AUSTRALIAN FOOD & GROCERY COUNCIL

Allergen Bureau

2023

Food Industry Guide to Allergen Management and Labelling

For Australia and New Zealand

PEAL updated

A partnership document of the
Australian Food and Grocery Council and the **Allergen Bureau**

Allergen Bureau | Informing the food industry

The Allergen Bureau is the peak industry body representing food industry allergen management. The overall aim of the Allergen Bureau is to lead the global food industry in best practice allergen management, sharing information that builds trust and transparency that supports allergen sensitive consumers to make informed choices. The Allergen Bureau has developed and provides key best practice allergen management and labelling guidance for the food industry, particularly the globally recognised VITAL® (Voluntary Incidental Trace Allergen Labelling) Program - a standardised allergen risk assessment process for food industry.

www.allergenbureau.net
Tel: +61 437 918 959

AUSTRALIAN FOOD & GROCERY COUNCIL

The AFGC is the peak industry body for Australian food and grocery suppliers. Founded in 1995, our vision is to create a thriving and trusted food and grocery supply industry delivering jobs, economic growth and helping people live well.

www.afgc.org.au
Tel: +61 2 6273 1466

Disclaimer

Material included in this publication is made available on the understanding that the Australian Food and Grocery Council (AFGC) and the Allergen Bureau are not providing professional advice, that the Food Industry Guide to Allergen Management and Labelling is intended as a guidance document which may assist in a total approach to allergen management, allergen communication and labelling, and that using the Food Industry Guide to Allergen Management and Labelling does not guarantee that a consumer will not suffer an allergic response.

If you intend to use information provided in this publication, you must exercise your own skill, care and judgement, evaluate the accuracy, completeness and relevance of any information or recommendation for your purposes, and obtain your own professional advice.

The AFGC and the Allergen Bureau provide no warranty and do not guarantee the accuracy or completeness of the material contained in this publication, or in any recommendation obtained from it, including regarding compliance with food labelling laws and regulations or the management of the risk of product liability and personal injury.

The AFGC and the Allergen Bureau disclaim all liability to any person in respect of any loss or liability suffered in connection with the reliance, whether wholly or partly, on any information contained in this publication.

Management of the Guide

The AFGC maintains this document with the support and input of the AFGC Allergen Forum and Allergen Bureau. The AFGC will update this document from time to time so it is recommended that companies check the AFGC (www.afgc.org.au) or the Allergen Bureau

(www.allergenbureau.net) websites regularly for the most recent version.

Terms of Use

Refer to

https://www.afgc.org.au/terms-and-conditions
and to

https://allergenbureau.net/allergen-bureau-website-terms-of-use

Legislative Compliance

This document is intended as a guide only, the relevant legal requirements may be found in the following Acts and other laws applicable in each jurisdiction:

For Australia
the Australia New Zealand Food Standards Code;
the Australian Competition and Consumer Act 2010 (Cth)

For New Zealand
the Australia New Zealand Food Standards Code;
Consumer Guarantees Act 1993 (NZ);
Fair Trading Act 1986 (NZ)

PEAL updated

Contents

1. INTRODUCTION

Managing the risks associated with the presence of food allergens in ingredients and products is a major food safety challenge faced by food producers and suppliers at all levels of the supply chain. Incorrect or unclear allergen information can be a life or death issue for individuals living with food allergy.

All food business operators (FBOs) (including processors, manufacturers, marketers, traders and importers) have a responsibility to manage both the intentional and unintentional presence of allergens in food products, and require stringent and robust food safety management practices, so they can offer products with a known allergen status.

FBOs have a responsibility to fully understand the allergen status of their food products including determining whether allergens are or are not present. If present, it involves determining what those allergens are, if the allergen is an ingredient, food additive or processing aid, or is present due to cross contact.

Allergen management and labelling practices are to be kept up to date and reviewed periodically to ensure compliance.

Clear and accurate information about the allergen status of each product should be communicated through labelling, specifications and electronic media to enable consumers with a food allergy to make safe and informed food choices.

These requirements are the same whether the product or ingredients are manufactured or sourced in Australia and New Zealand or are imported.

About the Food Industry Guide to Allergen Management and Labelling (Guide)

This document describes industry best practice for the management of allergens, allergen labelling, and allergen communication. In this Guide, 'allergens' are the foods (or their derivatives) that are listed in the Australia New Zealand Food Standards Code (the Code), Column 1 of the table to section S9-3 of Schedule 9 *Mandatory advisory statements and declarations*.

This Guide provides:

- an overview of food allergy and food intolerance
- a description of the requirements outlined in the Code regarding food allergens that require labelling in Australia and New Zealand
- information about international food allergen regulations
- guidance on the management of food allergens in the manufacture and supply of food ingredients and finished products
- information on analysis for allergens
- best practice guidance for allergen declaration and communication, including the application of the VITAL® (Voluntary Incidental Trace Allergen Labelling) Program for risk assessment and labelling of cross contact allergens. The VITAL Program is a resource of the Allergen Bureau
- guidance on the management and communication of a change in allergen status of a food product
- guidance on the management of reports in relation to alleged allergic reactions to a food the company has supplied
- information about food recalls.

Although some labelling considerations for allergen free claims are included in this Guide, it is not the intention of this document to describe the risk management requirements that deliver food products which make such claims.

This Guide was developed through a collaboration of the Australian Food and Grocery Council (AFGC) and the Allergen Bureau (which are not-for-profit organisations). The information was drawn from collective industry expert knowledge and is supported by additional resources and information freely available on both the AFGC (www.afgc.org.au) and Allergen Bureau (www.allergenbureau.net) websites.

This Guide is relevant to all sectors of the food industry involved in the supply, handling, production, distribution and sale of foods.

Scope

This Guide is relevant to all areas of the food industry involved in the supply, handling, production, distribution and sale of foods including but not limited to:

- food ingredient manufacturers, importers, and suppliers – both local and imported
- FBOs of packaged food for bulk sale, including business to business
- FBOs of packaged retail ready foods
- importers of packaged foods.

1.1 FOOD ALLERGY & ANAPHYLAXIS

An allergy is an overreaction by the body's immune system to a normally harmless substance. Foods or substances that can trigger an allergic reaction are called allergens. In most cases, food allergens are proteins and a food may comprise one or more allergenic proteins. For example, egg allergenic proteins have been found in both egg white and yolk, and egg white is known to contain several different allergenic proteins. People who are allergic to egg white may not be allergic to yolk. Similarly, cow's milk contains allergenic proteins in the whey fraction and different allergenic proteins in the casein fraction[1]. Individuals may be allergic to only one milk protein or more.

Allergic reactions to foods are characterised by the rapid release of powerful cellular chemicals, such as histamine, released by mast cells once the body recognises the allergen has been eaten. This allergic reaction most often occurs within minutes, though can take place up to two hours after ingestion.

Food allergies are usually mediated by immunoglobulin E (IgE) antibodies and can be confirmed by a skin-prick test or blood test. Diagnosis of an allergy should be performed by a specialist allergy medical practitioner. A medical practitioner needs results from clinical tests indicating the presence of IgE antibodies to a particular allergen, as well as the patient's medical history involving an allergic response to the food, to make a diagnosis of a food allergy to a particular substance.

An allergic reaction may occur after ingestion of food containing an allergen, even in small amounts. This can result in a mild/moderate allergic reaction or anaphylaxis, a potentially life-threatening allergic reaction. A mild or moderate allergic reaction can quickly become life threatening.

Food allergy symptoms vary in nature and severity between individuals. Signs of a mild to moderate allergic reaction can include:

- swelling of the lips, face, eyes
- hives or welts
- tingling mouth
- abdominal pain
- vomiting.

If an individual is allergic to a food, avoidance of the allergen is the only way to manage the condition.

Worldwide, there is limited data that describe the prevalence of food allergy. One 2011 Australian study reports that over 10% of 12-month-old infants have food allergy (of which raw egg is 8.9%, peanut is 3.0%, sesame is 0.8% and cow's milk is estimated at 2.7%)[2].

A 2015 study of hospital admissions in Australia, shows that the prevalence of food allergy is increasing in children and teenagers between 5 and 14 years of age and that overall there appears to be an increase in food allergy prevalence in Australia, the UK and the United States over the past ten or more years. Although food allergy is predominantly found in Westernised countries, it is expected that the prevalence will continue to increase globally[3].

The Australasian Society of Clinical Immunology and Allergy (ASCIA) estimates that food allergy occurs in around 1 in 20 children and in about 2 in 100 adults.

Allergy to cow's milk is more common in infants. In Australia and New Zealand, approximately 2% of infants have milk allergy. About 80% of children with cow's milk allergy can grow out of the allergy at around the age of 3-5 years.

Allergy to peanut and tree nut usually begins in infants and young children, although adults can also develop the allergy. In Australia, peanut allergy has been shown to occur in 3% of infants. About 20% of people with peanut allergy grow out of it, or the symptoms lessen, for others the allergy can become worse with time.

Seafood allergy is not common in young children but can occur in teenagers and adults in about 1% of the population. It has been reported that approximately 20% will grow out of the allergy over time.

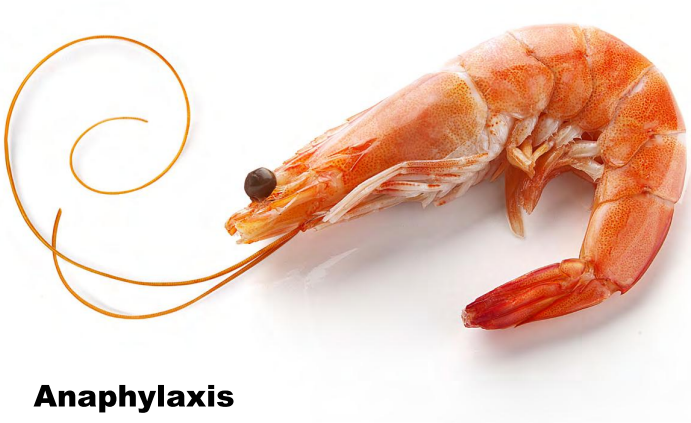
Limited information is available about the prevalence of lupin food allergy with 8 allergic reactions reported in South Australia from 2004-2009.

ASCIA www.allergy.org.au

More than 170 different foods and ingredients have been identified as potential allergens[4]. However, globally, most allergic reactions are attributable to a small number of foods which include cereals containing gluten, crustacea, eggs, fish, peanuts, soybeans, milk, tree nuts[5] and, in Australia and New Zealand, sesame and lupin. Allergens of importance can vary by global region, for example, buckwheat is regarded as an allergen in Japan and Korea.

The Code requires the mandatory allergen declaration of thirteen (13) foods which are listed in Column 1 of the table to section S9-3. Although it is recognised that there are many other foods that may cause an allergic reaction, these do not require mandatory declaration for foods sold in Australia and New Zealand.

It is generally acknowledged that it is unrealistic for food manufacturers to manage every potential allergen. In this Guide, the management of allergens is focussed on those listed in the Code. However, the principles can be applied to any other food allergen (such as allergens of importance in other global regions).



Anaphylaxis

A severe allergic reaction (anaphylaxis) to food is defined by the involvement of the respiratory system and/or the cardiovascular (heart and circulation) system. The incidence of anaphylactic reactions to food in allergic individuals is increasing. The condition can be fatal if not treated with adrenaline within minutes. Signs of anaphylaxis, as stated on the ASCIA[6] Action Plan, can include:

- difficult/noisy breathing
- swelling of the tongue
- swelling/tightness in the throat
- wheeze or persistent cough
- difficulty talking and/or hoarse voice
- persistent dizziness or collapse
- pale and floppy (young children).

Individuals who have been diagnosed with severe allergy are prescribed an adrenaline autoinjector (e.g. EpiPen® or other brand) for immediate administration while an ambulance is called.

A person that has experienced anaphylaxis previously is more likely to have another anaphylactic reaction when exposed to the same allergen. Similarly, individuals with a mild/moderate reaction may progress to anaphylaxis with a subsequent exposure.

Death from Anaphylactic Reaction

The consequence of an allergic reaction to a food can be tragic – in late 2013, a young boy died after becoming ill after dinner one evening. The child had a known allergy to cow's milk and consumed a coconut drink which was subsequently found to be incorrectly labelled, as the product contained an undeclared cow's milk ingredient.

This tragic death was investigated by the Coroner's Court of Victoria and the findings handed down in June 2016. The coroner found that:

"On the evidence available to me, I find that [name], who was highly allergic to dairy milk, died after ingesting 'Brand X Natural Coconut Drink', a product that has been imported from Taiwan and mislabelled, so as not to declare that it contained dairy."[7]

There have since been multiple recalls of imported coconut drinks and coconut milk powders that contained undeclared milk in Australia, New Zealand, and throughout the world. In response to this, in 2018, new laws were created in Australia where Victorian hospitals are required to notify the Department of Health and Human Services of all anaphylaxis presentations.

Some coronial investigation reports that are related to food allergy are available on the Allergy & Anaphylaxis Australia website.

1.2 COELIAC DISEASE

Coeliac disease is a genetic immune disease caused by gluten, a protein in wheat, rye, barley, oats and their various subspecies and hybridised varieties. Coeliac Australia report that coeliac disease affects approximately 1 in 70 Australians, however, around 80% of this number remain undiagnosed[8]. Coeliac disease can develop at any age, from infancy (when gluten is first introduced to the diet) to senior years.

When people with coeliac disease eat gluten, an inappropriate immune reaction causes inflammation and damage to the small bowel (intestine) and other areas of the body. Accidental ingestion is not immediately life threatening (as can be the case in those with food allergy). Symptomatic reactions can vary considerably, and may include diarrhoea, nausea, vomiting, abdominal pain, cramping, headache, and fatigue. Those with the condition are also at risk of complications. There is no correlation between symptoms and bowel damage so even if asymptomatic (patient displays no obvious symptoms), inflammation and damage can still occur if gluten is ingested.

People with coeliac disease, irrespective of the severity of their symptoms, need to adhere strictly to a gluten free diet.

1.3 FOOD INTOLERANCE

A food intolerance is an adverse reaction to a food but, unlike food allergy, it does not involve the immune system. Food intolerances can be dose-related and include reactions to non-protein substances in foods such as some carbohydrates, chemicals, food additives, toxins and irritants. Diagnosis of food intolerance can be difficult and is usually managed by the use of an elimination diet. Signs and symptoms of a food intolerance can occur many hours after ingestion and not within the first two hours like a food allergy reaction. Symptoms can include:

- hives, eczema and other itchy skin rashes
- mouth ulcers, reflux, bloating, stomach aches, constipation and/or diarrhoea
- incontinence and/or
- migraines or headaches.

