recent diagnosis of food allergy and poor English literacy.

In addition to advocating for clear labeling for common allergenic ingredients, our consensus statement calls for improving PAL by encouraging best practice allergen management and scientific risk assessment processes by food manufacturers. From the consumer's perspective, little had changed in relation to PAL between the 2014 and 2019 stakeholder roundtable discussions, despite the inception of VITAL 1.0 in 2007, and its subsequent revisions. Precautionary allergen labeling is common in Australia; up to 65% of products have PAL statements for one or more allergens,³⁶ and it is unclear from the packaging whether products that contain no PAL have undergone a risk assessment process to determine that the product contains no cross-contact allergens.³⁷ Reactions to foods with and without PAL are common. An Australian study conducted in 2018 showed that 6.7% of respondents with known allergies self-reported anaphylaxis to packaged foods in which the allergen was not listed as an ingredient.⁶ Of those reactions, 53% were from foods that did not contain a PAL statement for the suspected allergenic trigger, and 8.6% of the foods had no PAL statement.⁶ This is in line with international studies that detected food allergens in products with and without PAL,^{14,38-40} and suggests that the absence of a PAL statement does not necessarily convey a lower risk for allergen exposure.

At the 2019 roundtable, there was no stated intention from regulatory bodies to regulate PAL. Consumers believed that they had little choice but to continue as they were, either avoiding the many products on the shelves with PAL or taking risks and ignoring PAL statements because complete avoidance severely affects choices. Studies indicate that food-allergic consumers find PAL difficult to interpret, and that they attribute different degrees of risk for allergen contamination, depending on the wording of the PAL statement used; or that they assume that there is no risk if no PAL statement is present,⁴¹⁻⁴⁶ despite the demonstrated allergen content in products without PAL.^{14,38-40} Likewise, health professionals demonstrate poor knowledge, confusion, and skeptical attitudes regarding PAL statements, and like consumers, attribute different levels of risk to different PAL wording. However, this interpretation of risk is not always consistent with that of consumers.⁴⁷

The consensus statement reflects the strong support of industry and consumer stakeholders at the roundtable forums for a scientific risk assessment process such as VITAL to determine the requirement for a PAL statement. VITAL 3.0 allergen labeling is determined by action levels, based on calculating the amount of allergenic protein likely to be in the maximum amount of a food eaten on a typical eating occasion (the reference amount).¹⁶ This is then compared with VITAL 3.0 reference doses for each allergen. Reference doses are based on the eliciting dose 01 (ED01), the amount of an allergen below which only the most

TABLE III. Stakeholder input into discussion themes, 2019 roundtable

Discussion theme	Key points raised by stakeholders
Support for regulation of PAL	Stakeholders agreed that a risk assessment process should be applied to a product to determine the need for PAL. Of 68 respondents, 76% supported regulation for PAL (interactive live poll). Not all participants agreed with regulating PAL, but most agreed with the need to apply a scientific risk assessment to make PAL meaningful to consumers. Several participants suggested using VITAL as an example rather than mandating a specific program for all industry to use. Stakeholders emphasized that meaningful labeling was the goal, rather than the presence or absence of PAL without a risk assessment.
Barriers to regulation of PAL	FSANZ was not planning to address PAL soon because there were several other ministerial priorities being considered. There are many small to medium-sized enterprises (SMEs) in food manufacturing in Australia. The following points were raised by manufacturers: Understanding of current labeling laws including mandatory allergen labeling among SMEs is poor. Many food recalls are from SMEs that may not have robust allergen management practices. The SMEs would require significant support and resources to adopt risk assessment processes for PAL regulation. Obtaining accurate information from suppliers of raw ingredients is difficult, especially if the ingredients are sourced from overseas. There may be issues internationally if different nations apply different thresholds or reference values. FSANZ currently applies different legislation for gluten than do the Codex recommendations. There was a query regarding whether there may be other, similar issues that arise with regulating PAL.
Value of VITAL science	There is a lack of international agreement regarding what threshold levels should be applied for PAL (ED01, ED05, and ED10), which affects the ability to regulate PAL in international forums. Stakeholders believed that the current science and ED01 approach to the proposed VITAL 3.0 program were appropriate and should be adopted by industry. Consumer stakeholders indicated they would be willing to accept this level of risk and acknowledged that a zero-risk approach was not achievable. Emphasis was placed on VITAL being a systems-based risk assessment and risk reduction process, with thresholds and action levels just one part of the program. FSANZ would need to undertake its own examination of the evidence behind the reference or threshold levels before agreeing with VITAL science and moving forward with regulation. Consumers and health professionals would need to understand the individual's level of risk, and health professionals would need to understand food labeling in relation to threshold levels to provide better advice regarding food choices.
Role of food service	Work needs to be done with the food service sector, which demonstrates a poor understanding of food allergies and food allergen management, as evidenced by frequent reactions and some fatalities. Lack of trust in food service establishments impedes the ability of consumers with food allergy to eat out, and therefore has an impact on quality of life. A different scope and approach to labeling are needed because systems across the food service sector are not as methodical as in food manufacturing.
Actions that could be undertaken or supported now	Stakeholders supported education and the development of resources for SMEs to improve allergen management and PAL even if PAL remains unregulated. Manufacturers are encouraged to alert consumers to a change in allergen formulation of a product. Some companies are already doing this through a bold statement or sticker on the front of packaging when changes occur. There was support for limiting the number of different statements that can be used for PAL. There was strong support for VITAL developing an identification or logo system so that consumers can identify products that use the VITAL risk assessment tool. Stakeholders indicated support for engaging the food service sector, identifying a need for education and programs to improve food allergen management, including certification programs and training of food safety auditors and environmental health officers in food allergen management. The development of a stakeholder consensus statement was supported to advocate for improvements in food allergen management in relation to food labeling, including PAL; to advocate for support for industry to adopt risk assessment processes; and to improve allergen management in food service.

