

SPECIAL GUEST EDITOR SECTION: FOOD ALLERGENS MANAGEMENT

Food Allergen Management in Australia

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Food allergies are increasing globally, including numbers of allergens, the sensitization rate, and the prevalence rate. To protect food-allergic individuals in the community, food allergies need to be appropriately managed. This paper describes current Australian food allergen management practices. In Australia, the prevalence of food allergies, the anaphylaxis rate, and the fatal anaphylaxis rate are among the highest in the world. Interagency and stakeholder collaboration is facilitated and enhanced as Australia moves through past, current, and ongoing food allergen challenges. As a result, Australia has been a global leader in regulating the labeling of common allergens in packaged foods and their disclosure in foods not required to bear a label. Moreover, the food industry in Australia and New Zealand has developed a unique food allergen risk management tool, the Voluntary Incidental Trace Allergen Labelling program, which is managed by the

Allergen Bureau. This paper summarizes insights and information provided by the major stakeholders involved to protect food-allergic consumers from any allergic reaction. Stakeholders include government; consumer protection, regulation, and enforcement agencies; the food industry; and food allergen testing and food allergen/allergy research bodies in Australia. The ongoing goal of all stakeholders in food allergen management in Australia is to promote best practice food allergen management procedures and provide a wide choice of foods, while enabling allergic consumers to manage their food allergies and reduce the risk of an allergic reaction.

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Food allergies are characterized by an abnormal reaction of the human immune system to specific food proteins/food allergens. During the development of allergies, individuals will first become sensitized. Sensitization occurs when an allergen is encountered by the immune system and antibodies generated. Many different mechanisms and cells are involved in the allergy immune response, which is not yet fully understood. True food allergies are most commonly referred to as immunoglobulin E (IgE) antibody-mediated reactions. After the sensitization phase, every time the food allergen is in physical contact with or ingested by the allergic individual, an allergic reaction can occur. The symptoms of food allergies can

range from reactions that are mild (e.g., skin and/or gastrointestinal symptoms) to severe (i.e., respiratory and/or cardiovascular symptoms and anaphylaxis), possibly leading to death.

The prevalence of food allergies is increasing worldwide. Australia, particularly the city of Melbourne, has one of the world's highest prevalence rates, with more than 10% of 12 month old infants having a proven IgE antibody-mediated food allergy (1). In the HealthNuts study, five foods were tested, and the sensitization rate was highest for raw egg white (16.5%), followed by peanut (9.8%), cow's milk (5.6%), sesame (2.5%), and shellfish (0.9%; 1). The high rates of food allergies in this study ascribe to Australia the unfavorable status of being the food allergy capital of the world. The continuing increase in the prevalence of food allergies has led to an increase in associated hospital admittance in Australia (2). The anaphylaxis rate as well as the fatal anaphylaxis rate are highest in Australia and are still increasing when compared with the United Kingdom and United States (3). Overall, Australia has seen a 4-fold increase in presentations of anaphylaxis to hospitals in the last 14 years (8.9 out of 100 000 cases per year), and there has been an almost 10% increase in death from food allergies in recent years (2, 3).

The rise in the incidences of food allergy and preventable fatalities from food anaphylaxis has contributed to an increase in general allergen awareness in Australia. There is now greater collaboration and willingness by many individuals and organizations to work with and support each other as Australia addresses the ongoing challenges that face consumers, industry, regulators, enforcers, researchers, and analysts. The testing of food for the presence of food allergens in an analytical context is very challenging. Food allergens are currently primarily analyzed by antibody-based methods—predominantly ELISA and lateral-flow. However, antibody-based methods have well-known limitations. Moreover, the limited availability of food allergen reference materials and certified reference materials provides further analytical challenges. In Australia, consistent with other countries, alternative food allergen testing methods, e.g., PCR and MS (4), are continuously under investigation to expand the range of available techniques and provide orthogonal methods to assist with confirmation. To date, however, these methods are not yet able to provide a realistic alternative or adjunct to antibody-based methods.

Food allergen management in Australia involves several parties and key stakeholders and is recognized as an ongoing process. Figure 1 summarizes the main stakeholders involved in the different aspects of food allergen management. Recent government initiatives have significantly increased the regulatory monitoring and testing of domestic and imported foods for food allergens. Furthermore, the Department of Health (DoH) and State and Territory Departments of Health (State & Territory DoHs) are reporting allergic responses to a larger range of foods and allergenic proteins, which increases the management challenge for health professionals, regulators, and testing facilities. Although global analytical food allergen-testing protocols are fairly standard, the current food allergen management in place in Australia is unique in various aspects. The present paper will explain food allergen management practices in Australia, which incorporate the provision of information to all key stakeholders with the aim

of protecting food-allergic consumers from potential allergic incidents.

Protection of Consumers in Relation to Food Allergens

Food allergy is not a life-style choice, and it represents a concern for all consumers, health professionals, the food industry, and regulators. The main focus of food allergen management is to give individuals with food allergies accurate information on food labels, allowing them to make safe food choices. Table 1 provides useful links to information for consumers in Australia. The overall regulation in Australia is regarded as a lightly regulated rather than strictly regulated environment, the latter requiring extensive enforcement. Australia adopts a minimum-effect regulatory approach to minimize the cost burden on the Australian economy. This is a balance between consumers looking for more regulation and enforcement and the industry looking for the most efficient approach.