Some people can have an intolerance towards sulphites which can cause allergy-like reactions, most commonly asthma symptoms in those with underlying asthma[9]. A small number of people with asthma can experience wheezing, chest tightness and coughing[10] if foods containing sulphites are consumed.

Wheat allergy and gluten intolerance are not the same. Although wheat contains gluten, individuals can be allergic to wheat but not allergic to other cereals that contain gluten.

2. REGULATORY REQUIREMENTS

Australia and New Zealand share a multi-jurisdictional food regulatory system that is based upon harmonised food standards which assist industry by reducing compliance costs and trade barriers. Food Standards Australia New Zealand (FSANZ) develop and administer the Code. Various food regulation authorities within Australia and New Zealand are responsible for its interpretation and enforcement. A FBO seeking information about complying with the Code should contact their local enforcement agency for advice. A list of food enforcement contacts is available on the FSANZ website.

2.1 FOOD ACTS & PRODUCT LIABILITY LAW

Australia

Within Australia there are several Commonwealth and state and territory Acts that set out the legislative requirements for food and specify the agency responsible for the enforcement of the Act. The Acts are listed on the FSANZ website. Under Australian state and territory Food Acts, it is an offence to knowingly or under circumstances where it should have been known, handle or sell food that is 'unsafe', 'misdescribed' or 'unsuitable' or which otherwise does not comply with the law, regulations or the Code.

Under civil product liability law, a person who is responsible for selling food may be liable for any death, injury, illness, loss or damage caused by a 'defect' in that food. A 'defect' exists where, for instance, the product or its label does not deliver the "degree of safety that persons generally are entitled to expect". Every merchant in the supply chain, from manufacturer or importer, through to the seller, is potentially liable under the product liability laws.

New Zealand

Under the New Zealand Food Act 2014 (Food Act), persons who trade in food must ensure the food is 'safe' and 'suitable' and compliant with the Code. In New Zealand, the Ministry for Primary Industries (MPI) is responsible for enforcing the Code and Food Act. Local councils also assist with enforcing the Food Act through Food Safety Officers (Officers)[11].

Officers have a wide range of enforcement tools, including:

- issuing infringement notices (instant fines) for minor offences
- issuing improvement notices and notices of direction (e.g. require businesses to improve food safety)
- interrupting operations if necessary, to assist in their investigations
- issuing compliance orders that can be issued by a District Court to compel business operators to take certain actions.

If a food label does not comply with the mandatory declaration requirements for allergens, the Chief Executive of MPI may also issue directions for a mandatory product recall.

More serious offences could warrant MPI initiating a prosecution which may result in criminal penalties (depending on the offence).

If an allergic individual is harmed by consuming a food that is falsely labelled as not containing an allergen, other applicable legislation can potentially come into play such as the Consumer Guarantees Act 1993, the Fair Trading Act 1986, the Accident Compensation Act 2001 and the Contract and Commercial Law Act 2017 and damages claims may potentially be brought against the manufacturer and/or importer.

2.2 AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

All food sold in Australia and New Zealand, including imported foods, must comply with the allergen labelling regulations set out in the Code. The Code is divided into four Chapters and a list of Schedules. Chapter 1 provides most of the information about general food labelling requirements including the mandatory declaration of allergens. Refer to section 4.1 of this guide for information about the labelling requirements for allergens.

Packaged and Non-packaged Foods

A food for sale in a package must bear an attached label which declares the allergens present in that food. This includes packaged food sold to caterers. Refer to Table 3 Allergen declaration requirements for various foods being offered for sale for information about those labelling requirements.

The Code also sets out requirements for foods that are not in a package and therefore are not required to bear a label. For any food that is not required to bear a label, information that specifies the allergens present in the food must still be provided either upon request, displayed in connection with the food or accompanying the food. Refer to Standard 1.2.1 *Requirements to have labels or otherwise provide information* for detailed information.

Table 1 Examples of foods not required to bear a label

Foods for sale that are not required to bear a label	Example
made and packaged on the premises from which it is sold	sandwiches made in a café
packaged in the presence of the purchaser	bread from a bakery
whole or cut fresh fruit and vegetables (other than seed sprouts or similar products) in a package that does not obscure the nature or quality of the food	apples in clear plastic wrapping
delivered packaged, and ready for consumption, at the express order of the purchaser (other than when the food is sold from a vending machine)	take-away pizza
sold at a fund-raising event	sausages at a sausage sizzle
displayed in an assisted service display cabinet	cheese from a delicatessen
food that is not in a package, including non-packaged foods sold to caterers	a restaurant meal

For food sold in a hamper, each package must declare the allergens and each item of food not in a package must be accompanied by a declaration of the allergens present in that food.

Legibility Requirements

Allergen declarations must meet the legibility requirements as described in section 1.2.1—24 *General legibility requirements* of the Code, which sets out how the information should be presented. The description is as follows:

1. *If this Code requires a word, statement, expression or design to be contained, written or set out on a label—any words must be in English and any word, statement, expression or design must, wherever occurring:*
   a) be legible; and
   b) be prominent so as to contrast distinctly with the background of the label.

2. *If a language other than English is also used on a label, the information in that language must not negate or contradict the information in English.*

2.3 INTERNATIONAL FOOD ALLERGEN REGULATION

The labelling guidance provided in this document is focused on Australia and New Zealand allergen declaration requirements as set out in the Code. It is important for businesses to be aware that allergen labelling differs across countries and regions. This is a result of different prevalence, sensitivities and exposure to allergenic foods and ingredients in those areas. In addition to the allergens required to be declared in Australia and New Zealand, there are other allergens of concern that should be considered for products which are exported from or imported into Australia and/or New Zealand.

A summary of the international allergens of concern compiled by the Food Allergy Research and Resource Program (FARRP)[12] is available on their website. This is a useful tool for identifying differences amongst geographical locations. However, when importing foods and ingredients into Australia and New Zealand a more detailed regulatory understanding is then needed. An example is coconut (from the palm *Cocos nucifera*) which may be included as a tree nut in some jurisdictions including the USA and not in others.

FBOs importing foods or ingredients into Australia and New Zealand may not be aware of the specific allergen declaration requirements in this market. This can result in raw material specifications or product labels failing to declare the presence of certain allergens. For example, the US do not require the declaration of any highly refined oil derived from their prescribed list of allergens (which are milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans[13]). Therefore, a FBO importing foods or ingredients from the US must carefully confirm the allergen status of the material as the US supplier may not have considered that many highly refined oils must be declared in Australia and New Zealand.

The European Union has one of the most comprehensive lists of allergens that require mandatory declaration, which includes 14 foods (including mustard and celery) that cause allergies or intolerances in Annex II of Regulation No1169/2011. Most foods listed as allergens in the regulations of other countries or markets are also present in this list.

Another example of international differences in allergen declaration requirements is CODEX (STAN 1-1985) which requires the declaration of eight allergens and sulphites but currently does not require the declaration of sesame seeds or lupin.

Imported Foods

Foods that are imported into Australia and or New Zealand must comply with the Code, as set out in provisions in the Australian Commonwealth Imported Food Control Act 1992 and the NZ Food Act that relate to importation of food.

In addition to the Australian product liability laws mentioned previously, importers should take specific note of clause 8(1) of the *Imported Food Control Act 1992* which makes it a criminal offence to import food that the importer knows "*poses a risk to human health*". This term is explained further in section 3(2) but importantly, and unlike the Food Acts, it does NOT exclude allergies or sensitivities. It may well be a criminal offence, then, to (knowingly or recklessly) import a food containing an allergen unless that allergen is clearly identified and communicated to customers and consumers.

In New Zealand, the same requirements around allergens apply for imported food as they do with food made and or sold in New Zealand.

3. ALLERGEN MANAGEMENT

This section of the Guide describes the risk management approach required for the control of food allergens in manufacturing. Allergen management in a food company should be considered as a fundamental element of existing food safety management plans and processes including Good Manufacturing Practice (GMP). The recommended approach to allergen risk management is by following the seven principles and steps outlined in the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, published by the Codex Alimentarius Commission/RCP-1 (1969), Rev.4 (2003).

The HACCP Plan should include allergens as an independent category of food safety hazard. This involves evaluating the hazards associated with the whole 'lifecycle' of the product, starting with raw materials and assessing every step of the process through to labelling and packaging of the final food for sale. Manufacturers providing partially prepared foods or ingredients from business to business and not to the end consumer must also maintain a thorough allergen management program. The critical points where allergens can be introduced as ingredients or into foods during processing should be identified, and systems established to prevent the unintentional cross contact of allergens to other products.

Allergen risk management starts with investigating the manufacturing process for allergen risks and the information obtained can be used to develop an Allergen Management Program (AMP). The implementation and use of an effective AMP in conjunction with an allergen risk review approach contributes to food businesses meeting food safety, quality and legal requirements.

It is recognised that small and medium size businesses may not have the same level of technical support and resources available as larger businesses. Irrespective of this, all companies are obligated to manage their allergens appropriately, and it is up to the business to determine how this is done. Allergen management and risk review best practice approaches can be adapted to suit the size and level of complexity for each company.

3.1 ALLERGEN MANAGEMENT

Allergen management embodies the procedures, policies and practices contributing to the control of allergens within a food business. It should be considered as a component of existing food safety management plans and processes, such as GMP controls. An effective allergen management system covers all aspects of the food product supply chain from sourcing raw materials through manufacturing and packaging through to the finished product sold to another business or to consumers.

Implementing an effective AMP involves applying a documented systematic approach to identifying and controlling allergens. The program formally identifies allergen risks, allergen challenges and includes documented procedures that manage them. As allergen risks may be unique to each food manufacturing facility, a food company should design a plan that meets its specific needs.

Effective allergen management is dependent on the interaction of several areas and activities associated with food production process. Table 2 summarises the key principles and practices for best practice allergen management for facilities manufacturing, handling and packaging food products.

Table 2 Key principles and practices for best practice allergen management for facilities manufacturing, handling and packaging food products

Area	Key principles and practices for best practice allergen management
Management Commitment	A documented Allergen Management Program is in place which is authorised by senior management and communicated to all staff. Authorised personnel are responsible for development and implementation of allergen management plan.
Management Review	The Allergen Management Program should be reviewed at least annually or when changes are made.
Regulation	Procedures and monitoring practices are in place to ensure compliance with Australian and New Zealand regulatory requirements.
Food Safety Plans	Certification by a recognised Food Safety Management Scheme and a documented and implemented HACCP based Allergen Management Program that is underpinned by Good Manufacturing Practices.
People Management	Documented procedures for the management and control of personnel that includes personal protective equipment (PPE), hygiene, meals, movement, facilities, staff changes and visitors should be in place.
Supplier / Vendor Assurance	A documented supplier approval program is in place.
Premises & Factory Design	The manufacturing plant, equipment and line layout is designed to facilitate the management of allergens and minimise the risk of allergen cross contact.
Traceability	Systems in place trace the flow of allergens in relation to raw materials, processing (including rework), cleaning, labelling and distribution of finished products.
Storage	Documented procedures in place to control the receipt and storage of raw materials and packaging.
Production Process	Standard operating procedures for the management and control of food allergens during the manufacturing process are documented and in place.
Labelling	Procedures to control the changeover of labels are in place. Internal audits are conducted to verify that the formulation matches the ingredients specified on the label. Procedures for ensuring allergens are labelled as per the Code's requirements are in place.
Cleaning	Procedures to manage raw material spills, and for cleaning the facility, equipment, and tools to prevent allergen cross contact are in place. Cleaning validation and verification is monitored and reviewed.
Product Development	Procedures are in place for formulation changes, control of factory trials, and introduction of new products to manage changes to allergens.
Waste	Procedures in place to control waste product and packaging that contain allergens.
Monitoring & Review	Internal audits are conducted to confirm allergen management procedures are as documented. All incidents involving uncontrolled allergens trigger a root cause analysis and corrective actions are put into place.
Training	New staff are provided with induction training and current staff undertake annual refresher training in allergen management.
Allergen Analysis	When relevant, procedures are in place for raw material and/or finished product allergen analysis that include a review of the results and actions to be taken.
Product Specifications	AFGC Product Information Forms and raw material specifications are stored in a central location and are updated and reviewed regularly.
Food Recall Pan	A documented food recall plan in place which has been tested through mock recall exercises.

For further detail about each area listed in Table 2, refer to the Allergen Bureau Allergen Risk Review website (discussed further in the following section). Conducting an allergen risk review can assist in identifying areas that need to be included when creating an AMP or provide additional considerations for when updating an AMP that is already in place.

3.2 ALLERGEN RISK REVIEW

Allergen risk review (as defined by the Allergen Bureau) is the thorough investigation of the allergen status of a food product. The investigation process identifies the presence of allergens that are intentionally formulated into a product and quantifies the risk of allergens which may be unintentionally present (cross contact allergens). This information can be used to create or update an AMP or for making allergen labelling decisions.

Allergen Risks Occur in Two Separate Circumstances

1. **Direct incorporation of known allergenic material:** where allergens are part of the formulation or processing conditions required for the manufacture of the finished product. This is also known as 'intentionally added' allergens. Components to be considered and managed include:
    - ingredients, including ingredients of ingredients
    - additives (including solvents and media for additives or flavourings)
    - processing aids.

    Direct incorporation can also occur by accidental addition through errors in formulation, use of rework etc. An effective AMP will identify and manage these risks.

2. **Cross contact with allergenic material:** where the unintentional presence of food allergens occurs. This includes:
    - where a product formulation contains an ingredient that carries a known cross contact risk
    - when a residue or material that has accumulated at a specific location, usually within processing equipment, is incorporated into the next product manufactured on the same line
    - where processing conditions or equipment permit contamination of the environment (e.g. powder clouds or aerosols) and subsequently that allergen can contaminate other product lines
    - contamination from storage environment, tools or clothing, packaging etc.