ED, eliciting dose; FSANZ, Food Standards Australia New Zealand; PAL, precautionary allergen labeling; VITAL, Voluntary Incidental Trace Allergen Labelling.

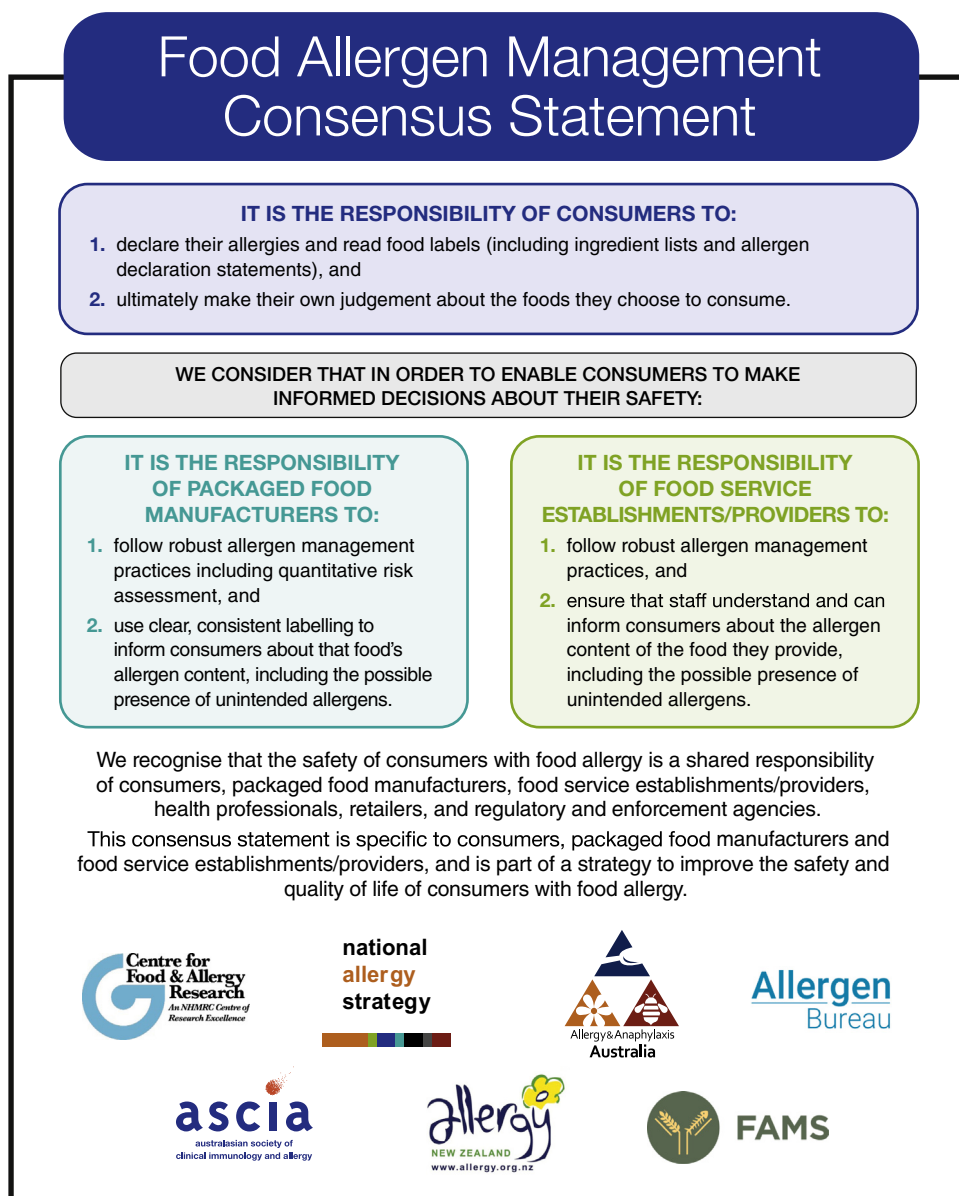


FIGURE 2. Food allergen management consensus statement.

sensitive 1% of the allergic population is predicted to react. Precautionary allergen labeling statements are assigned only if the product is likely to contain more than the reference dose.¹⁶ VITAL 3.0 recommends using a single standardized PAL statement: “May be present: allergen *x*, allergen *y*.” The consensus statement indicates support for programs such as VITAL, which assist manufacturers in applying meaningful allergen labeling to products to improve consumer confidence and safety. Consumer stakeholders at the roundtables accepted that a zero-risk approach was infeasible. There was a clear preference in the wider stakeholder group for adoption across the industry of the ED01 reference dose protecting 99% of food-allergic consumers. Future stakeholder engagement could address whether and how to communicate the risk associated with products when the allergen is present in quantities less than the ED01, and thus when it does not require a PAL statement. In addition, further work to

educate consumers and health professionals in relation to the meaning of PAL would be required if reference doses differ among countries and if more than one type of PAL statement is allowed. This was not specifically discussed in the stakeholder forums, but the consensus statement can be used to advocate for further discussion and the use of resources to address these issues.

A major current limitation of VITAL is that its use is voluntary. By 2011, approximately 19% of packaged foods were using VITAL; however, products that had the VITAL process applied were indistinguishable from those that had not undergone a risk assessment, because there was no VITAL mark on the product.⁴⁸ The “may be present” specified wording is not exclusive to VITAL. It may be used by any manufacturer, including when no risk assessment has occurred. Hence, this wording implies only that VITAL may have been used. Likewise, consumers are unable to discern whether VITAL has been