Australia has been a global leader in the regulation of labeling common allergenic ingredients in packaged foods and also their disclosure in foods not required to bear a label. The introduction of the requirement of mandatory labeling and the inclusion in the Australia New Zealand Food Standards Code (hereto "Food Standards Code") in 2002 enabled people with a food allergy and their carers to identify suitable food products more easily. Support that changes to labeling made a positive difference to allergic consumers was found in consumer studies (5–7). In a benchmark survey, 53% of people who had noticed changes chose the response "Yes, suitable products are now easier to identify" (6), and this was even higher in a follow-up survey number identifying the same in 69% of respondents (statistically significant; 7). Only 16% in the benchmark survey and 14% in the follow-up survey felt that the changes they had noticed made no difference to their ability to identify suitable products. In the benchmark survey, 28% indicated that the changes they had noted made it more difficult for them to choose appropriate foods. This was reduced to 13% in the follow-up survey (statistically significant; 8, 9). Henderson et al. (5) also found that allergy support group members had noticed changes to food labels and that these changes provided useful information to allergy sufferers. Among the support group members, 92% had noticed changes to allergen declarations on food labels, and 80% had noticed changes to the ingredient list. Forty-two percent of respondents agreed that the new Food Standards Code requirements made finding safe foods easier, and just fewer than 20% strongly agreed with this. A total of 25% of food-allergic individuals that responded disagreed or strongly disagreed that the changes made it easier (5–7).

The Food Standards Code requires the declaration of prescribed allergens when present in a food, unless an exemption is stipulated. However, the Food Standards Code does not regulate the use of voluntary precautionary allergen-labeling (PAL) statements. The use of PAL is intended to be applied only when the food allergen presence is unintentional, sporadic, or unavoidable. PAL is used by the food industry to inform consumers that food allergens may be present, e.g., when unintentional cross-contact may be suspected. Unfortunately, PAL statements are used inconsistently by food manufacturers, leading to reduced food choices for allergic consumers. The perception that PAL is used inconsistently and is, in some cases, unnecessary, has led to a decreasing trust in food allergen