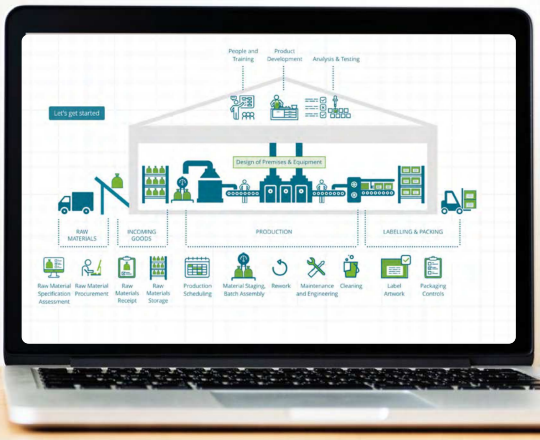
An allergen risk review applies to the entire manufacturing process from raw material sourcing to the labelled finished product. The review should:

- assess the intentional and unintentional allergen status of materials including raw materials and ingredients, work-in progress, and processing aids. This includes the quantification of unintentional allergens within each raw material
- identify where raw material and ingredient suppliers may change facilities or production processes
- identify and quantify any accumulated residue or material within the manufacturing line by physical assessment, chemical analysis and visual inspection including the dismantling of equipment and identification of hang up points
- identify and assess the risk of airborne cross contact from production and cleaning processes
- consider the form of the allergen such as whether it is particulate or readily dispersible
- be assessed on an annual basis or when changes are made to the facility, process or materials used, including where products are introduced or deleted from the facility
- include documentation of the allergen risk review and the outcomes.

The Allergen Bureau's Allergen Risk Review website is a freely available, interactive tool that guides the food industry through the process of thoroughly investigating the allergen status of ingredients, the manufacturing process and the final product.

Figure 1:

Image of the Allergen Risk Review website factory map



New Guidance Available!

CODEX has published a new Code of Practice on Food Allergen Management for Food Business Operators CXC 80-2020 which provides guidance on allergen management beginning at primary production and continuing throughout the manufacturing process.

The Allergen Bureau has published the revised and updated Unexpected Allergens in Food which contains an expanded and updated list of foods, ingredients and raw materials that may unexpectedly contain allergens as well as new information about agricultural co-mingling and food fraud.

3.3 ALLERGEN ANALYSIS

The analysis of a material or surface for the presence and/or amount of an allergen is a valuable tool for a risk–based approach to allergen management. Analytical test results can provide assurance and verification of critical controls within a comprehensive allergen management plan and assist the implementation of a quantitative risk assessment.

Understanding the nature of the allergen, its form (i.e. powder, liquid, homogenous or particulate) and its behaviour in the food in which it is used will play a major role in the choice of methodology applied.

Allergen analysis is appropriate for:

- confirmation of allergen status of raw materials
- validation of appropriate cleaning protocols
- verification or ongoing monitoring of cleaning efficacy including flushing and push through volumes
- environmental monitoring (which should run in parallel with microbiological and hygiene monitoring)
- monitoring the effects of process critical changes in the process
- identifying sources of cross contact
- confirming risk assessment assumptions
- assessing customer complaints
- investigating potential control failures
- assisting in verification of free from claims.

Analysis should be used for validation and verification purposes as part of a HACCP based food safety program.

The Allergen Bureau website provides detailed information on food allergen analysis.

Allergen analysis plays an important role in allergen management but is not a substitute for a robust allergen management program.

4. ALLERGEN LABELLING & COMMUNICATION

Allergen labelling is one of the most important pieces of information people with food allergy rely upon when deciding if a product is suitable and safe to consume. A thorough understanding of the Code's allergen labelling requirements is necessary to ensure allergen labelling is compliant within Australia and New Zealand, and it is strongly encouraged that the relevant standards in the Code are referred to whenever preparing labelling information. The purpose of this allergen labelling guidance is to assist the food industry with achieving consistency in how allergens are declared. It builds upon the Code's requirements by including examples and rationale for some allergen declarations, with the aim to provide consumers with clear and easily understood allergen information. This guidance is voluntary and represents industry best practice.

This section of the Guide

- Describes the allergen labelling requirements gazetted in the Australia New Zealand Food Standards Code on 25 February 2021, which is generally referred to as Plain English Allergen Labelling (PEAL).
- Explains the importance of understanding the allergenic nature of foods and how this relates to allergen declarations.
- Provides guidance for composing an ingredient list.
- Describes the format, terminology and location requirements for statements of ingredients and summary statements including examples and rationale for declaring allergens within an ingredient list.
- Describes best practice for applying precautionary allergen labelling statements.
- Explains the importance of clearly communicating the allergen status of foods and provides guidance on the management and communication of a change to allergen status of a food.

4.1 ALLERGEN DECLARATION REQUIREMENTS

The Code sets out the mandatory declaration requirements for foods that are allergens in Division 3 *Mandatory Declarations* of Standard 1.2.3 *Information requirements – warning statements, advisory statements and declarations*. If a food for sale contains an allergen (or a derivative of that allergen) listed in Column 1 of the table to section S9-3 in Schedule 9 *Mandatory advisory statements and declarations*, the label must declare the allergen as per the requirements set out in Standard 1.2.3.

Allergens may be present in a food for sale as:

- an ingredient or as an ingredient of a compound ingredient; or
- a substance used as a food additive, or an ingredient or component of such a substance; or
- a substance used as a processing aid or an ingredient or component of such a substance.

The mandatory allergen declaration requirements (including the format and location of the allergen declaration) differ depending on the food being offered for sale [refer to Code Standard 1.2.1]. Whether allergen information is provided on labels, specifications, through verbal communication for unpackaged foods, or in the increasing segment of online food shopping, it must be accurate, clear, and consistent. The following table provides some examples of the different declaration requirements.

Table 3 Allergen declaration requirements for various foods being offered for sale.

Examples of foods being offered for sale	**Allergen declaration requirements** (If allergens are not present, then an allergen declaration is not required.)
Packaged foods for retail sale (foods required to bear a label with a statement of ingredients) [refer to Code Standard 1.2.3 and subsection 1.2.3—6(2)].	The food requires an allergen declaration within its statement of ingredients. • Format and location requirements apply. • Required names from Column 3 of the table to section S9-3 apply. The food requires an allergen declaration within a summary statement. • Format and location requirements apply. • Required names from Column 4 of the table to section S9-3 apply.

continued...

Continued... Table 3 Allergen declaration requirements for various foods being offered for sale.

Examples of foods being offered for sale	Allergen declaration requirements (If allergens are not present, then an allergen declaration is not required.)
Packaged foods for retail sale not requiring a statement of ingredients [refer to Code section 1.2.4—2]. An allergen declaration should be printed on the packaging. Examples of these foods include: • individual portion packs [also refer to Code section 1.2.1—6] • foods contained in small packages [defined in Code Standard 1.1.2] • packaged and labelled water [also refer to Standard 2.6.2] • standardised alcoholic beverages [defined in Code Standard 1.1.2]. Foods not required to bear a label (examples are provided in Table 1) [refer to Code Standard 1.2.1]. The allergen declaration should accompany (for example using ink jet or digitally printed labels) or be displayed with the food. Food that is sold to caterers [refer to Code Standard 1.2.1 Division 3]. Allergen declarations are provided to the caterer with the food either on a label or in documentation. All other sales of food (including intra-company transfer) [refer to Code Standard 1.2.1 Division 4].	The food requires an allergen declaration. • Format and location requirements do not apply. • Required names from Column 4 of the table to section S9-3 apply.
Foods for special medical purposes or certain infant formula products [refer to the Code subsection 1.2.3—6 (4)].	The food requires an allergen declaration. • Format and location requirements do not apply. • Required names do not apply. Names from Column 1 of the table to section S9-3 or any other name by which the allergen is commonly known applies.
Foods where the possible presence of cross contact allergens has been established and a risk assessment has determined that a precautionary allergen labelling statement is necessary. Refer to section 4.1.11 in this Guide.	A precautionary allergen labelling statement is recommended. • Precautionary allergen labelling statements are voluntary. • For consistency, required names from Column 3 of the table to section S9-3 are recommended.

Some packages can display an allergen declaration which is neither a statement of ingredients nor a summary statement. An example is an individual portion pack with an allergen declaration ink jetted onto the sachet. The Code does not require a bold font for required names for declarations on individual portion packs, and in this example, ink jetting in a bold font could make the text more difficult to read.

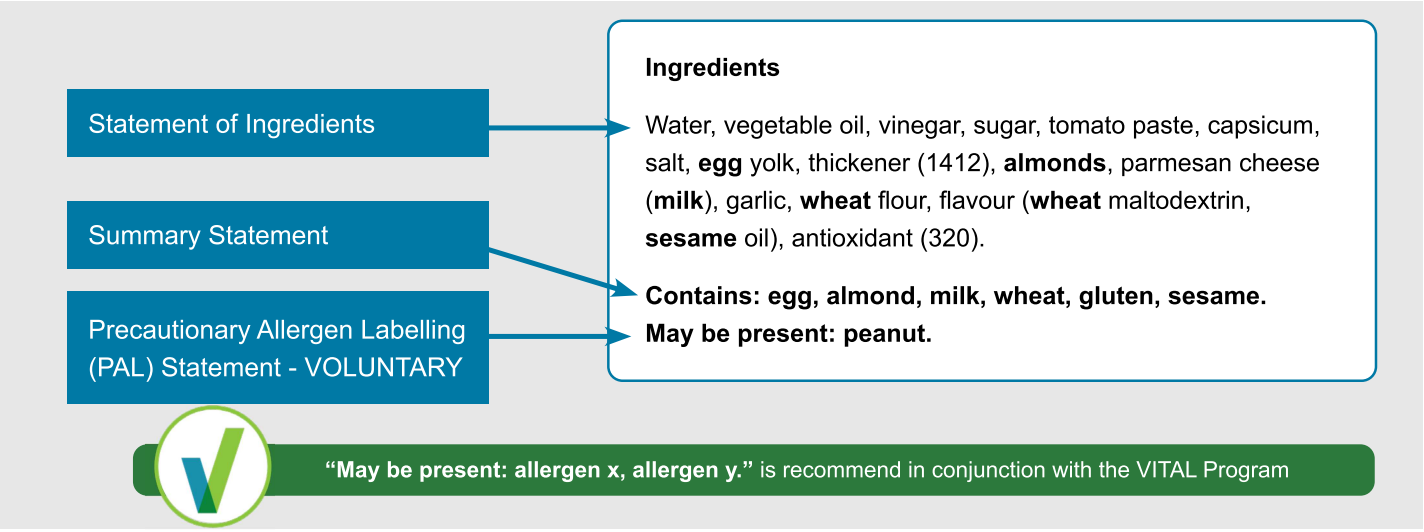
4.1.1 RECOMMENDED ALLERGEN LABELLING FORMAT

In this Guide an 'ingredient list' is a collective term which represents up to three labelling elements.

1. a mandatory statement of ingredients (refer to Code Standard 1.2.4 *Information requirements – statement of ingredients*); and
2. a mandatory summary statement (refer to Code section 1.2.3—4 *Mandatory declarations of certain foods*); and
3. a voluntary precautionary allergen labelling statement (refer to section 4.1.11 in this Guide).

The three elements work together to provide consumers with clear and consistent allergen labelling.

Figure 2. The allergen labelling elements of an ingredient list.



4.1.2 UNDERSTAND THE ALLERGENIC NATURE OF INGREDIENTS

To declare ingredients that are (or contain) allergens accurately, FBOs should be aware of the nature of the ingredients used in their products. In addition to allergens being present in ingredients, components in compound ingredients, additives and processing aids, allergens may also be present from carry-over, agricultural co-mingling, or cross contact. For more information, refer to the Allergen Bureau's Unexpected Allergens in Food which is a document that provides the food industry with a list of foods, ingredients and raw materials that may unexpectedly contain allergens, and a list of questions FBOs can ask their suppliers to support their allergen risk review process.

In Australia and New Zealand, regardless of the nature of the allergen, in most cases, if it is present in a food for sale, it must be declared.

Apart from sulphites, the allergens listed the table to section S9-3 are proteins. Depending on the food processing method, proteins can change (for example, denaturation due to extreme pH or heating). It should not be assumed that normal food manufacturing processes will make the proteins less allergenic. Foods and ingredients that contain denatured proteins can still trigger an allergic reaction in a consumer with food allergy. Also, if manufacturing processes result in the allergen protein not being detected by analytical means, it cannot be assumed that the allergen is not present. An example is a fermented food where the allergen may be difficult to detect using some analytical methods because the structure of the protein has changed.

Some ingredients undergo processes which remove most of the allergenic proteins. Unless these ingredients meet the requirements for an allergen labelling exemption, the allergenic source of these ingredients must be declared irrespective of how highly refined or processed they may be. An example of a material that can be highly processed is wheat, where wheat declaration would apply equally to wheat flour, wheat starch, wheat maltodextrins and caramel derived from wheat.

Allergen labelling exemptions

Some foods or substances have undergone processing steps and have been assessed by FSANZ as safe and suitable for people who have allergies. These foods and their derivatives are exempt from mandatory allergen declaration when the specific conditions set out in the Code are met. The allergen labelling exemptions (and their conditions) are listed in Column 2 of the table to section S9-3. An example of an ingredient which is exempt from allergen labelling is alcohol distilled from whey. Its derivative, vinegar distilled from the alcohol distilled from whey, is also exempt from allergen labelling.

Suppliers of ingredients should have access to the information necessary to advise whether allergen labelling exemptions apply to their ingredients.

4.1.3 ALLERGENS AND REQUIRED NAMES

When allergen declarations are simple and the terms are based on plain English, consumers can identify and understand the allergen more easily. For example, the ingredient sodium caseinate may not be readily recognised by a consumer as being a milk product, but the expression ‘sodium caseinate (milk)’ makes the milk allergen easier to identify.

Required names are specified terms (in plain English) that must be used for declaring allergens in foods.

The Code sets out the required names in the table to section S9-3. These are mandatory declarations to be used when stating the allergen in an ingredient list or in other allergen declarations.

A thorough understanding of each ingredient that is (or contains) an allergen is necessary for determining if and how a required name should be declared.

The following section of this Guide provides:

- information about each allergen; and
- examples showing how the required names can be displayed.

This section does not provide detailed information about required names in the context of a complete ingredient list. This is explained in sections 4.1.5 and 4.1.6 of this Guide.

Added sulphites

Unlike true food allergens which are usually proteins, sulphite compounds are minerals and are used as a food additive, usually to perform a preservative function. The term 'sulphites' includes sulphur dioxide and sodium and potassium sulphites [International Numbering System (INS) or Food Additive Code numbers 220, 221, 222, 223, 224, 225, 228].

Labelling requirements for food additives are set out in Standard 1.2.4 Information requirements – statement of ingredients, and Schedules 7 and 8 of the Code. In addition to meeting the labelling requirements for food additives, added sulphites must be declared when present in foods at concentrations of 10 mg/kg or more [table to section S9-3]. This also applies when they are present as a processing aid or are an ingredient within a compound ingredient comprising less than 5% of the food for sale [Standard 1.2.4].

Example where added sulphites are present in food at concentrations of 10 mg/kg or more.