TABLE IV. Comparison of international food allergen regulations for manufactured foods and food service

Regulations in place for mandatory labelling of specific allergens added as ingredients																								
Country	Codex Alimentarius allergens								Region specific allergens under regulation												Precautionary allergen labeling regulated	Food service regulated		
	Tree Peanuts	nuts	Egg	Milk	Soy	Fish	Crustaceans	Cereals with gluten	Sulfites	Wheat	Sesame	Celery	Mustard	Lupin	Mollusks	Buckwheat	Shrimp	Crab	Beef	Chicken			Pork	Tomato
#United States	•	•	•	•	•	•	•		•	•	‡													Some states
Australia and New Zealand	•	•	•	•	•	•	•	•	•	•	•			•	•									•
Canada	•	•	•	•	•	•		•	•		•													
United Kingdom	•	•	•	•	•	•	•	•	•	•	•		•	•	•									•
European Union	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•							•
Switzerland*	•	•	•	•	•	•	•	•	•	•	•		•	•	•								•	
Iceland	•	•	•	•	•	•	•	•	•	•	•		•	•	•									
Ukraine	•	•	•	•	•	•	•	•	•	•	•		•	•	•									
Turkey	•	•	•	•	•	•	•	•	•	•	•		•	•	•									
North Macedonia	•	•	•	•	•	•	•	•	•	•	•		•	•	•			•						
Saudi Arabia, United Arab Emirates, Kuwait, Bahrain, Oman, Qatar, Yemen	•	•	•	•	•	•	•	•	•		•		•	•	•									Saudi Arabia
‡Japan			•	•						•			•				•	•	•					•
🇰🇷South Korea		•	•	•		•	•		•						•		•	•	•	•	•	•	•	•
Singapore	•	•	•	•	•	•	•	•	•								•							
Malaysia	•	•	•	•	•	•	•	•	•															
Thailand	•	•	•	•	•	•	•	•	•															
Hong Kong	•	•	•	•	•	•	•	•	•															
China	•	•	•	•	•	•	•	•	•															
India	•	•	•	•	•	•	•	•	•															
Philippines	•	•	•	•	•	•	•	•	•															
‡Argentina	•	•	•	•	•	•	•	•	•														•	
Brazil	•	•	•	•	•	•	•	•	•	•													•	
Bolivia	•	•	•	•	•	•	•	•	•															
Chile	•	•	•	•	•	•	•	•	•															
Colombia	•	•	•	•	•	•	•	•	•		•												•	
Costa Rica	•	•	•	•	•	•	•	•	•															
Cuba	•	•	•	•	•	•	•	•	•	•														
Mexico	•	•	•	•	•	•	•	•	•															
Nicaragua	•	•	•	•	•	•	•	•	•															
Venezuela	•	•	•	•	•	•	•	•	•														•	
§South Africa	•	•	•	•	•	•	•			•				•									•	•
Malawi	•	•	•	•	•	•	•	•	•															