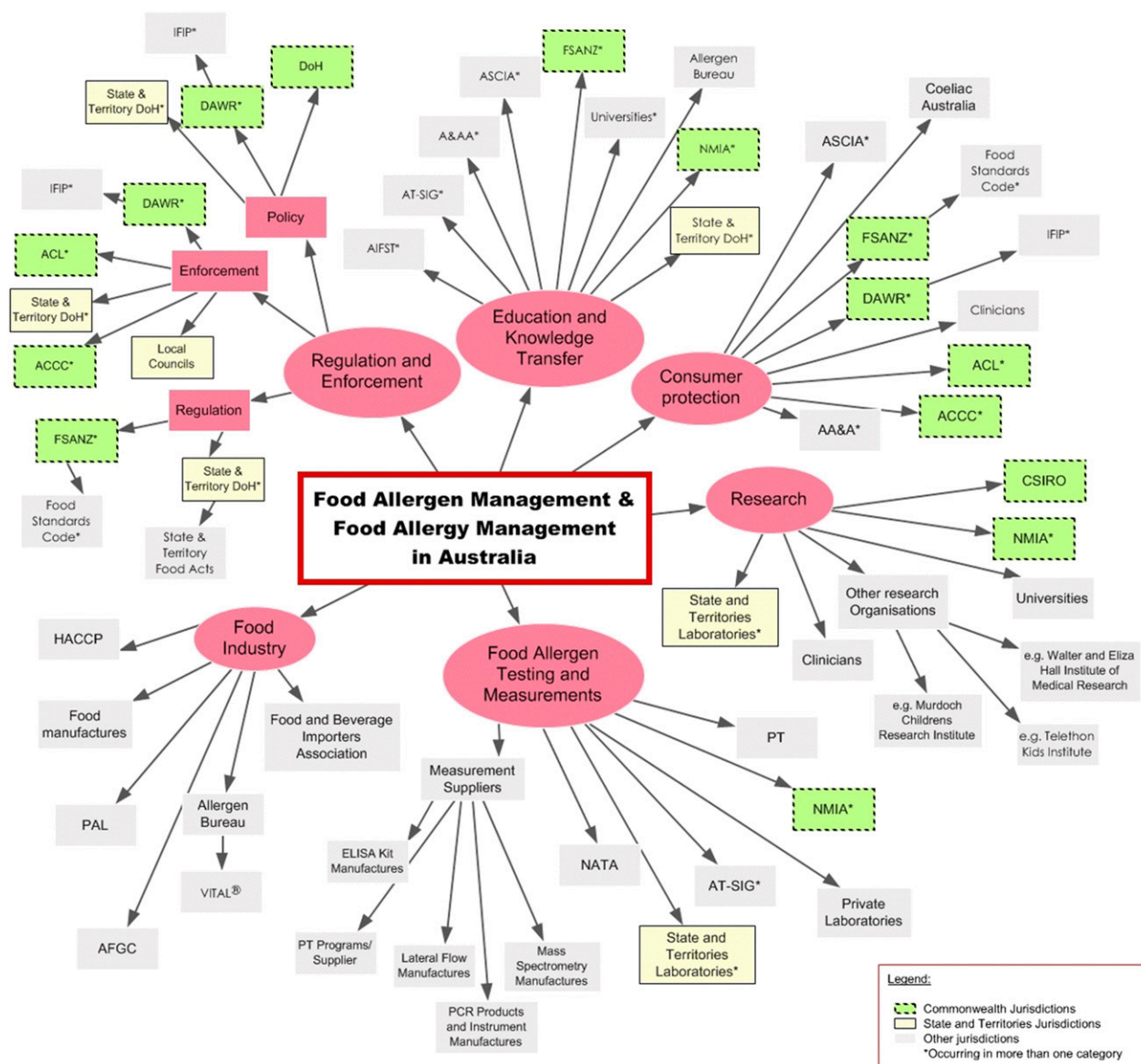


Figure 1. Major stakeholders and parties involved in the food allergen management in Australia. A&AA = Allergy & Anaphylaxis Australia; ACCC = Australian Competition & Consumer Commission; ACL = Australian Consumer Law; AFGC = Australian Food and Grocery Council; AIFST = Australian Institute of Food Science and Technology; ASCIA = Australasian Society of Clinical Immunology and Allergy; AT-SIG = Allergen Testing Special Interest Group; CSIRO = Commonwealth Scientific and Industrial Research Organisation; Council EHO = Council Environmental Health Officers; DAWR = Department of Agriculture and Water Resources; DoH = Department of Health; FSANZ = Food Standards Australia New Zealand; HACCP = Hazard Analysis and Critical Control Points; IFIP = Imported Food Inspection Program; NMIA = National Measurement Institute of Australia; NATA = National Association of Testing Authorities, Australia; PT = proficiency testing; State & Territory DoH = State and Territory Departments of Health; and VITAL = Voluntary Incidental Trace Allergen Labelling.

labeling (10). The majority of consumers have little understanding of the challenges of food manufacturing, and this often overshadows the goodwill and extreme efforts manufacturers undertake in an attempt to reduce risks to those with food allergies. Moreover, often consumers and small business are not aware of the difference between the requirement for mandatory declaration of food allergens (regulated by the Food Standards Code) and voluntary PAL. The language used in statements for food allergen labeling (including PAL) is often inconsistent. This inconsistency includes the terminology for specific allergen declarations. As an example, the terminology for mandatory egg allergen labeling, when present as an ingredient, can range across the

following terms: egg, egg white, egg powder, albumin, ovalbumin, lysozyme, etc. On the other hand, the language used for PAL ranges, including “may contain,” “may be present,” “processed in a facility that also processes,” and “made on equipment with.” The Australian Food and Grocery Council (AFGC) has published a guide (*Food Industry Guide to Allergen Management and Labeling*) that makes recommendations regarding consistent and clear terminology for food allergen labeling (11).

Despite the Allergen Bureau, the AFGC and many food manufacturers spend substantial resources and efforts in managing both food allergens and risk communication (including through PAL), and, notwithstanding, it appears that

Table 1. Information for allergic consumers in Australia

Organization	Web site link
FSANZ	http://www.foodstandards.gov.au/industry/foodrecalls/recalls/Pages/default.aspx http://www.foodstandards.gov.au/consumer/foodallergies/Pages/default.aspx
A&AA ^a	https://allergyfacts.org.au
ACCC ^b	https://www.accc.gov.au/consumers
AFGC	https://www.afgc.org.au/our-expertise/afgc-supported-forums/the-allergen-forum
Food Recall app	http://www.foodrecallaus.com.au
Allergen Bureau	http://allergenbureau.net
ASCIA ^c	https://www.allergy.org.au
Food allergen portal	http://www.foodstandards.gov.au/consumer/foodallergies/foodallergenportal/Pages/default.aspx

^a A&AA = Allergy & Anaphylaxis Australia.

^b ACCC = Australian Competition and Consumer Commission.

^c ASCIA = Australasian Society of Clinical Immunology and Allergy.

significant concerns remain. Allergic consumers, health professionals who work in this area, and some of the stakeholders believe that a regulation of PAL may be the best option for its consistent and meaningful use. One option for consideration is for food manufacturers to adopt the Voluntary Incidental Trace Allergen Labelling (VITAL[®]) process (12). Although this will be a step toward improving consumer choices and, therefore, quality of life, there is also a debate as to whether there should be a regulatory framework around the use of precautionary statements.

Despite the level of collaboration and interaction, which has resulted in considerable progress, Australia continues to struggle with the need for further standardization of communications, improved implementation of what is currently in place, and appropriate enforcement. Additionally, further education to consumers and the industry, especially industry with fewer resources, is required.

Food Allergen Regulation in Australia

Australia has comprehensive controls in place for food safety, including the management and labeling of food allergens. There are three different levels of government involved in protecting public health and safety, namely the Government of the Commonwealth of Australia, state and territory government, and local government.