Ingredients
preservative (sodium metabisulphite) (**sulphites**)

Contains: sulphites.

Or alternatively

Ingredients
preservative (223) (**sulphites**)

Contains: sulphites.

Example where added sulphites are present in food at concentrations of less than 10 mg/kg.

Ingredients
preservative (sodium metabisulphite)

Or alternatively

Ingredients
preservative (223)

Gluten

- The table to section S9-3 requires the mandatory declaration of barley, rye and oats *if they contain gluten*. When wheat is present, 'wheat' requires mandatory declaration regardless of whether gluten is present or not.
- Gluten is defined in Standard 1.1.2-2(3) of the Code as "the main protein in wheat, rye, oats, barley, triticale and spelt relevant to the medical conditions coeliac and dermatitis herpetiformis".
- The gluten proteins in wheat, barley, rye and oats differ. A gluten declaration is required in the summary statement only if the wheat, barley, rye or oats ingredient or substance that is present contains gluten.
- This applies if gluten is contained in wheat, barley, rye or oats that is present as:
    - an ingredient or as an ingredient of a compound ingredient; or
    - a substance used as a food additive, or an ingredient or component of such a substance; or
    - a substance used as a processing aid, or an ingredient or component of such a substance.
- FBOs need to apply due diligence principles and take all practical precautions or measures to determine if gluten is present or not including reviewing supplier information, understanding the ingredient processing, testing, and monitoring. (refer to the Box on Due Diligence Principles)
- Note that oat gluten proteins will also need to be declared.

Barley, rye and oats

The table to section S9-3 requires that barley, rye, oats or their hybrids which contain gluten (refer to the Box on 'Gluten') require mandatory declaration. For such products, the Code specifies a required name in the statement of ingredients and that the required name 'gluten' is displayed in the summary statement to inform individuals with coeliac disease or dermatitis herpetiformis that the food contains gluten.

Example where barley containing gluten is present in a food.

Ingredients
Barley flour

Contains: gluten.

Example where rye containing gluten is present in a food.

Ingredients
Rye flour

Contains: gluten.

Example where oats which contains gluten is present in a food.

Ingredients
Rolled **oats**

Contains: gluten.

Where gluten is determined not to be present in barley, rye or oats there is no requirement for mandatory declaration of these foods. Refer the Box on 'Gluten' which states that FBOs need to apply due diligence principles and take all precautions or measures to determine if gluten is present or not.

Example where barley is present which contains no gluten and good process control exists (under such conditions, barley grass should not contain gluten).

Ingredients
Barley grass

If gluten is present as determined through the application of due diligence principles taking all practicable precautions or measures including supplier information, testing and/or monitoring to determine gluten is present. Refer to the Box on Due Diligence Principles for further information.

Ingredients
Barley grass

Contains: gluten.

Due Diligence Principles

Apply due diligence principles and take all practical precautions or measures to determine if gluten is present or not including reviewing supplier information, understanding the ingredient processing, testing, and monitoring

Relevant Legislation in each Australian State and Territory and in New Zealand contains a provision for due diligence defence in relation to certain offences related to food which should be considered.

There are three important considerations – the first is taking all **reasonable precautions or measures**, the second is **exercising all due diligence** and the third is to ensure that all **relevant action** was taken to manage a situation. Due diligence in general requires a high level of inquiry and verification.

"Exercising all due diligence" means finding out what precautions or measures are necessary, implementing the reasonable precautions or measures and ensure ongoing monitoring is in place.

Generally, there are very few ingredients which are derived from wheat, rye, barley or oats, which do not contain gluten, and as a general rule unless specified in the raw material supplier information, it is recommended to assume that gluten is present.

However, as in all food safety risk assessments, FBOs should have processes in place to assess, determine and quantify the level of risk which may exist. When understanding if an ingredient you procure, or manufacture does not have gluten present the below points can be used as a guide for FBOs to apply due diligence and take practical precautions or measures to verify this outcome.

Reviewing Supplier information

- Does the Approved Supplier procedure provide guidance on the level of detail which may be required to assess an ingredient which "does not have gluten present" or where the supplier has indicated that wheat or gluten "have been removed"?
- Additional information may be required from the supplier to validate this statement regarding their ingredient. For example, an understanding of how the ingredient is processed and verification records that support that wheat or gluten are not present.

Understanding the ingredient processing

- Obtaining a thorough understanding of the ingredient processing / manufacturing, provides the general knowledge required to assess the level of risk that may be associated with the ingredient, and if the wheat and/or gluten are not present. Or the potential likelihood that they may be present from time to time.
- The level of separation or refining in the process will impact on the level of protein which remains in the ingredient. As such, an understanding of the process will assist in informing the level of risk associated with the product.

Analytical Testing

- Allergen ELISA analysis is used widely to verify the presence or absence of allergens. The method is designed in most cases to detect intact proteins or a group of proteins. As discussed on the Allergen Bureau Food Allergen Analysis page and Allergen Risk Review website, any production process which changes the physical form of the proteins, will result in detection difficulties. In particular, ingredients which have undergone a fermentation process, will result in the partial breakdown of allergenic proteins, which in many cases will render them undetectable in the assays. As such, a negative result may suggest the absence of proteins however, undetectable allergenic protein may remain and this could pose a hazard to allergic individuals. It is important to discuss analytical analysis for these products with your laboratory provider
- Where ingredients rely on processes to change the nature of the protein, or remove protein, the exclusive use of allergen ELISA analysis may not be suitable to assess if gluten is present. As such, analysis to detected specific proteins (i.e. LC-MS, SDS-PAGE etc), and at very low levels may be employed by the manufacturer to validate and verify the process is effective. It is recommended organisations seek clarity on what analytical methods are used in addition to traditional ELISA analysis to support that gluten is not present.

Monitoring

- It is recommended that businesses work with their suppliers to understand the way in which the ingredient is monitored / verified to meet the claim that gluten is not present.
- Best practice allergen management should also include a system to allow an organisation to monitor and identify when changes may occur to suppliers, ingredients procured or the supply chain.

Wheat

'Wheat' must be declared in the statement of ingredients when it is present. Only declare gluten in the summary statement if gluten is present in the wheat ingredient or substance. FBOs need to apply due diligence principles and take all practical precautions or measures to determine if gluten is present or not including reviewing supplier information, understanding the ingredient processing, testing and monitoring. Refer to the box on "Due Diligence Principles".

Example where wheat is present in a food.

Ingredients
wheat

Contains: wheat, gluten.

Where gluten is not present, there is no requirement to declare gluten.

Example where the gluten has been eliminated through breeding.

Ingredients
wheat

Contains: wheat.

Example of a wheat-derived ingredient.

Ingredients
maltodextrin (**wheat**)

Contains: wheat, gluten.

Example of a wheat-derived ingredient where gluten is not present.

Ingredients
maltodextrin (**wheat**)

Contains: wheat.

There are two main types of wheat (of the genus Triticum) grown in Australia and New Zealand (bread wheat and durum wheat), and although less commonly grown, there are several other species of wheat from the same genus often considered to be 'ancient wheat' such as spelt, Kamut® khorasan wheat, einkorn, farro/ emmer, and freekeh. Where these foods are present, wheat must be declared.

Example where spelt is present in a food.

Ingredients
spelt (**wheat**)

Contains: wheat, gluten.

For hybridised strains of wheat such as triticale (which is a hybrid of wheat and rye) both the required names are declared in the statement of ingredients, but specific cereal names (except for wheat) cannot be displayed in the summary statement.

Example where a hybridised strain of wheat and rye is present in a food.

Ingredients
triticale (**wheat, rye**)

Contains: wheat, gluten.

For wheat processed into the ingredient wheat gluten, the term gluten is not a required name in the statement of ingredients and therefore is **not bolded**.

Example where wheat gluten is added to a food.

Ingredients
wheat gluten

Contains: wheat, gluten.

Tree nuts

The table to section S9-3 lists the required names for the nine tree nuts (almonds, Brazil nuts, cashews, hazelnuts, macadamias, pecans, pine nuts, pistachios, and walnuts). These are considered by FSANZ to be tree nuts of public health significance for allergies in Australia and New Zealand. A declaration is always required for these tree nuts, or derivatives of these tree nuts (such as oils). Coconut and nutmeg and tree nuts such as chestnut, pili nut, shea nut, illipe nut, and hickory nut are not included in the table and therefore do not have required names.

Example where coconut, pecans and almonds are present in a food.

Ingredients
coconut, **pecans**, **almonds**

Contains: pecan, almond.

Crustacea

The ordinary meaning for crustacea includes aquatic arthropods (marine and freshwater) such as crabs, prawns, lobsters, crayfish and shrimps. Including further information that describes the species name (for example 'Tiger' Prawns as opposed to simply 'Prawns') within the statement of ingredients is permitted, however additional information in the summary statement is not.

Example where crustacea is present in a food.

Ingredients
prawns (**crustacean**)

Contains: crustacean.

Egg

This should include all avian (bird) eggs, including quail and duck eggs.

Example where egg is present in a food.

Ingredients
egg yolk

Contains: egg.

Fish

The ordinary meaning of fish includes cold-blooded aquatic vertebrates such as bony and cartilaginous fish like fin fish, shark, rays and eels. Fish does not include crustacea and mollusc. For foods or ingredients that contain a mixture of seafood such as surimi (colloquially known as crab sticks), care should be taken to ensure the fish, mollusc and crustacea are declared separately when present.

Example where fish is present in a food.

Ingredients
hoki (**fish**)

Contains: fish.

Lupin

Lupin is a legume which is increasingly used in foods in Australia. Limited information is available about lupin food allergy, however, some lupin proteins are similar to peanut proteins.

Example where lupin is present in a food.

Ingredients
lupin flour

Contains: lupin.

Milk

Milk is the mammary secretion of all milking animals [section 1.1.2—3 of the Code]. Most people who are allergic to cow's milk will be allergic to other animal milks (goat, sheep or horse/mare) and products that are made from these milks[14]. The use of a bold font for the word 'milk' in the summary statement will assist consumers with a milk allergy to be able to distinguish mammalian milk from other plant-based dairy alternatives. The term 'dairy' cannot be used to meet the allergen declaration requirement for milk. It could be included in an ingredient name if 'milk' is also included (and 'milk' is in a bold font as per the requirements for allergens).

Example where milk is present in a food.

Ingredients
milk solids

Contains: milk.

Example where milk is present in a food from an identified animal source.

Ingredients
Goat **milk**

Contains: milk.

Mollusc

The ordinary meaning of mollusc includes aquatic invertebrates such as clams, cockles, oysters, scallops, octopus, squid, cuttlefish, calamari, sea urchins, and jelly fish. For allergen labelling purposes mollusc means a marine mollusc and excludes common garden snails. Molluscs were previously included as part of fish but are now separated from fish to provide further clarity to allergen declarations.

Example where mollusc is present in a food.

Ingredients
oysters (**mollusc**)

Contains: mollusc.

Peanut

Peanut is a legume and is not botanically related to tree nuts.

Example where peanut is present in a food.

Ingredients
peanuts

Contains: peanut.

Sesame seed

Example where sesame is present in a food.

Ingredients
sesame oil

Contains: sesame.

Soybean

The required names ‘soy’, ‘soya’ or ‘soybean’ may be used in the statement of ingredients, however, the required name ‘soy’ must be declared in the summary statement.

Example where soybean is present in a food.

Ingredients
soybeans

Contains: soy.

If soybean oil meets the allergen labelling exemption conditions set out in Column 2 of the table to section S9-3 (for example it has been degummed, neutralised, bleached, and deodorised) soy is not a required name and does not need to be declared in a bold font or included in summary statement.

Example where soybean oil (which meets the requirements for the exemption) is added to a food.

Ingredients
vegetable oil

Or alternatively

Ingredients
soybean oil

4.1.4 COMPOSITION OF ALLERGEN LABELLING INFORMATION

Prior to generating an ingredient list for label artwork, the relevant information needs to be collated. Table 4 describes the recommended process for preparing allergen labelling for packaged foods, however, the same principles can be applied to non-packaged foods. The process outlined applies to the development of new labels and updating or changing existing labels when the allergen status of a product changes.

Table 4 Process for composing an allergen declaration – packaged foods.

Step	Description	Reference/Resources
1	Obtain the product formulation/recipe including amounts of each ingredient.	
2	Obtain Product Information Forms (PIFs) and/or specifications for all ingredients. Ensure all sources of allergens as ingredients and cross contact allergens are identified and recorded.	• AFGC - Product Information Form (PIF) • Allergen Bureau - Allergen Risk Review website
3	Identify allergens in the product using the formulation and ingredient information, including: • Ingredients • Food additives • Processing aids • Compound ingredients • Cross contact from ingredients	• ANZ Food Standards Code Standard 1.2.3 • AFGC - Product Information Form (PIF) • AFGC & Allergen Bureau– Food Industry Guide to Allergen Management and Labelling • Allergen Bureau - Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program • Allergen Bureau - Unexpected Allergens in Food
4	Compose the statement of ingredients and the summary statement and declare the allergens formulated into the product using the appropriate required names.	• ANZ Food Standards Code Standards 1.2.3 &1.2.4 • ANZ Food Standards Code Schedule 9 & Schedule 10 • AFGC & Allergen Bureau– Food Industry Guide to Allergen Management and Labelling • Allergen Bureau - VITAL Best Practice Labelling Guide for ANZ
5	Conduct a VITAL risk assessment to determine the presence of cross contact allergens from ingredients and processing.	• Allergen Bureau - Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program • Allergen Bureau – VITAL Online (web-based VITAL calculator) • Allergen Bureau - Allergen Risk Review website
6	Finalise allergen labelling: • Confirm the allergens in the ingredient list, • Confirm the allergen summary statement, and • Compose the appropriate precautionary allergen statement	• Allergen Bureau – VITAL Online (web-based VITAL calculator) • AFGC & Allergen Bureau– Food Industry Guide to Allergen Management and Labelling • Allergen Bureau - VITAL Best Practice Labelling Guide for ANZ

4.1.5 STATEMENT OF INGREDIENTS

Format

In a statement of ingredients, the allergens are declared using the required names (from Column 3 of the table to section S9-3). They are to be declared:

- in a bold font; and
- in the same or larger text size; and
- in distinct contrast with the other text.

This is set out in the Code section 1.2.3—7.

Legibility requirements are specified in section 1.2.1—24 of the Code. Ideally, the print size should be big enough to be easily read, preferably at a minimum 1.5mm sans-serif font, and the font colour should contrast distinctly from the background.

Consideration should be made for print on clear packaging, avoiding situations where the colour of the food makes the text less prominent.