PAL, precautionary allergen labeling.

*Switzerland allows PAL only if an allergen is present in concentrations above 1,000 ppm; otherwise no PAL is allowed.

†Japan does not allow PAL. If an allergen is present above 10 ppm, it must be declared an ingredient.

‡Argentina does not allow PAL unless authorization is sought.

§South Africa only allows the use of PAL if documented evidence of cross-contamination risk is supplied.

||Brazil requires the use of PAL if a manufacturer cannot guarantee the absence of the allergen.¹⁵

¶South Korea mandates the use of PAL if the process used for manufacturing an allergen-free food does not differ from the usual process.

#The United States has mandated declaration for sesame beginning in 2023.

applied to products for which no PAL is needed. In late 2019, the Allergen Bureau developed the VITAL certification scheme, which is available to manufacturers that have implemented the VITAL program. Although uptake has been slow to date, this certification program is a positive step forward, allowing use of the VITAL mark on packaging and enabling consumers to identify that the product has undergone the VITAL risk assessment process.¹⁶ From the roundtable and discussions, consumers were supportive of regulating PAL. Although regulators showed a lack of appetite for regulation, industry stakeholders supported implementing scientific risk assessment processes in relation to PAL across the food manufacturing industry. Ontiveros et al²⁴ found that PAL statements were as common in countries with PAL regulations as in those without them; however, the stakeholder discussions focused on the need for meaningful labeling by applying a scientific risk assessment process, rather than reducing PAL per se. Industry stakeholders raised a major question in relation to many small to medium enterprises that are inadequately skilled or lacked the resources to implement and conduct risk-based PAL processes. The consensus statement captures the need for further work and allocation of resources in this area.

Our consensus statement is timely, aligning with the recommendations of *Walking the Allergy Tightrope*,⁴⁹ the report of the Australian Parliamentary Inquiry into Allergies and Anaphylaxis by the Standing Committee on Health, Aged Care, and Sport report, released in May 2020. The report recommended leadership from FSANZ in relation to clear allergen labeling, including finalization of Plain English Allergen Labelling; prioritization by FSANZ to require manufacturers to alert consumers to changes in allergen content when products are reformulated; and collaboration between FSANZ and the Allergen Bureau to work with the food industry to promote and encourage the consistent use of the VITAL risk assessment process for PAL, including the promotion of VITAL certification to inform consumers that a product has been assessed using this process.⁴⁹ Recommendations included training to improve food allergen management in the food service sector.

CONCLUSIONS

Significant challenges persist for food-allergic consumers when choosing appropriate foods. There are persistent, ambiguous food labeling and poor allergen management practices in food service, resulting in accidental allergen exposure, including anaphylaxis hospitalizations and deaths. Major problems also remain for the food industry in managing allergens and standardizing risk assessment processes. The development of this Australian and New Zealand stakeholder consensus statement represents stakeholder unison and is intended to advocate for the allocation of resources and regulation to support improvements in allergen management in food service and food labeling. This includes promoting the adoption of scientific risk assessment processes in food manufacturing such as VITAL 3.0 for food allergen management and PAL, training for the food service sector, and encouraging consumers to be vigilant in always checking food labels and declaring food allergies when eating out. This collaborative work is timely and sets the foundation for

consumers, food manufacturers, food retailers, researchers, and health professionals working together with regulators and legislators to improve outcomes for food-allergic consumers.

Acknowledgments

The authors acknowledge the organizations (The Centre for Food and Allergy Research, National Allergy Strategy, Allergy and Anaphylaxis Australia, Allergen Bureau, Australasian Society of Clinical Immunology and Allergy, Allergy New Zealand and Food Allergen Management Symposium), and the organizing committees and participants of the 2014 Roundtable, 2019 Roundtable, and 2019 to 2020 virtual meetings.

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