Today, the Government of the Commonwealth of Australia works with state and territory agencies to develop, review, and implement national food regulation policies (model legislation). Food Standards Australia New Zealand (FSANZ) has regard to binational needs when it develops food standards for gazettal of the Food Standards Code. Likewise, the Department of Agriculture and Water Resources (DAWR) administers relevant legislation at the border. All imported food must meet Australian quarantine requirements (under the Quarantine Act), which is then subject to the requirements of the Imported Food Control Act of 1992. Labeling of imported food is assessed for compliance with the requirements under the Imported Food Inspection Scheme. However, not all imported foods are checked for their food allergen labeling.

FSANZ administers the Food Standards Code, and its functions are governed by the Food Standards Australia New Zealand Act of 1991. These functions include developing and reviewing food standards either by external application or by proposals raised internally by FSANZ. Food components of potential allergenicity, such as newly expressed proteins and enzyme processing aids, are assessed by a weight-of-evidence approach (13, 14). Established scientific criteria are applied to assess whether a food (whole food or ingredient) should be required to be declared as an allergen, including clinical significance and its use in the food supply (15–17). When the assessment consideration is completed, including public consultation, standards or variations are approved for gazettal, registered as legislative instruments, and given legal effect through Australian State and Territory food acts. State and territory governments develop and administer food legislation and adopt the provisions in the Food Standards Code within their own food acts to give them legal effect. State and territory food acts usually cover food-processing requirements through to retail sale requirements. Local governments, along with state and territory governments, are responsible for monitoring the regulatory compliance of food in their jurisdiction.

The Australian Consumer Law includes broad prohibition against misleading or deceptive conduct and a specific prohibition against representations that mislead the public, as to the nature, manufacturing process, and characteristics of all goods, including food. The Australian Competition and Consumer Commission is engaged in both compliance and enforcement efforts in relation to mandatory allergen labeling and “free from” food label claims (e.g., “gluten-free”).

Mandatory allergen declaration requirements for food are set out in labeling standards in the Food Standards Code (18). These requirements apply to food produced or imported for sale in Australia and New Zealand. As summarized in Table 2, the Food Standards Code requires the presence of peanuts, lupin (added in May 2017), tree nuts, milk, egg, sesame seeds, fish, crustacea, soybeans, cereals containing gluten (wheat, rye, barley, oats, and their hybrids), and added sulfites to be declared on food labels when present as an ingredient or as an ingredient of a compound ingredient, food additive, or processing aid, irrespective of the amount. Sulfites are not implicated in food allergies, but are associated with food intolerances and can cause allergy-like symptoms. There are a few exemptions to these requirements, including certain highly refined products, such as some oils and distillates, and glucose syrups derived from wheat starch with a gluten protein content not exceeding 20 mg/kg.

The Food Standards Code requires an ingredient list, but does not specify how an allergen declaration is to be made or its location on the label. If a generic name for an ingredient is used in the statement of ingredients, there is a requirement to declare the allergen source [e.g., “starch (wheat)”. General legibility requirements are that mandatory declarations must be legible and in English. If the food is exempt from bearing a label, such as meals from a café or restaurant, allergens must be declared on or near the food display or made available to the purchaser when requested. Key industry groups also provide voluntary guidance to assist food suppliers in meeting their regulatory obligations.

Celiac disease is caused by the consumption of gluten and is not an IgE-mediated food allergy. However, the presence of gluten is analyzed with the same analytical methods as food allergens. The Food Standards Code also sets conditions for voluntary claims about “gluten-free.” For example, gluten-free

Table 2. Mandatory food allergens in Australia listed alphabetically

Allergen to be labeled	Exemption
Cereals containing gluten, namely, wheat, rye, barley, oats, and spelt and their hybridized strains ^a	When these substances are present in beer and spirits Glucose syrups from wheat starch that have been subjected to a refining process that has removed the gluten protein content to the lowest level reasonably achievable and have a gluten protein content not exceeding 20 mg/kg Alcohol distilled from wheat
Crustacea	
Egg	
Fish	Isinglass derived from swim bladders and used as a clarifying agent in beer and wine
Lupin ^b	
Milk	Alcohol distilled from whey
Peanut	
Sesame seeds	
Soybeans	Soybean oil that has been degummed, neutralized, bleached, and deodorized Soybean derivatives that are a tocopherol or a phytosterol
Tree nuts	Coconut from the fruit of the palm, <i>Cocos nucifera</i>

^a The Food Standards Code requirement to declare cereals containing gluten captures both wheat for wheat allergy and gluten for celiac disease.

^b The Food Standards Code was changed on May 25, 2017, to require lupin to be declared when present in a food as an ingredient or component of ingredients, including food additives and processing aids. There is a 12 month transition period to allow food businesses time to comply with the mandatory declaration. By May 26, 2018, all foods must comply with the new requirement.

products must not contain detectable gluten, oats or oat products, or cereals containing gluten that have been malted or their products. Food products can only be labeled as “low gluten” if the products contain no more than 20 mg gluten/100 g food.

Food Allergen Enforcement in Australia

As described in the previous section, state, territory, and local governments are responsible for monitoring and enforcing the compliance of food in their jurisdiction, and DAWR is responsible for the inspection and sampling of imported food. However, until recent times, there has been little inspection of imported food for undeclared food allergen content. Australia consists of six states and two territories (jurisdictions). The DoH and State & Territory DoHs also lead the ongoing development of tools and resources to assist both council officers in their enforcement role as well as industry compliance. This includes fact sheets, online training, and workshops on food allergens.