The use of lower or upper case within the statement of ingredients is not regulated but can impact upon the overall presentation of labelling information. Text that is presented in CAPITAL LETTERS can be more difficult to read.

In this Guide, the ingredient list heading '**Ingredients**' is used for the purpose of providing consistent guidance. Headings such as 'Ingredients', 'Consists of' or 'Made from' are not regulated by the Code and are usually applied by industry to make the ingredient list prominent on the label. It is recommended that the format of the heading does not prevent the required names from being in distinct contrast with any other text within the statement of ingredients.

The overall presentation of the ingredient list and its heading should be taken into consideration when determining if the required names are in distinct contrast with the other text in the statement of ingredients.

Table 5. Considerations for headings and distinct contrast requirements.

Scenario	Example	Consideration
Heading is separate from statement of ingredients	**Ingredients** Rice flour, **milk**, sugar, **egg**.	When the heading is separate from the statement of ingredients, the header in a bold font should not prevent the required names from being in distinct contrast with any other text within the statement of ingredients.
Heading precedes the statement of ingredients	**Ingredients:** Rice flour, **milk**, sugar, **egg**.	A heading in a bold font preceding the statement of ingredients may not provide distinct contrast (such as being noticeably different) from the required names in a bold font.
	INGREDIENTS: Rice flour, **milk**, sugar, **egg**.	Formatting such as capitalisation may make the header prominent and allow the required names to remain in distinct contrast with any other text within the statement of ingredients.

Terminology

Standard 1.2.3 of the Code sets out requirements for how allergens are to be listed in a statement of ingredients.

Each allergen should be displayed using its required name which is to be listed separately so that it is clearly and easily distinguishable from the other ingredients.

This table shows some examples for how the required names could be displayed in a statement of ingredients.

Table 6 Examples of how required names can be displayed for individual ingredients.

Scenario	Example	Example (when displayed in a statement of ingredients)	Rationale
The ingredient name is identical to the required name.	almond	**almond** or **almonds**	When the name of the ingredient and the required name are identical, the ingredient is written in a bold font. Refer to Code paragraph 1.2.3—7 (2) (c) and Column 3 of the table to section S9-3. The required name can be singular or plural. [Code section 1.2.3—8].
	egg	**egg**	
The ingredient name is different from the required name.	salmon	salmon (**fish**)	The required name is displayed as a separate word and is located next to the ingredient that is (or contains) the allergen [refer to Code paragraph 1.2.3—7 (2) (c)].
	oysters	oysters (**mollusc**)	
	edamame	edamame (**soy**)	
	maltodextrin	maltodextrin (**wheat**)	
	sodium caseinate	sodium caseinate (**milk**) or sodium caseinate (from **milk**)	
	preservative (sodium metabisulphite) (added at concentrations of 10mg/kg or more)	preservative (sodium metabisulphite) (**sulphites**) or preservative (223) (**sulphites**)	
	pasta	pasta (**wheat**, **egg**)	
The required name is contained in the name of the ingredient and is displayed as a separate word	soy flour	**soy** flour	When the allergen is part of the name of the ingredient, and the name of the allergen and the required name are identical, it is written in a bold font if it is separate [refer to Code paragraph 1.2.3—7 (2) (b)].
	sesame seeds	**sesame** seeds	
	almond meal	**almond** meal	
The required name is contained in the name of the ingredient but is part of the word	buttermilk	buttermilk (**milk**)	If the name of the allergen is part of the name of the ingredient, the allergen cannot be written in a bold font because it is not a separate word. The required name is then displayed as a separate word next to the ingredient [refer to Code paragraph 1.2.3—7 2 (b)].
	oatmeal	oatmeal (**oats**)	
	wheaten cornflour	cornflour (**wheat**) or wheaten cornflour (**wheat**)	

International allergens (celery and mustard)

Although in Europe (EU) celery and mustard are allergens of public health significance, they are not in Australia and New Zealand and they are not listed in the table to section S9-3. As mustard and celery are not required names, and as additional words are not permitted in a summary statement, they cannot be included within it. When listed in the statement of ingredients they cannot be displayed in a manner that prevents the required names in a bold font from contrasting distinctly from the other text.

Example where mustard is present in a food.

Ingredients
Mustard seeds, sugar, vinegar, **egg** yolk.

Contains: egg.

When exporting foods to the EU, or importing foods into Australia and New Zealand, ensure that the labels comply with the relevant regulations for that jurisdiction. For example, voluntary 'contains' statements are not permitted on the labels of foods sold in the EU[15] .

Location of required names

In a statement of ingredients, the required name must be listed separately for each ingredient.

If more than one ingredient contains the same allergen, the required name for that allergen is displayed separately from, but next to, the name of those ingredients.

Figure 2. *The allergen labelling elements of an ingredient list* shows each allergens declared as a required name in bold font, noting that there are two ingredients that contain or are a product of wheat and wheat is declared in a bold font each time.

Ingredients should be listed by their common name or a name that describes the true nature of the ingredient [refer to Code section 1.2.4—4]. A statement of ingredients can also contain other information to provide further context about ingredients. In the following example, the name of the ingredient is 'tuna' and further information is provided describing the true nature of the ingredient (the tuna species).

The required name 'fish' is located separately from, but next to, the name of the ingredient. In this example, the percentage of the characterising ingredient immediately follows the common and descriptive name of the ingredient.

Example: Statement of ingredients for canned tuna in water.

Ingredients
Tuna (*Katsuwonus pelamis*) (60%) (**fish**), water, salt.

When locating the required name and the percentage of a characterising ingredient, also consider whether the information is clear, and compliant with the Code's requirements for characterising ingredients [refer to Standard 1.2.10].

Example of alternative positioning of the tuna characterising ingredient percentage.

Ingredients
Tuna (*Katsuwonus pelamis*) (**fish**) (60%), water, salt.

If the required name is located before the percentage of characterising ingredient, consider whether that percentage could be mistaken for the quantity of the allergen rather than the quantity of the ingredient.

Example of butter biscuits where it may appear that the milk allergen is present at 15%.

Ingredients
Cornflour, unsalted butter (**milk**) (15%), sugar.

In this example it is clear that the unsalted butter proportion is 15%.

Ingredients
Cornflour, unsalted butter (15%) (**milk**), sugar.

Compound ingredients

The order of the statement of ingredients can vary if it contains compound ingredients and this can impact how required names are displayed. A compound ingredient is defined in Standard 1.1.2 and is an ingredient of a food made from two or more ingredients. Allergens present in compound ingredients must be declared [refer to section 1.2.3—4] including when those compound ingredients are added at less than 5% [refer to paragraph 1.2.4—5(6)(b)(i)]. When composing a statement of ingredients which has compound ingredients, it is encouraged to consider the most appropriate format that enables consumers to readily identify the presence of allergens.

In the following three examples the Seafood Chowder consists of several crustaceans and molluscs, and the statement of ingredients displays the required names each time. Each statement of ingredients is a different length, with the third example displaying the allergens the most simplistically. The percentages of some ingredients are shown to assist with explaining the descending order of weight in this scenario.

Example: Statement of ingredients for Seafood Chowder where the required names are displayed each time.

Ingredients
Stock (50%) (water, **fish**, salt, sugar, spices), **milk** (15%), potatoes, onion, prawns (4%) (**crustacean**), squid (4%) (**mollusc**), octopus (4%) (**mollusc**), clams (4%) (**mollusc**), crab (4%) (**crustacean**), **wheat** flour, vegetable oil, garlic.

The following example shows the crustaceans and molluscs added as a compound ingredient named ‘seafood mix’, and the statement of ingredients displays the required names each time within that compound ingredient.

Example: Statement of ingredients for Seafood Chowder with a ‘seafood mix’ compound ingredient.

Ingredients
Stock (50%) (water, **fish**, salt, sugar, spices), seafood mix (20%) [prawns (**crustacean**), squid (**mollusc**), octopus (**mollusc**), clams (**mollusc**), crab (**crustacean**)], **milk**, potatoes, onion, **wheat** flour, vegetable oil, garlic.

In this next example the compound ingredient is based on seafood type which are crustaceans and molluscs. As the seafood type is identical to the required name, these are in a bold font.

Example: Statement of ingredients for Seafood Chowder with compound ingredients based on seafood type.

Ingredients
Stock (50%) (water, **fish**, salt, sugar, spices), **milk**, **molluscs** (12%) (squid, octopus, clams), **crustaceans** (8%) (prawns, crab), potatoes, onion, **wheat** flour, vegetable oil, garlic.

4.1.6 SUMMARY STATEMENTS

A summary statement is essentially a summary of the allergens displayed in a statement of ingredients. Its purpose is to improve the consumer's ability to identify allergen information. **Consumers can use the summary statement for an initial allergen search and then seek more detailed information from the statement of ingredients.** Ensure the allergen summary statement makes sense, is logically consistent, and is not contradictory to the statement of ingredients (i.e., there should be no missing allergens or extra allergens).

Format

Summary statements are to begin with the word 'Contains' in a bold font and list the appropriate required names in a bold font which provides a distinct contrast with any other text in the statement of ingredients that are not required names. The text typeface and size should be the same as the allergen declarations in the statement of ingredients [refer to Code subsections 1.2.3—7 (3) and (5)].

In this Guide, the preferred summary statement format is:

Contains: allergen a, allergen b, allergen c.

Alternative summary statement formats and punctuation can also be used if the overall presentation of the summary statement meets the requirements of the Code, noting that **CAPITAL LETTERS** can be more difficult to read.

Examples include:

Contains allergen a, allergen b, allergen c.
Contains: allergen a, allergen b, allergen c.
CONTAINS: ALLERGEN A, ALLERGEN B, ALLERGEN C.
CONTAINS ALLERGEN A, ALLERGEN B, ALLERGEN C.

The order of the required names in a summary statement is not regulated by Code. **To achieve consistency within the food industry, it is recommended that the order of the required names aligns with the order displayed in the statement of ingredients.**

This generally represents order of magnitude, often aligns with labelling software outputs, and makes cross-referencing with the allergens in the statement of ingredients easier. To assist consumers with finding information quickly, it is preferred that wheat and gluten are located together, and individual tree nuts are located together if possible.

Location

Summary statements must appear in the same field of view as the statement of ingredients, be located directly next to the statement of ingredients and be distinctly separated from it [refer to Code subsection 1.2.3—7 (4)]. For consistency it is encouraged that wherever possible the summary statement is located below the statement of ingredients and separated by a line space. An example of this format is shown in Figure 3. *Examples of summary statement locations*. This figure shows the preferred formatting for an ingredient list. It also provides some alternative formats which may be useful, particularly for packages which have limited space, or where it is difficult to obtain a distinct separation between the summary statement and the statement of ingredients.

Where there are space limitations on the label, the summary statement can be distinctly separated by other means. Alternative methods to separate (differentiate) the summary statement from the statement of ingredients could be by using boxing or another noticeable shape or using a different text colour.

When deciding whether a summary statement is distinctly separate, view the statement of ingredients and the summary statement together and consider whether a consumer can easily find the summary statement. If the summary statement is not obvious or identified quickly, it may not be regarded as separated distinctly, and an alternative format should be considered.

Figure 3. Examples of summary statement locations.

Preferred format - the summary statement is below, and distinctly separated from, the statement of ingredients.

Ingredients
Water, vegetable oil, vinegar, sugar, tomato paste, capsicum, salt, **egg** yolk, thickener (1412), **almonds**, parmesan cheese (**milk**), garlic, **wheat** flour, flavour (**wheat** maltodextrin, **sesame** oil), antioxidant (320).

Contains: egg, almond, milk, wheat, gluten, sesame.

Alternative formats - the summary statement is next to, and distinctly separated from, the statement of ingredients

Ingredients
Water, vegetable oil, vinegar, sugar, tomato paste, capsicum, salt, **egg** yolk, thickener (1412), **almonds**, parmesan cheese (**milk**), garlic, **wheat** flour, flavour (**wheat** maltodextrin, **sesame** oil), antioxidant (320).

Contains: egg, almond, milk, wheat, gluten, sesame.

Contains: egg, almond, milk, wheat, gluten, sesame.

Ingredients
Water, vegetable oil, vinegar, sugar, tomato paste, capsicum, salt, **egg** yolk, thickener (1412), **almonds**, parmesan cheese (**milk**), garlic, **wheat** flour, flavour (**wheat** maltodextrin, **sesame** oil), antioxidant (320).

Alternative format for labels with very limited space - the summary statement is in a box, providing a distinct separation between the statement of ingredients and the summary statement.

INGREDIENTS: Water, vegetable oil, vinegar, sugar, tomato paste, capsicum, salt, **egg** yolk, thickener (1412), **almonds**, parmesan cheese (**milk**), garlic, **wheat** flour, flavour (**wheat** maltodextrin, **sesame** oil), antioxidant (320).
Contains: egg, almond, milk, wheat, gluten, sesame.

Terminology

The required names for summary statements, except for soybean and cereals containing gluten, are the same as those in the statement of ingredients. These are listed in Column 4 of the table to section S9-3. The following example shows how the required names can be presented in a statement of ingredients and summary statement using the required names.

Example: Ingredient list for Frozen Green Vegetable Mix.

Ingredients
Green beans, sugar snap peas, edamame (**soybean**).

Contains: soy.

Note that soy, soya and soybean are required names in the statement of ingredients, but not in the summary statement where soy is the only permitted required name.

Foods that are not listed in the table to section S9-3 are not required names. In this next example, although pili nuts are a tree nut and shea nut butter is a product of a tree nut, they are not included in the list of foods with required names and therefore not do not require declaration as set out in Standard 1.2.3—4 (such as text in a bold font or displayed in the summary statement). However, they are ingredients and therefore should be declared in the ingredient list as per Standard 1.2.4.

Example: Ingredient list for Nutty Fudge.

Ingredients
Condensed **milk**, shea nut butter, sugar, **pistachio** nuts, pili nuts, salt.

Contains: milk, pistachio.

4.1.7 USE OF EXTRA WORDS LIKE 'CONTAINS' OR 'FROM' IN THE STATEMENT OF INGREDIENTS.

Extra words such as 'from' or 'contains' preceding the required name in a statement of ingredients are not necessary, and for the purposes of achieving consistency, are not recommended. However, there may be situations when adding extra words to clarify the allergen source may be appropriate for reducing consumer confusion. Additional words in a summary statement are not permitted.

Table 7 Example showing where using an extra word before a required name may be appropriate.

Scenario	Example (when displayed in an ingredient list)	Rationale
Coconut milk	**Ingredients** Coconut milk	Coconut milk is a plant-based dairy alternative, and in this scenario, the term 'milk' does not represent cow's milk, or more specifically a product of the 'mammary secretion of milking animals' [Code section 1.1.2—3]. Therefore, in this example, 'milk' is not a required name. "Milk is not declared in bold font in the statement of ingredients or summary statement, distinguishing it from mammalian milk."
The coconut milk contains added sodium caseinate (a milk derivative)	**Ingredients** Coconut milk, sodium caseinate (**milk**) **Contains: milk.**	The required name is displayed in the statement of ingredients and in the summary statement. The sodium caseinate is clearly the source of the milk allergen.
A food contains less than 5% of the compound ingredient 'coconut milk, sodium caseinate'	**Ingredients** Other ingredients …, coconut milk (contains **milk**), … **Contains: milk.**	When a food contains less than 5% coconut milk, the sodium caseinate is not declared, however the milk allergen from the caseinate is. In this example, a statement 'coconut milk (**milk**)' may be confusing to a consumer who may not realise that the milk allergen is added by means of a different ingredient. Including the word 'contains' such as 'coconut milk (contains **milk**)' provides context and therefore more clarity.

Dairy alternatives labelled as 'milk' such as soy milk, oat milk and almond milk, may not affect those with cow's milk allergy but can potentially cause an allergic reaction in other individuals. For example, people with an allergy to almonds must avoid almond milk. For plant-based dairy alternatives, ensure the legume, cereal or tree nut source of the product is clearly stated in the name of the food on the front of pack to allow consumers with food allergy to make an informed choice.

4.1.8 SINGLE INGREDIENT FOODS

For a single ingredient food where the name of the food is the allergen (e.g., a carton of eggs), if the required name is displayed on the label (e.g., 'Eggs'), it does not require a statement of ingredients or a summary statement [refer to Code subsection 1.2.4—2(2) and Code subsection 1.2.3—6(3)] and the name of the food is the allergen declaration.

For a package of pure wheat flour, the declaration of both 'wheat' and 'gluten' is required [Column 4 of the table to section S9-3], however, the package does not require a statement of ingredients or a summary statement. It is recommended that the allergen declaration for wheat and gluten is displayed together on the label.

An ingredient list may be included voluntarily and is recommended in situations that would provide clarity for a consumer. An example is a package comprising of only powdered milk. Its label states 'milk powder' and a statement of ingredients and a summary statement are not required. A package of instant milk powder that contains the emulsifier soy lecithin is also offered for sale and is located next to the plain milk powder in the supermarket. This label is required to display both a statement of ingredients and a summary statement. To provide consistent information, it would be helpful to include an ingredient list onto the package of plain milk powder in the same location that the ingredient list will be positioned on the package of instant milk powder, so that a consumer can easily compare the two packages.

4.1.9 USE OF OTHER INFORMATION

The location of a characterising component declaration is not regulated by the Code and can be displayed anywhere on the label. If it is displayed within the statement of ingredients, the information should not compromise the location of the summary statement and its compliance with the Code's requirements (such as distinct contrast).

Example: Confectionery label displaying a characterising component declaration which is not located within the statement of ingredients.

Ingredients
Nougat [sugar, glucose syrup, vegetable oil, **egg** white, condensed **milk**], **milk** chocolate [sugar, **milk** solids, cocoa butter, cocoa mass, emulsifiers (322 (**soy**), 476)].

Contains: egg, milk, soy.

Milk chocolate contains 30% cocoa solids and 20% milk solids.

The Code's requirement for allergen declarations to be in distinct contrast with the other text also applies to information such as 'vegetarian' or 'organic', or advisory statements such as 'contains caffeine' if this information is located within the statement of ingredients. Other information located outside of the statement of ingredients and the summary statement **can be in a bold font**.

In this example, additional information 'organic' is included within the statement of ingredients **and is not in a bold font**. The other information about phenylalanine and seeds (from the fruit) is located outside of the statement of ingredients. The use of a heading 'caution' is voluntary.

Example: Canned fruit in sweetened syrup displaying an advisory statement and other information.

Ingredients
Organic lychees, organic rambutans, water, organic **wheat** flour, sweetener (962).

Contains: wheat, gluten.

CAUTION: This food contains phenylalanine and may contain seeds or seed fragments.

4.1.10 PROCESSING AIDS

If a processing aid is, or contains, an allergen, the Code [refer to section 1.2.3—6] sets out requirements for how it is declared (for example the processing aid is listed in the statement of ingredients with the words 'processing aid' displayed in conjunction with the required name). The location of processing aids within the statement of ingredients is not specified by the Code so can be positioned either:

- in descending order of ingoing weight; or
- at the end of a compound ingredient containing the processing aid; or
- at the end of the statement of ingredients

The following example shows how processing aids can be presented in an ingredient list.

Pork & Rice Curry is a refrigerated packaged meal comprising a pork ingredient that contains the milk based processing aid lactoperoxidase. The lactoperoxidase does not have a technological purpose in the food for sale and ordinarily would not require declaration. However, because it is derived from an allergen (milk), it meets the requirements for mandatory declaration of allergens.

Table 8 Displaying allergens from processing aids in a statement of ingredients and allergen declarations

Scenario	Example	Rationale
The words 'processing aid' are displayed in the statement of ingredients in conjunction with the required name. The required name is also displayed in the summary statement.	**Ingredients** Pork, …other ingredients…, curry spices, processing aid (**milk**). **Contains: milk.**	The processing aid declaration is located at the end of the statement of ingredients. This may be appropriate when there is a small quantity of the processing aid (last in descending order of weight), or its quantity is variable, or the processing aid is used in the manufacturing process rather than being present as carry over from an ingredient. This is the preferred location as it provides consistency.
	Ingredients Pork (processing aid **milk**), …. other ingredients. **Contains: milk.**	Alternatively, the processing aid declaration is located beside the ingredient which contains it. This may also be appropriate for compound ingredients.
Extra words such as 'contains' are not necessary in the statement of ingredients, and for the purposes of consistency, are not recommended However, there may be situations where, including the word 'contains' or 'containing' can provide consumers with some context about the processing aid.	**Ingredients** Pork (contains processing aid **milk**), …other ingredients. **Contains: milk.**	The word 'contains' preceding the processing aid in the ingredient provides further context about the source of the processing aid.
	Ingredients Pork, …other ingredients…, curry spices, processing aid containing **milk**. **Contains: milk**.	Alternatively, a processing aid may be comprised of several ingredients so use of the word 'contains' or 'containing' could indicate that the processing aid is not solely consisting of milk but contains milk.
	Ingredients Pork, …other ingredients…, curry spices, processing aid (containing **milk**). **Contains: milk**	The use of brackets is also acceptable.

Continued...

Continued...Table 8. Displaying allergens from processing aids in a statement of ingredients and allergen declarations

Scenario	Example	Rationale
The Pork & Rice Curry meal was offered in a format where it was not required to bear a label or display a statement of ingredients.	Contains: milk	The allergen declaration would consist of the required name (from Column 4 of the table to section S9-3). Foods not required to bear a label are exempt from the requirements have use a bold font for required names, the use of a statement of ingredient or summary statement location requirements. In this case, the use of a bold font is voluntary. However, for consistency, the use of a bold font for the required names is preferred if it makes the allergen declaration prominent and legible.
Processing aids can be grouped together.	**Ingredients** …processing aids (**soy**, **milk**, **egg**). **Contains: soy, milk, egg.**	The order of the grouping is not specified in the Code, however for the purpose of consistency, the grouping can be in descending order of ingoing weight, which aligns with practices applied when composing a statement of ingredients.

4.1.11 PRECAUTIONARY ALLERGEN LABELLING

Precautionary allergen labelling (PAL) is a voluntary statement displaying allergens that may be present due to cross contact. A PAL statement is not considered to be a mandatory allergen declaration as described in Standard 1.2.3 of the Code.

Cross contact allergens occur when a residue or other trace amount of an allergen is unintentionally incorporated into another food.

Clear and consistent PAL statements, when applied using a science based risk assessment, are as important as a correctly displayed statement of ingredients and summary statement because the three elements together enable consumers with food allergy and their carers to identify foods that are safe to eat, and those that they should avoid.

An example of PAL is shown in Figure 2. *The allergen labelling elements of an ingredient list* of this Guide.

The declaration of a cross contact allergen in a PAL statement does not diminish the requirement to apply HACCP and GMP to ensure that the cross contact allergen is present at the lowest practicable level and is controlled at this level.

The inconsistent use of standardised or generic PAL statements can lead to consumer distrust of the product label and is often assumed to be 'FBOs protecting themselves' rather than informing the consumer of the true allergen status of the food.

Using statements such as 'manufactured on equipment that also processes xxx' or 'made in a facility that also makes products on the same production line containing xxx' are confusing and fail to communicate the risks presented by such products to the allergic consumer.

However, when PAL is applied after a robust scientific risk-based assessment process, which involves the reduction and/or elimination of cross contact allergens wherever possible, and is described in a clear, accurate and consistent manner, it enables consumers to trust the information provided.

Presentation of a PAL Statement

To achieve consistency within the food industry the general recommendations for declaring allergens in a PAL statement are as follows:

FORMAT

- When a VITAL risk assessment has been applied (refer to this Guide, section 4.1.12 *The Voluntary Incidental Trace Allergen Labelling (VITAL®) Program)*, the PAL statement should be printed in the following format:
  May be present: allergen x, allergen y.
- Use the same typeface and text size as any required name in the statement of ingredients.
- Print in a bold font that provides a distinct contrast with any other text except for the summary statement and the required names in the statement of ingredients.

LOCATION

- Display the PAL statement separately from but next to the summary statement.
- The preferred location is below the allergen summary statement on a separate line as shown in Figure 2. *The allergen labelling elements of an ingredient list* of this Guide.
- The PAL statement cannot be located such that it prevents the summary statement from being directly next to the statement of ingredients (for example it cannot be between the statement of ingredients and the summary statement).
- If a summary statement is not used because there are no allergens in the statement of ingredients, display where the summary statement would usually be located.

TERMINOLOGY

- Declare cross contact allergens, when assessed as being present at Action Level 2 in the VITAL Program, using the required names set out in Column 3 of the table to section S9-3 (except in the case of cereals).
- For cereals, use the required name set out in Column 3 and where the cereal contains gluten, also declare ‘gluten’.
- If ‘gluten’ is already declared in the summary statement, it is not necessary to repeat it in the PAL statement.
- If more than one cereal is present at Action Level 2, each should be declared separately in the PAL statement. e.g., **May be present: barley, oats, rye, gluten.**
- If more than one tree nut is present at Action Level 2, each should be declared separately in the PAL statement. e.g., **May be present: almond, hazelnut.**
- The terms ‘other cereals’ or ‘other tree nuts’ are only acceptable when there are other allergens from the group which are listed in the summary statement and the terms are used to provide clarification. For example, **May be present: other cereals (barley, gluten).**
  Or **May be present: other tree nuts (cashew, pine nut, Brazil nut).**
- Cross contact allergens should be listed individually. Avoid, wherever practicable, the use of terms which describe a group of allergens – these include ‘cereals containing gluten’, ‘cereals’ and ‘tree nuts’.
- There may be situations where, after a thorough risk review has been completed and opportunities to reduce or eliminate cross contact allergens have been exhausted, FBOs may need to apply a PAL statement that declares all (or virtually all) tree nuts or all (or virtually all) cereals containing gluten. In this situation alternative descriptions such as the use of terms which describe a group of allergens may be appropriate to communicate this risk to the allergic consumer.
- Singular terms for allergens are recommended in the PAL statement – however plural terms are also acceptable.

OTHER

- Ensure the PAL statement is logically consistent and is not contradictory to the statement of ingredients or summary statement. For example, if a product contains added soy which is declared in the statement of ingredients and the allergen summary statement, do not also include soy in the PAL statement.
- Alternative PAL statements might be used when a VITAL risk assessment has not been applied. To achieve consistency in the food industry, these statements usually commence with the words “May Contain”.
- The use of alternative PAL statements must consider product liability laws and must not be false, misleading or deceptive. Consumers should have a reasonable expectation that the presence of allergens indicated in a PAL statement is unintended, and the occurrence is random and with relatively low frequency. This does not preclude advice that allergic consumers should not consume a product with PAL statements towards those allergens to which they are sensitive.
- This Guide does not offer examples of alternative PAL statements. It is the FBO’s responsibility to take the above requirements into account when determining an appropriate alternative precautionary allergen statement.

4.1.12 THE VOLUNTARY INCIDENTAL TRACE ALLERGEN LABELLING (VITAL®) PROGRAM

The VITAL Program is a standardised allergen risk assessment process for the food industry. It provides a consistent methodology to assess the impact of allergen cross contact from raw materials and the processing environment. It determines appropriate labelling outcomes for the purpose of PAL statements which are based on quantitative risk assessments by using Action Levels[16] that are underpinned by scientific evidence. The VITAL Program can be used to assist FBOs in presenting allergen labelling information consistently for people with food allergy.

The standardised statement, “**May be present: allergen x, allergen y.**”, is the recommended PAL statement to be used in conjunction with the VITAL Program. This statement should only be used where the VITAL Program has been implemented and the cross contact allergen concentration is determined to be present at Action Level 2[17] .

For a product which has been assessed using the VITAL Program, each opportunity for cross contact should be identified and eliminated. Where elimination is not practicable, cross contact should be reduced wherever possible and controlled to the lowest attainable level.

The use of “**May be present: allergen x, allergen y.**” for an allergen in a PAL statement does not preclude the ongoing requirement to manage and control the allergen at the lowest practicable level.

FBOs implementing VITAL must understand the VITAL Program. Details about the VITAL risk assessment process and a range of tools which support the VITAL Program are available on the Allergen Bureau website including the:

- Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program
- VITAL Online (web-based VITAL Calculator)
- VITAL Best Practice Labelling Guide for Australia and New Zealand
- Allergen Risk Review website.

Allergen Risk Review Anomaly – Dark Chocolate

In commercial operations, where dark chocolate is manufactured following the production of milk chocolate, milk remains in the dark chocolate at variable (and not insignificant) levels. The milk cross contact concentration is often above the VITAL Program Action Level 2 where precautionary allergen labelling is recommended. This is also above the allergic consumer and their carer's expectation of trace or minimal milk levels.

The risk review anomaly occurs where the milk is not an intended ingredient nor is it included as part of the recipe as an ingredient, additive or processing aid in the product but is present at potentially significant levels. It falls outside the mandatory labelling requirements in Standard 1.2.3 of the Code and does not necessarily fit with the principles of best practice risk review and PAL.