All jurisdictions conduct periodic surveys for allergen-labeling compliance with the Food Standards Code. These surveys include routine inspections as well as responses to intelligence, indicating a potential issue (overseas or from another state/territory jurisdiction). The targeted sectors

include all parts involved in the food chain, such as food service, manufacturing, marketplaces, restaurants, and, more recently, importers. The surveys assist in ensuring compliance with food safety standards, including food allergen management and cross-contact. This will involve investigation of a food business, checking for documentation, handling ingredients, and testing foods at an accredited laboratory. The sale of mislabeled foods may result in a warning, a fine, or prosecution, depending on the level of risk to public health. Surveyed food samples are analyzed for their allergen content by accredited laboratories. The testing of food allergens is described later.

Response to Food Allergen Complaints and Incidents

There are a number of documented examples of serious reactions and fatalities from undeclared allergens in food in Australia. When complaints or incidents occur that relate to a food allergen, such as the sale of a packaged food that contains undeclared allergens or the provision of a meal at a restaurant containing peanuts and causes an allergic reaction, despite the customer disclosing their allergy and asking for a meal free of peanuts, the relevant local council typically investigates the allegation at the premises in question. Council Environmental Health Officers (Council EHO) are authorized to undertake a number of enforcement actions, such as seizing food and prosecuting food premises' owners. When a Council EHO investigation reveals the need for a food recall, which is typically the case when a packaged food contains undeclared food allergens, FSANZ has a role in coordinating and communicating the recall with the DoH, DAWR, and state/territory food regulators.

One reason for a food recall is when an individual has an allergic reaction to the food because an allergen is present in the food but is not declared (i.e., noncompliant), such as when a supplier/manufacturer has not advised of a possible allergen cross-contact incident during processing or confusing terminology is used to declare the presence of an allergen (e.g., “sodium caseinate” is listed as an ingredient, but the consumer is unaware it is derived from milk). Food recalls are undertaken by food businesses, are an immediate response to remove a potentially harmful product from the market, and are a means to inform individual consumers who may have already purchased the product. Recalls for undeclared allergens are the single most common reason for food recalls in Australia (19). Most food recalls are initiated voluntarily by the food manufacturer and are not due to enforcement actions. Other actions available to regulators include powers to seize food and fine or prosecute businesses for breach of allergen regulations.

Food Industry and Food Allergens

The presence of undeclared food allergens in ingredients and products is a critical food safety issue at all levels of the food supply chain, requiring stringent and robust food safety management strategies. Codes of practice and guidance documents to support the regulations were developed by the food industry in Australia to ensure that a consistent industry approach was adopted. The *Food Industry Guide to Allergen Management and Labelling* (11) sets out best practice guidance. The guide provides recommendations for the manufacture and

labeling of foods containing allergenic substances as defined in the Food Standards Code. The industry has further developed a risk management approach for allergen cross-contamination. This initiative, VITAL, seeks to standardize the risk assessment process for cross-contact allergens and PAL declarations so that the community of allergic consumers can better judge the risks posed. VITAL is based on scientific evidence (20, 21).

Industry Compliance

Although required by legislation and regulation, the food industry works very hard to ensure that food for sale is labeled correctly and is safe.

Imported food products represent more contentious issues. Australia requires imported product to comply with Australian legislation and regulations. This is a particular challenge for small imports, as the cost of compliance (i.e., the translation of ingredients and compliance) and the Imported Food Inspection Program (IFIP) import compliance may be substantial for small commercial importations. This is often coupled with the trend to use "may contain" in the PAL as a legal solution to the risk of undeclared allergens. The consequence of this approach is to reduce allergen consumer choice.

Larger manufacturers, importers, and established retailers in Australia are well aware of requirements for allergen labeling and the risks of undeclared allergens in food products. These companies typically have systems for supplier documentation and allergen declaration and in-house technical expertise and conduct their own testing of products and ingredients to assist with verification that foods do not contain any undeclared allergens.

A challenge for regulators and enforcers are small-to-medium-size businesses, particularly importers who may not bring in large consignments of food on a regular basis. It is important to raise the level of awareness around the requirements for allergen management and risks associated with incorrect declarations. Food products imported from non-English-speaking countries pose a particular risk due to language difficulties, compositional labeling in a foreign language, and for some, ignorance of Australian labeling regulations. Smaller retail businesses may not be aware of the consequences of cross-contamination or fully understand the risks associated with allergens. Training resources, education campaigns, and ongoing monitoring and survey work are being undertaken to address these issues at a national and local level.

Food Allergen Testing

Food samples collected by food processors, food importers, the DAWR, or Council EHOs need to be tested for the presence of food allergens. Food samples may include raw materials, work-in-progress samples, environmental surface swabs, and finished food products. A number of laboratories in Australia provide these services, including internal, commercial or contract, and government laboratories. Food-testing laboratories in Australia accredited by the National Association of Testing Authorities, Australia (NATA) to ISO/IEC 17025 standards (*see below*) for food allergen detection are preferred by regulatory and enforcement agencies and the food industry.

Overall, in Australia, the preferred method for food allergen analysis is antibody-based: either ELISA or lateral-flow devices (LFDs). The selection of the method is usually dependent on the food allergen, sample type, assay performance, and the capability of the laboratory. Antibody-based methods are commercially available for most food allergens and relatively easy to use, but have some shortcomings. The selection of either ELISA or LFD is mostly dependent on the sample matrix and a judgment as to whether the test is fit-for-purpose. Analyzing the surface in a food-manufacturing facility for cleaning efficiency is mainly conducted with LFDs, whereas for more complex food samples and in cases in which quantification is required, ELISA methods are preferred.

Laboratories in Australia are mostly seen as integral participants in food allergen management. The selected laboratory/analyst assists the client, within their capability, by choosing the most appropriate method for the particular food allergen and food matrix to be analyzed. When the laboratory/analyst obtains an unexpected test result, which may impact a consumer's health, the laboratory manager will (following local protocol and retesting) advise the client (government or private) of the likely noncompliance. Retesting may involve analysis of new test portions, use of a different manufacturer's test kit (if available), or testing by another independent laboratory when requested by the client.

Reliable food allergen analysis is a challenging science. The disadvantages of antibody-based methods as well as a lack of reference materials need to be considered. Analysts of government laboratories have identified one potential reference material initially as a suitable QC sample (D. Clarke, National Measurement Institute Australia, Port Melbourne, VIC Australia, unpublished data). This material is a commercial off-the-shelf custard powder for low-level gluten analysis. A suitable portion of material has been prepared and made available to Australian testing laboratories for use as an analytical QC sample, with assigned values derived from an interlaboratory collaborative study coordinated by the National Measurement Institute of Australia (NMIA, unpublished data, 2011/2012). Reference materials can help standardize results, thereby overcoming current difficulties with translating/comparing the reported units in food allergen detection. For antibody-based methods/kits, the units are most commonly reported in milligrams per kilogram or parts per million. However, different ELISA kit manufactures may report different analytes, e.g., some report peanut in milligrams per kilogram of food or peanut protein in milligrams per kilogram of food. In VITAL, reference doses are expressed as milligrams of allergen protein. However, the VITAL risk assessment refers to either allergenic protein in milligrams per kilogram of food or allergenic protein in milligrams per food serving. Other methods that can be used for food allergen detection report the food allergen content in DNA copies (PCR) or moles (MS).

In Australia, various ELISA and PCR assays are used for food allergen detection. Most manufacturers market their analytical assays worldwide. Universities and research bodies in Australia, as in the rest of the world, investigate alternative methods/approaches to food allergen detection, such as PCR and MS. For example, NMIA and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) use these techniques in a research and development context.

Australia's Unique Aspects on Food Allergen Testing

Usually the goal of analytical laboratories and research bodies is to develop methods that are more reliable and robust with less cross-reactivity and a lower LOD or LOQ. Better methods increase confidence that the analyte or food allergen is not present. However, the conditions set out in the Food Standards Code for voluntary “gluten-free” claims include the requirement that gluten is not detectable by analytical methods. Increased sensitivity of analytical methods may further limit the possibility of “gluten-free” claims as well as increase the likely detection of allergen cross-contamination during food processing, limiting food choices for sensitive consumers. To resolve these issues, there are ongoing discussions within certain stakeholder groups in Australia to adopt action values for food allergens and gluten. One proposal is to adopt VITAL risk assessment values, with proposed improvement of mandatory allergen labeling, PALs, and “gluten-free” claims.

Another valuable initiative in Australia was the formation of the Allergen Testing Special Interest Group (AT-SIG), which is coordinated by the NMIA in conjunction with the Allergen Bureau. Members of this group include representatives from all parties involved in food allergen management in Australia, including consumer representatives, regulatory bodies, enforcement agencies, the food industry, testing laboratories, kit manufacturers, NATA, the Allergen Bureau, researchers, clinicians, and universities. The purpose of AT-SIG is to discuss any current matters in regards to food allergen management and testing in a confidential, collaborative, and noncompetitive environment. For example, AT-SIG is part of the above-mentioned discussions on method sensitivity for allergen detection and facilitated the management of a milk in coconut incident (*see the Case Study: Milk in Coconut* section).

National Association of Testing Authorities, Australia

NATA (22) offers accreditation across a wide range of testing areas, including food and beverages, human pathology, and concrete and electrical testing to the ISO/IEC 17025 international standards for general requirements for the competence of testing and calibration laboratories. Medical laboratories (ISO 15189) have particular requirements for quality and competence. A conformity assessment (ISO/IEC 17020) is for requirements for the operation of various types of bodies performing inspection.

NATA offers accreditation for laboratories for the testing of samples for allergenic proteins in the field of life sciences. Accreditation is in accordance with ISO/IEC 17025 and supplementary requirements specific to allergens testing developed by NATA in consultation with stakeholders. Accreditation is driven by demand for testing. Tree nuts, milk, eggs, sesame seeds, fish, shellfish, soy, and wheat/gluten are the most common allergens for which accreditation has been sought. Accreditation may cover the testing of raw materials and finished products and their production environments.