Guidance for food industry on the dark chocolate allergen risk review anomaly which includes key guiding principles and a decision tree is available on the Australian Industry (Ai) Group website and the Allergen Risk Review website. This guidance is specific to dark chocolate only and cannot be transferred to other ingredients simply because cleaning and GMP practices impinge on allergen management best practice.

4.2 LABEL ARTWORK APPROVAL & SIGNOFF

FBOs should have processes in place for reviewing and approving their allergen declarations on label artwork. Individuals responsible for compiling information, reviewing and approving the artwork, labels and product information should have:

- An understanding of the requirements for allergen labelling – both regulatory and best practice.
- Access to up to date information about the product, including any changes that have been made to the formulation, ingredients or processing that may affect the allergen status.
- An understanding of how the information will be presented on the package. For example, an ink jet code might only consist of an allergen declaration, however, a package that has a front of pack label, back of pack label, neck label and print on the cap, may require more detailed consideration about the placement of any allergen declarations, and clarity and consistency of other information.

Finished Product Specification

Records should be maintained detailing the allergen status and the format of the allergen labelling declaration for every product – this can be done in the form of specification or an artwork brief and may be recorded as a document or a within an electronic database. A process for checking and approving the allergen declaration within the specification should be in place.

Label Artwork

Records of the review of label artwork should be maintained. This should document who reviewed the artwork, any requests for changes, and details of the final approval. A process for checking and approving the final artwork or packaging should be in place.

When reviewing the allergen information on label artwork, the information in Table 9 should be considered.

Table 9 Packaging considerations

Packaging aspect	Consideration
Statement of ingredients	Does it declare allergens present in the food? Do these allergens meet the format, location and terminology requirements of the Code?
Summary statement	Is it consistent with the information in the statement of ingredients? Does it meet the format, location and terminology requirements of the Code? Is it clear? Does it make sense? Are there any contradictions that can be removed or corrected?
Precautionary allergen labelling (PAL) statement	Is it clear? Does it make sense? Are there any contradictions that can be removed or corrected?
Claims or statements	Does the label contain any claims about the allergen status of the food? Are these correct and substantiated?
Impressions	Are there any words, images or graphics on the label that give the consumer an impression of the allergen status of the food? Are the impressions consistent with the allergen status of the food?
Differentiation	How does the allergen information on this artwork compare to others in the product range? Is there sufficient differentiation for a consumer to recognise differences in allergen status throughout the range?
Foods in small packages	Does the package declare allergens present in the food?
Packages that bear more than one label	Is the information on all label components clear and consistent?
Foods with inner and outer packages, including trays & cases	Does the information on all packaging formats align?

Change Approval Process

Changes to product formulations, ingredients and processing conditions need to be risk assessed, documented, and approved prior to any changes being implemented. If there is a change to the allergen status of the product, the labelling must be updated prior to product reaching the market.

4.3 ALLERGEN FREE CLAIMS

Allergen free claims are claims that food companies use that emphasise the absence of an allergen in a food product. Allergen free claims are intended for consumers with food allergy. An example of an allergen free claim is 'Egg Free'.

Free From

Consumers with food allergy may seek out products that make claims that they are 'free' from an allergen. Products with a free from claim must not have any ingredients or derivatives of that allergen formulated directly into the product. Also, the product must not have any cross contact for that allergen at any level, and therefore does not require a PAL statement identifying that allergen as a cross contact risk.

There are no requirements set out in the Code for making allergen free claims, so the criteria for making the claim falls to each company and consumer laws. When making an allergen free claim, the manufacturer is targeting a high-risk population, and therefore more stringent risk management controls than those described in this Guide are required. Allergen free claims should be supported by documented evidence of the controls and measures in place, and where possible, relevant and appropriate analysis should be applied to support these claims. To provide a safe product in this context it is critical to apply all established parameters of allergen management with the utmost stringency and to understand the consumer's perception of 'free'.

Further information is available on the Allergen Bureau website.

Consumer Law and Free Claims

The Australian Competition and Consumer Commission (ACCC) and the New Zealand Commerce Commission view 'free' to literally mean 'zero' or 'no traces' and is particularly likely to do so in relation to allergen free claims given the reliance that affected consumers might place on such a claim. Claims that a food is free of an allergen, in the absence of any specific regulation to the contrary, should therefore be understood in terms of three conditions:

- the food should not have the allergen present as an ingredient, or as any ingredient components, or as a food additive or processing aid (including as an additive or processing aid in an ingredient component) as set out in section 1.2.3—4 of the Code;
- the food and its ingredients should be produced in an environment where the allergen is not present and not subject to cross contact (noting that this may be by the use of dedicated lines and equipment, or by ensuring a relevant AMP is in place ensuring that the allergen is not present); and
- the allergen should not be detectable in the food using a current recognised test method such as Association of Official Analytical Chemists (AOAC) or alternate accepted method.

The final point should be treated as a confirmation process of the previous points rather than in substitution for them.

It follows from this approach that it is inconsistent for a product to contain both a PAL statement and a 'free' claim in relation to the same allergen.

Gluten Free and Lactose Free Claims

A 'gluten free' claim, and a 'low gluten' claim are nutrition content claims, the conditions of which are set out in Standard 1.2.7 *Nutrition, health and related claims* and Schedule 4 of the Code. In Australia and New Zealand, a gluten free food must not contain detectable gluten. The method of analysis to detect gluten or the detection limits are not specified. This criterion differs in other countries. For example, in the US and in Europe, a gluten free product can contain less than 20 parts per million (ppm) of gluten. Care is required when importing foods and ingredients from overseas, as the supplier may not have considered the Australian and New Zealand criteria for gluten free.

The food industry should not assume that foods that do not contain added cereals containing gluten are gluten free. The presence of cereal traces, cereal cross contact, highly refined cereals or products derived from these may not constitute gluten free. An example is the presence of cereals into other grains or legumes as a result of agricultural co-mingling.

A 'lactose free' claim, and a 'low lactose' claim are nutrition content claims, the conditions of which are set out in Standard 1.2.7 and Schedule 4 of the Code. In Australia and New Zealand, a lactose free food must not contain detectable lactose. The term 'dairy free' is not regulated by the Code. A 'dairy free' claim should only be used on products where the manufacturer has verified that the product does not contain milk or milk products as an ingredient or a cross contact allergen.

Manufacturers and importers need to further consider the impact of 'free' claims as markers used by consumers for allergen purposes. Care should be taken with wheat free claims as they may give the impression to consumers that the product is gluten free. A wheat free claim may not necessarily mean that the product is free from gluten, as other cereals containing gluten may have been used as an ingredient. Additionally, to some consumers a lactose free claim may imply the product is dairy free when this may not necessarily be the case. The need to highlight allergen presence (whether intentional or incidental) is elevated in such circumstances, for example by making a more prominent 'contains' allergen declaration than might otherwise be considered.

4.4 ALLERGEN COMMUNICATION

This section of the Guide focuses on consumer facing communications in relation to the allergen status of food products.

Alerting Changes to Allergen Status of Existing Products

Recipe reformulation, variations in ingredient supply, or changes to production process, line or facility, can result in changes to the allergen status of a food. When this occurs, updating the allergen declaration on labels is required. However, without careful reading of the label it may not be obvious to a consumer that the allergen status of the food has changed. Additionally, a consumer may not realise that the original product and the reformulated one may be in a store, or in their pantry, at the same time.

Clearly communicating any changes to the allergen status of a product on the front of the pack can assist with alerting consumers. Possible approaches to altering the label or package so that it is visually different include:

- changing a product's name or descriptor
- changing colours or other visuals on the label
- including a temporary flash or icon alerting the allergen change.

Figure 3: Examples of graphics that indicate a change to allergen status

In addition to front of pack communications, consideration should be given to alerting consumers with food allergy through patient support organisations such as Allergy & Anaphylaxis Australia (A&AA) or Allergy New Zealand, and Coeliac Australia/New Zealand. These organisations can notify their members of the nature and timing of the change to support the company. Information can also be communicated via a company website or social media.

When determining the duration of an alert, consider shelf life and stock in trade practices (e.g. first-in, first-out).

Packaging Differentiation

When designing packaging artwork, consideration should be given towards providing a visual cue that distinguishes between products of different allergen status. An example is a range of pasta sauces that share the same branding. This range consists of both cream and tomato-based variants which have different allergens. Labels bearing clear visual differences can help shoppers recognise the variants more easily, reducing the chance of an incorrect purchase.

A company should review each product range and identify the potential for consumer confusion. Consider whether there are similar products with different allergen status within a product range, their proximity in-store and/or online, and whether products can be readily substituted for each other.

If determined to be of moderate to high potential for consumer confusion, then the company should differentiate the products using measures such as:

- colour of packaging and label
- using other visual cues such as ingredient pictures
- creating differences in visual appearance of the product (within the package)
- consistent location of variant descriptor across the range.

Alternatively, consider only using formulations that harmonise the allergens across similar products.

A food packed in different formats should have the same allergen status and declaration

Consumers may assume that the allergen status of a food is always the same, even when that food is sold in various packaging formats.

In commercial operations, products sold in more than one pack format, or size, may require slight variations in composition (such as a less viscous formulation for a squeeze bottle). They may also be manufactured in different facilities or lines (such as filled into cans or pouches). This can result in different allergens being declared on the various packaging formats.

Business should make every effort to ensure that the allergen status and declarations on a food that is packed in various formats, are consistent.

1. Consider aligning formulations so that allergens present in the food, and therefore declared in the ingredient list and allergen summary statement, are the same
2. Where differences in manufacturing lines, equipment or facilities result in inconsistent cross contact allergens, business should eliminate or reduce cross contact wherever practicable. PAL statements should be aligned amongst the packaging formats.

If alignment is not possible, then measures to visually differentiate products outlined above should be employed.

Parallel Imports

Parallel imports are foods that resemble locally produced brands that are imported and sold into Australia or New Zealand outside of formal manufacturer distribution channels and without authorisation of the manufacturer. Due to the branding and overall appearance of the packaging, it may be difficult for a person with food allergy to recognise that they are purchasing a parallel import. The consumer may not realise that the allergen status of these imported foods may be different to the same food from an Australian or New Zealand authorised supplier.

A seller or supplier of parallel imports is required to ensure the product complies with the mandatory allergen declaration requirements of the Code. When a company becomes aware of the existence of a parallel import being sold within their market, if the allergen status of the imported food is different, the company may wish to alert consumers through their website or through social media.

Other Forms of Communication

Product labels are no longer the only means by which to communicate the allergen status of a food product.

In Store Demonstrations

Manufacturers should assess the need for in-store demonstrators to provide consumer advice about the presence of allergenic ingredients, as consumers often do not have the opportunity to read the label before tasting the product.

Online Shopping

With the increasing rates of online grocery shopping, people with food allergy will rely more heavily on online food label information. This information should be presented in a way that assists consumers with their purchasing choice. Vigilance is required in ensuring online information regarding the ingredient and allergen content is correct as shoppers are likely to assume that this information reflects the food that will be delivered.

It is critical the information online clearly reflects what is on pack. Food manufacturers should have procedures in place that alert retailers and distributers when the allergen status of a food changes so that the shopping websites can be updated.

For those who maintain the websites, it is recommended that measures are in place to ensure that the online food label information is up to date. An example is to include the date of the label upload and artwork version control information.

Websites, Social Media etc.

Many companies provide product information via their own website or social media. As with the provision of allergen information on product packaging, it is critical that information provided on a company's website or through social media is up to date and consistent with product packaging which is in the marketplace. Consideration is needed for clear communication when there are different versions of a label in the marketplace such as old stock in trade potentially having a different allergen status compared to new stock. Additionally, allergen product lists should be kept up to date and aligned with the foods for sale.

Consumer and Customer Contact

Many companies operate Consumer or Customer Care Lines or Call Centres providing the opportunity for consumers to seek information about the allergen status of a product.

Call Centre staff must be trained and have access to up to date information about the product, including any changes that have been made to the formulation, ingredients or processing that may affect the allergen status.

What to Do When a Consumer Reports an Allergic Reaction to Your Product?

In the event of a business being contacted by a consumer or authority regarding an alleged allergic reaction to a product, the report should be evaluated and investigated carefully in order to determine the next course of action. See Appendix 6.1 *Management of Reports of an Alleged Allergic Reaction* for guidance on how to conduct the review.

5. FOOD RECALLS

FSANZ describe a food recall as an action taken by a food business to remove unsafe food from distribution, sale and consumption[18]. A consumer level food recall involves the removal of unsafe or unsuitable food from all points in the production and distribution networks including any affected food in the possession of consumers. The public must be informed of a consumer level recall and this usually involves the use of media such as newspaper advertisements, point of sale notices and publication of information about the recall by FSANZ and/or MPI on their website and social media sites.

Australian food recall data is collected and collated by FSANZ to identify common trends and problems occurring across the food industry in Australia. In the last decade, most recalls (30% of all) have been conducted due to undeclared allergens (266 recalls in total). During this time, the most common allergen related recall was undeclared milk (30% of all allergen related recalls), the second being undeclared peanut (18% of all allergen related recalls).

Undeclared food allergen recalls have been steadily increasing over the last ten years in Australia and over the last five years in New Zealand.

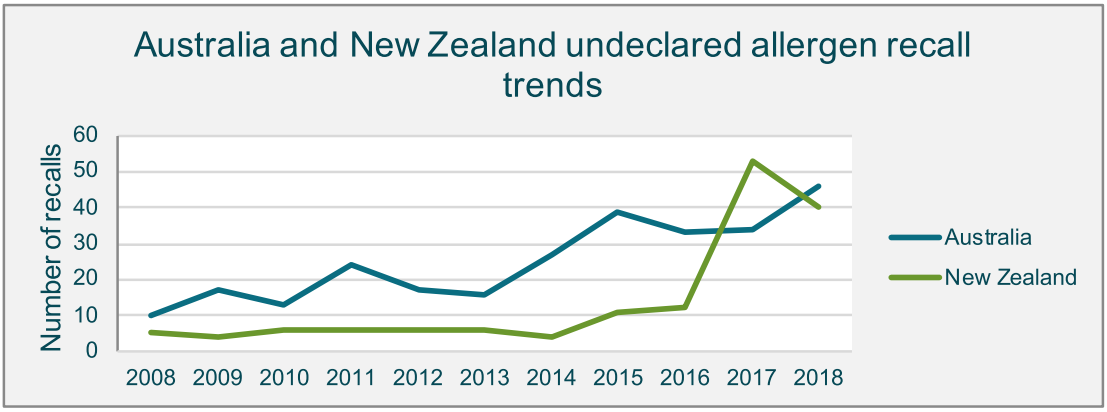
The most common reasons for undeclared allergen recalls coordinated by FSANZ are:

- lack of skills and knowledge
- supplier verification issues e.g. ingredients
- packaging errors
- accidental cross contact in raw materials and finished product.