NATA does not mandate methods or techniques to be used by accredited testing facilities. A facility is free to choose the methodology, technique, and matrixes for target allergens that will be accepted for testing. However, in compliance with

ISO/IEC 17025, NATA requires each facility to provide evidence of meeting a number of accreditation requirements:

- If a commercial kit is used, the kit must be validated and evidence of this validation by the manufacturer must be provided to NATA. Validation by a third-party provider, such as AOAC INTERNATIONAL, provides additional recognition of the kit.

- If a commercial kit is used, the user must demonstrate competency for use of the kit by undertaking verification studies. Verification is required to be performed on a range of sample types that the kit has been validated against. If sample types outside the scope of the kit validation are tested, the kit must be further validated in-house against these prior to use.

- Applicant and accredited facilities must participate in proficiency testing (PT) programs covering the testing they perform. NATA recognizes that not all allergen–matrix combinations are available from PT providers and do not require all combinations to have PT data available. In the absence of a third-party program, NATA may expect the laboratory to undertake sample exchange or retest samples to further demonstrate competency.

- Measurement uncertainty (MU) must be established for each quantitative determination. A number of approaches are available for the estimation of MU. A reasonable estimate may be obtained from the intralaboratory reproducibility of QC samples. This involves measurements made across different days with different analysts preferably using different kit lot numbers. The appropriateness of the reproducibility SD may be assessed by reference to the Horowitz equation, which takes into account the lower precision at reduced concentrations of analyte. Although progress is being made in the provision of internationally certified reference materials for allergen proteins, the current limited availability has hampered the measurement of bias. As these become available, an assessment of the accuracy of the results for different analytical kits in different matrixes will permit a more complete determination of MU. In the interim, the recovery of spiked samples may provide a reasonable estimate of method bias.

- Results below the LOQ cannot be reported as “nil” or “zero.” Facilities must establish a procedure for reporting results that fall between the LOD/lower limit of application and the LOQ. When relevant, the customer must be informed that a signal was detected, but that it could not be quantified. It is crucial that the units of reporting are clearly stated (i.e., refer to specific protein, total protein, or whole commodity) and that there is some understanding of the relationship between these different calibrator units. When appropriate, the laboratory report must include reference to the test kit used, as different manufacturers’ kits may focus on and report different allergen levels for the same sample.

Food Allergen Research in Australia

Historically, Australian scientists have been at the forefront of allergen research, including the development of monoclonal antibody sandwich enzyme immunoassays for gluten in raw, processed, and cooked foods published by CSIRO scientists Skerritt and Hill (23). Currently, various universities and other research organizations are investigating food allergens in Australia, including food allergens of interest to Australia. Overall, allergen prevalence and exposure can be quite different as compared with data originating from Northern

hemisphere studies. Highly prevalent food allergens in Australia are peanut, egg, milk, tree nuts (e.g., cashew nut and macadamia nut), and legumes (e.g., peanuts and, increasingly, lupin). Certain emerging food allergens, e.g., from tropical fruits, as well as Southern hemisphere fish and shellfish are of research interest.

One study unique to Australia is the HealthNuts study (24). The HealthNuts study involving 5300 children is the world's first comprehensive population-based study of food allergy with the objective measurement of true food allergy. Divided into four phases, the same children are monitored from 1 to 10 years of age. Currently, the study is concluding its second phase (25). A major finding to date includes that Australia has the highest prevalence of IgE-mediated food allergies in the world (1, 26). Further results will enable the investigators to better understand the natural history of allergic disorders, including food allergy, asthma, eczema, and hay fever, and the risk factors for developing these conditions in childhood. The study will have important implications for clinical guidelines and public health policy.

Fish and shellfish allergies are of particular interest to Australia, as the consumption is high in comparison with other countries. Moreover, the variety of seafood species consumed in Australia differs largely from European or U.S. consumption, but is very similar to the Asia-Pacific region. The prevalence of fish/shellfish allergy is not known in Australia. However, recent studies by the Westmead Children Hospital in Sydney demonstrated that seafood allergy was unexpectedly high, with 167 children from 2999 successive cases with allergy between 2006 and 2009 having confirmed clinical allergy. Research for fish and shellfish allergy is investigated by NMIA, the Molecular Allergy Research Laboratory (MARL) at James Cook University, and the Australian Research Council (ARC) Training Centre for Advanced Technologies in Food Manufacture, headquartered at the University of New South Wales. MARL has characterized over 20 novel allergens in different seafood species, which are now registered with the World Health Organization/International Union of Immunological Societies (*see ref. 27 as an example*). The current diagnostic tests for seafood allergy are very specific to Northern hemisphere species, and hence do not provide the necessary specificity to confirm the allergy status of a patient in Australia and the Asia-Pacific. For example, many patients identify barramundi and mackerel to be allergy-causing fish species; however, the current diagnostics do not cover these important Australian species (28–31). A particular guideline for confirming shellfish allergy has recently been developed by MARL and published in the *Molecular Allergology Handbook* of the European Academy of Allergy and Clinical Immunology (32).

Lupin is of special interest to Australia because Australia grows 75–80% of the global lupin crop, particularly blue (sweet) lupin, and, therefore, is the main world producer (33, 34). Lupins belong to the genus *Lupinus* and are part of the Leguminosae family. Other common foods belonging to the Leguminosae family are peanuts, soy, peas, beans, chickpea, and lentils. There are more than 450 different lupin species (35). However, three main species have agricultural significance as they are used for human consumption, namely *Lupinus angustifolius* (blue lupin or Australian sweet lupin), *L. albus* (white lupin), and *L. luteus* (yellow lupin). Some of the commercially available ELISA kits unfortunately favor the detection of white lupin. Research for lupin allergy is investigated by the NMIA, ARC Training Centre

for Advanced Technologies in Food Manufacture, CSIRO (36), and the Royal Prince Alfred Hospital Allergy Unit.

The last example of food allergens of particular interest in Australia is macadamia, belonging to the group of tree nuts. *Macadamia* is a genus of four species of trees indigenous to Australia. Nowadays, macadamia plantations have been expanded in China, South Africa, and Australia, with Australia being the second largest producer in the world. Currently, there is little known about the allergenic proteins in macadamia and their impacts. Research for macadamia allergens is under investigation by NMIA and the ARC Training Centre for Advanced Technologies in Food Manufacture. The latter has discovered seed storage protein 7S and 11S globulins to be putative allergens in macadamia nuts (J. Rost, University of New South Wales, Australian Research Council Training Centre for Advanced Technologies in Food Manufacture and School of Chemical Engineering, Sydney, NSW, Australia).

Case Study: Milk in Coconut

This case study is included in this paper to demonstrate how different parties involved in food allergen management in Australia are working together in the interest of the allergen community.

In Australia, there have been recent mass recalls of coconut-based products containing undeclared cow's milk. In 2013, a child with known cow's milk allergy died after consuming an imported coconut drink that contained undeclared cow's milk as an ingredient. Previously, there had been reports of casein detected in coconut milk. Milk is added (often as caseinate) as an emulsifier to some coconut products. Unintentional cross-contact in the manufacturing process is also a possible source of contamination of these products. The coconut product was not in compliance with Australian food-labeling regulations. Subsequently, many coconut products were tested as a result of this fatality, and another reported anaphylaxis about 18 months later resulted in over 25 coconut products being recalled due to the presence of undeclared cow's milk. In mid-December 2015, AT-SIG/NMIA in conjunction with the AFGC and the Allergen Bureau convened a meeting of regulators, allergen-testing laboratories, and State & Territory DoH representatives to harmonize and develop confidence in the analysis of these products with current available technologies. Other pressing issues included testing laboratory ISO/IEC 17025 accreditation and NATA accreditation. A number of projects have since been initiated as a result. Due to the sensitive legal and health implications of these products, the allergen-testing community in Australia implemented an increased testing regime, including three individual milk ELISA test kits covering casein, β -lactoglobulin, and total milk. This approach has also been adopted by the DAWR IFIP. In late 2015, a legal case relating to the fatality of the child regenerated interest in these coconut products. Subsequently, State & Territory DoHs conducted a survey of coconut products to assess labeling integrity and milk content. At the same time, the IFIP increased the frequency of their inspections and analysis program. At present, the outcomes of this case study are that no further fatalities have occurred, and there is an agreement to use three individual milk ELISA test kits for confirmation of the presence of cow's milk in any food product. The AFGC has convened a key stakeholder round table to identify key

initiatives, which can reduce the potential for an impact of such incidence of undeclared allergens in imported foods.

Conclusions and Future Directions

Food allergen management procedures, globally and in Australia, are designed to protect public health and specifically the safety of food-allergic individuals. Australia was among the first countries worldwide to introduce mandatory food allergen labeling. However, consumers are still confused by mandatory labeling and PAL. To harmonize food allergen labeling, key stakeholders in Australia are undergoing continuous discussions. Some stakeholders support a risk assessment approach. Food manufacturers presently can use VITAL for the labeling of possible allergen presence in food products. Current discussions include the possibility for the food industry to declare on the food label whether the food product has undergone a VITAL risk assessment. Depending on this risk assessment, the discussion includes harmonizing the PALs used. Moreover, in response to Allergen Bureau stakeholders, the Allergen Bureau investigated the establishment on an industry standard, and, as a result, has developed a VITAL Standard. [Note: The VITAL program has been drafted as the VITAL Standard, a supplementary certification program for food manufacturers that are already certified to Global Food Safety Initiative-recognized food safety management standards that include allergen management. It is anticipated that the VITAL Standard will be certified by certification bodies accredited to ISO/IEC 17065:2012 (or subsequent version) and audited by auditors trained in the VITAL Standard and registered with the Allergen Bureau, Ltd. Manufacturers that achieve VITAL certification will be able to use the VITAL mark on products within their scope of certification. The Allergen Bureau will trial the draft VITAL Standard with industry and certification bodies in 2017–2018. Accreditation of the VITAL Standard is slated to be sought in 2018.] Another important aspect of global food allergen management is the improvement of food allergen testing. Future challenges for food allergen testing include (1) the development and availability of reference materials for accurate determinations and traceability; (2) the development of confirmatory methods; (3) the development of tests for new and emerging allergens in a variety of foods; (4) the harmonization or standardization of results, including the translation/interpretation of units obtained by various food allergen analytical methods; and (5) the harmonization and application of measurement and sampling uncertainty to test results and their impact on consumer risk and labeling regulations. To address and resolve current and future challenges in food allergen management, further harmonization and communication needs to occur in Australia, as well as worldwide.

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