The Ministry for Primary Industries coordinates food recalls in New Zealand and publishes recall information on their website. Notifications of all food product recalls are shared between Australia (FSANZ) and New Zealand (MPI) irrespective of whether the recalled product is sold in that country.

Further information on food recalls is available from the FSANZ website and the MPI website.

Figure 4: Undeclared allergen recall trends



Cost Impact of a Food Recall

Undertaking a food recall is a major commercial expense, with the additional risk of very serious adverse publicity and brand damage. Costs incurred as a result of a food recall may be due to:

- potentially ceasing production
- loss of time when investigating the cause
- cost to recall the product from distribution and/or point of sale
- loss of sales
- disposal of the unsafe product
- disposal of incorrectly printed packaging / labels
- communicating the recall
- loss of reputation with retailers and consumers
- restocking
- legal action.

Have a Food Recall Plan in Place

All food companies should have a documented Food Recall Plan which can be implemented if a food safety issue is identified. The food recall plan should include an allergen related communications plan with a designated, responsible person identified to provide information to customers, consumers, and regulatory authorities in a timely manner. The plan should include an up to date allergen related stakeholder contact list.

Information about preparing a Food Recall plan for foods sold in Australia is available on the FSANZ website, and in New Zealand on the MPI website.

FSANZ also provide the Food Industry Recall Protocol which is a useful resource that provides information on how to recall foods in Australia. The crisis management page on the AFGC website provides an ANZ Product Recall / Withdrawal form which is an industry-agreed template to be used for the recall or withdrawal of products from leading Australian and New Zealand retailers.

Mock Recall

Conducting a mock recall assists with identifying gaps demonstrating the ability to withdraw and recall affected product, contacting relevant customers, and maintaining records of these incidents. The traceability system should be tested at least annually with results documented and corrective actions implemented. Traceability should be achievable within two to four hours.

Recall Communication

In the event of a product recall due to the presence of an undeclared allergen, it is important that companies communicate information in a timely manner. In addition to communication via the required recall notification protocols, other channels such as the company website and social media should also be considered. Online solutions are also available to both Australia and New Zealand that assist with communicating food recalls and withdrawals to trading partners and regulators.

All food companies should have a documented Food Recall Plan which can be implemented if a food safety issue is identified.

6. APPENDIX

6.1 MANAGEMENT OF REPORTS OF AN ALLEGED ALLERGIC REACTION

Each company should maintain, as part of their food safety plan, a recording and reporting process for contacts related to allergic reactions. Additionally, in Australia under the ACCC mandatory reporting requirements, manufacturers and/or suppliers are required to report consumer goods including foods associated with the death or serious injury or illness of any person. The guideline clearly includes severe allergic reaction, such as anaphylaxis or contact dermatitis. All reports of allergic reactions should be evaluated and investigated as necessary by appropriately skilled and knowledgeable officers of the company. Factors to consider as part of the evaluation are described below.

1. Contact or Complaint Receival of an Allergic Reaction to a Product.

The initial contact may occur in the form of a consumer complaint or through correspondence from another authority (e.g. State Health Authority) or patient support organisation (e.g. A&AA) who was notified by the consumer.

Upon receival, the contact should be transcribed, and a record generated. Where possible, additional information relating to the consumer or contact to assist with investigating the incident further should be captured. This may include:

- name, address and phone number of the complainant
- details of the contact including the circumstances of the event
- details of the food product including date marks/ batch number, customer order
- details of the location, date and time of purchase
- details of other people involved in the incident
- allergen of concern (what food or substance the consumer is allergic to)
- description of symptoms, whether medication was administered, whether medical treatment was sought
- disposition of the suspect food, whether any of the product was retained
- whether the same food had been consumed before
- other foods eaten at the time
- reason the complainant suspects that this is the food that triggered the reaction
- time between eating the food and the reaction
- obtaining the sample food for future escalation and analysis if required.

All records created regarding consumers are subject to the Australian Privacy Act 2018 and the New Zealand Privacy Act of 2018. Notwithstanding any further investigation, in Australia all anaphylaxis or other severe allergic reactions should be reported to the ACCC within 2 days of the initial notification. Consumers must provide their express permission to share their details with the ACCC else only manufacturer details may be provided. Manufacturers and/or suppliers must also provide their consent for the ACCC to disclose their reported incident to FSANZ and the corresponding State or Territory food regulators.

As previously mentioned in Death from Anaphylactic Reaction in this Guide (section 1.1 *Food Allergy & Anaphylaxis),* since late 2018 Victorian hospitals are required to notify the Department of Health and Human Services of all anaphylaxis presentations.

2. Preliminary Evaluation and Investigation

Investigations should be conducted in a timely manner. Preliminary investigation should rapidly gather and evaluate relevant consumer, product and manufacturer data to allow an expeditious evaluation of the situation and determine the level of consumer risk.

- Determine if the consumer has any known sensitivities.
- Determine if the consumer is sensitive to an ingredient in the product as declared.
- If the consumer is sensitive to an ingredient as declared determine why the consumer was exposed to the product and if there are any circumstances which would warrant further action.
- Determine if the consumer is sensitive to an ingredient in the product PAL statement.
- If the consumer is sensitive to an ingredient declared in the PAL statement determine why the consumer was exposed to the product and if there are any circumstances which would warrant further action.
- Determine the manufacturing location and review production records to affirm potential presence of allergen in the food.
- Where the consumer is sensitive but not to an ingredient as declared or in the PAL statement, determine if there is a potential source associated with the product and/or manufacturing site.
- Considerations:
  - Is the material present in the product but not declared?
  - Is the material present on the same line?
  - Is the material present on the manufacturing site?
  - Could the material be contaminated prior to arrival on site?
  - Could the product have been contaminated post leaving the manufacturer?
- Review production records to determine the likelihood of the source allergen in the food, including:
  - manufacturing records/lot, time of manufacture/ production schedule order
  - cleaning records
  - ingredient records
  - procedural divergence (e.g. incorrect tool use, poor cross contact controls, storage and handling control)
  - mislabelling/wrong product packed
  - use of rework
  - recipe changes
- Review records to determine if any other similar incidents have occurred, consider products:
  - from the same batch
  - from the same line
  - with the same ingredients
- Ensure all correspondence and findings from the investigation are recorded.
- Multiple incidence of similar allergic response over the same batch of products or products from the same facility must trigger immediate attention from company managers for more detailed investigation and actions.
- Internal tracking of the suspect product may include holding further sale or distribution of suspect product.

3. Detailed Investigation and Analysis

Where possible, the product causing the allergic reaction should be retrieved to assist with the investigation. Based on the preliminary investigation, allergen analysis of the product may be warranted.

Where a product/process/ingredient failure is determined through preliminary investigation, allergen analysis may not be required, and the incident can move to Point 4. Report, Resolve and Monitor.

Allergen analysis may be warranted when there is no clear attributable source to the allergic reaction and multiple similar incidents have been reported. Although analysis may not necessarily yield positive results, it is recommended because it provides valuable data for investigation and trouble shooting and even a negative result can provide information. Analysis results need to consider a range of factors including the form of the allergen (particulate versus readily dispersed), the sensitivity of the test, the sampling plan (number of samples taken for the analysis), the matrix of the sample and the age of the sample.

To ensure appropriate sample preparation and analysis, competent personnel or laboratories familiar with allergen testing techniques and limitations should be used. Expert advice may be sought from industry and testing experts.

Based on preliminary investigation, additional samples of suspect product or materials may also be sourced for confirmatory analysis or evaluation. Care should be taken to maintain the integrity of the sample(s) and prevent any contamination or spoilage. Careful consideration is with required with the choice of sampling plan and sample size. Acceptable Quality Limit (AQL) statistical sampling may be a useful guide.

4. Report, Resolve and Monitor

Products that contain allergens as described in section 1.2.3—4 of the Code, but which are not declared must be treated with utmost care and seriousness and reported. This may include the initiation of a food recall. See in this Guide section 5 Food Recalls for further information on planning and managing a food recall.

Even isolated allergic reactions should be recorded, and ongoing monitoring put in place to determine potential systemic issues to help in preventing future incidents.

Results of the investigation may also be reported to the original source for evaluation and tracking.

6.2 RECALL CASE STUDIES

Case Study 1: Packaging mix-up

Overview

This case study shows how a slight alteration to process, and a new operator who was inexperienced, led to products being packed in the incorrect pre-printed boxes resulting in a food allergen recall. Allergen management procedures must include steps to control alteration to process and training for new staff, contractors and casuals.

Case Study

Company A uses a high care room where the utensils, ingredients and packaging materials are passed through a small window to ensure that the high care environment is not compromised.

The line has several product changeovers a day, and the company has implemented checks and sign in and sign out clearance sheets to ensure the right pre-printed box is used for the right product at each changeover. At changeover, any leftover boxes from the previous product, are removed from the packing line, placed on a trolley, and wheeled out of the room to the warehouse.

On this day, the line experienced start-up issues and instead of making 5,000 units only 4,500 boxes were packed. Instead of removing the boxes from the room as per standard procedure, the operator placed the unused packaging on the bottom shelf of the trolley, with the intention to take it out of the room at break time, which was in 5 minutes.

A short time later the operator was called to assist with issues at the filler which was located on the other side of the line. Once the problem was resolved, the operator went on break and forgot about the packaging placed on the bottom of the trolley.

In preparation for the next product changeover, the new packaging was passed through the window and placed on the trolley ready for start-up. As this packaging ran low, the next operator (a casual on their first day) called for more to be passed through the window. Unfortunately, there was a slight delay. Noticing the boxes on the bottom of the packaging trolley, the operator loaded them into the magazine to prevent the line from stopping. Five minutes later, more packaging was delivered to the line. The operator completed the packaging check shortly thereafter as per procedure.

Unfortunately, the 500 boxes taken from the bottom of the trolley and loaded into the magazine were for a product that did not contain milk and the product running at the time, did contain milk. This meant that 500 units of product were released containing milk that was not declared. Twenty-five days later the product was recalled.

Case Study 2: Remember the rework

Overview

This case study shows how a simple oversight where a rework matrix was not updated led to a food allergen recall. Allergen management practices must include steps for a complete review of procedures including scheduling, cleaning and rework, whenever there are any changes to the allergen status of products.

Case Study

Company B manufactured a snack product coated in batter for both the retail and food service markets.

To ensure economic viability, the company identified several ways to rework certain products with like formulations into similar products. The Quality Department was responsible for controlling the use of rework. This was done via a version-controlled spreadsheet detailing the allergen content by product formulation (an allergen matrix). The schedulers planned the production order very carefully based on this allergen matrix, which included rework allocations.

The supplier of the batter ingredient offered a newly reformulated alternative which presented cost savings and contained one less allergen with the soy component removed. After assessing the ingredient, trials were conducted and approval to proceed was granted. The appropriate paperwork was completed. The recipe and product artwork were modified, and the rework matrix was updated to remove the soy allergen from the product that used the new batter ingredient. This meant that the updated product could now be reworked into five other products instead of just the one. Use of the new batter ingredient commenced.

Shortly after the supplier advised that they had an issue with the supply of the new batter, due to ingredient availability. Instead, they could provide some batter from the previous formulation that contained soy as they still had some old stock available.

The Company had a pending snack order that was urgent and agreed to receive a small quantity of the previous batter formulation as a short-term supply solution. The Company's procedures were adjusted and the old version of the label that declared soy was used for this product run. When the customer order was filled, paperwork was changed back to the new formulation and the Company was pleased they had managed to avoid an out of stock situation.

Two weeks later at a tasting of another product, it was noticed that the batter was slightly different in texture to standard. This texture was typical to when soy was in the recipe. A review of the records from the production showed no soy recipes appeared to have been used. The stock was released, and no further action was taken.

The company was informed that a consumer had had an allergic reaction to soy whilst eating one of their products. The date code was provided, and the Quality Department commenced an investigation.

A review of the production records showed no evidence of where the soy could have come from. Allergen testing of the retention sample found it was positive for soy.

Upon further investigation into the records it was found when the site had changed its recipes for the one-off production to prevent the out of stock, they had not updated the rework matrix to reflect limited use of waste from that one run. As such the rework had been used in another product. At the time there had been no update made to the rework matrix to manage the change, nor any documentation to hold the rework produced. The product was recalled.

7. ENDNOTES

1 The University of Manchester InformAll Allergenic Food Database http://research.bmh.manchester.ac.uk/informall/allergenic-foods. Accessed 08/09/19

2 Osborne NJ, Koplin JJ, Martin PE, Gurrin LC, Lowe AJ, Matheson MC 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.

3 Tang ML, Mullins RJ. Food allergy: is prevalence increasing? Intern Med J. 2017 Mar;47(3):256-261

4 Hefle, S.L., Nordlee, J.A. & Taylor, S.L. 1996. Allergenic foods. Crit. Rev. Food Sci. Nutr., 36: S69-S89

5 CODEX STAN 1-1985 General Standard for the Labelling of Prepackaged Foods

6 ASCIA – Australasian Society of Clinical Immunology and Allergy

7 Coroners Court of Victoria, Finding into Death without Inquest. Case ID 586613, June 2016

8 Coeliac Australia - https://www.coeliac.org.au/coeliac-disease/. Accessed 02/01/2019

9 FSANZ, http://www.foodstandards.gov.au/consumer/additives/sulphite/Pages/default.aspx. Accessed 09/04/2019

10 Source: ASCIA https://www.allergy.org.au/patients/other-allergy/sulfite-allergy. Accessed 30/08/2019

11 For completeness, MPI also employ Officers to enforce the law in this regard.

12 FARRP is based at the University of Nebraska-Lincoln

13 US Food & Drug Administration Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). Accessed 14.04.19

14 https://www.allergy.org.au/patients/food-allergy/cows-milk-dairy-allergy, ASCIA, accessed 30 June 2018.

15 European Commission (2017) Official Journal of the European Union (2017/C 428/01)

16 Action Levels are the concentrations (of protein) which define the labelling outcomes for each cross contact allergen. They are determined using the Reference Dose and the Reference Amount.

17 Action Level 2 represents a significant concentration of a cross contact allergen which may cause an adverse reaction in a sensitive person and a PAL statement for the allergen is required.

18 FSANZ http://www.foodstandards.gov.au/industry/foodrecalls/Pages/default.aspx. Accessed 11.04.19