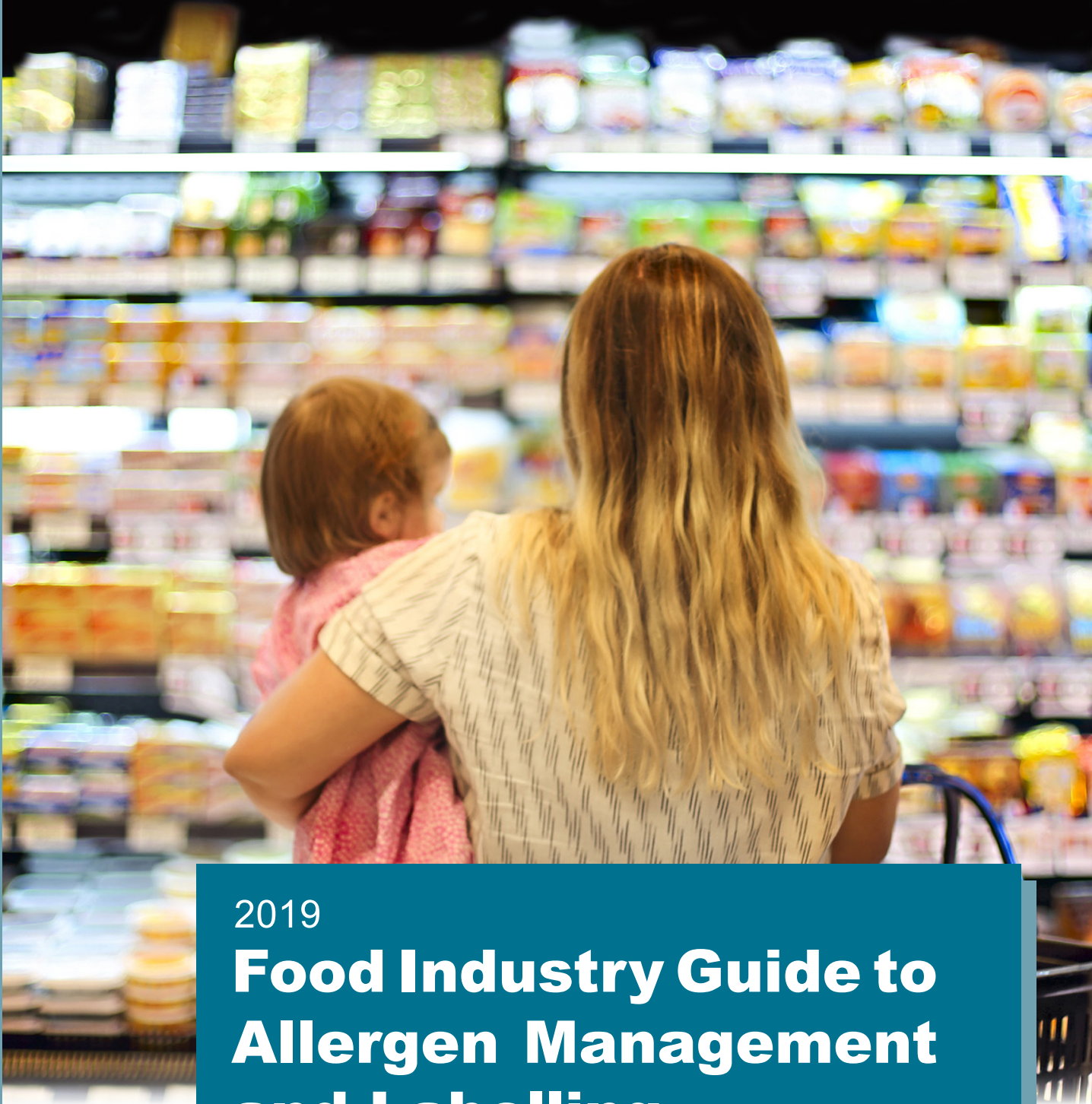




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2019

# **Food Industry Guide to Allergen Management and Labelling**

For Australia and New Zealand



The Allergen Bureau is the peak industry body representing food industry allergen management in Australia and New Zealand. Our mission is to provide consistent, science-based, allergen risk assessment and labelling. 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. The Allergen Bureau was established in 2005 and operates on a membership basis.

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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.

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#### 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)

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# 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 companies (including manufacturers, marketers 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 sell products with a known allergen status.

Food companies have a responsibility to fully understand the allergen status of their food products. Knowing the allergen status of a food includes 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 substances that are listed in the Australia New Zealand Food Standards Code (the Code) Section 1.2.3—4 *Mandatory declaration of certain foods or substances in food*.

### *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](http://www.afgc.org.au)) and Allergen Bureau ([www.allergenbureau.net](http://www.allergenbureau.net)) websites.

## Scope

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

- food ingredient manufacture and supply – both local and imported
- manufacture of packaged food for bulk sale, including business to business
- manufacture of packaged finished product (retail ready)
- imported packaged foods.

***This Guide is relevant to all sectors of the food industry involved in the supply, handling, production, distribution and sale of 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<sup>1</sup>. 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%)<sup>2</sup>.

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<sup>3</sup>.

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](http://www.allergy.org.au)

More than 170 different foods and ingredients have been identified as potential allergens<sup>4</sup>. 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<sup>5</sup> and, in Australia and New Zealand, sesame and lupin. Allergens of importance can vary by global region, for example, buckwheat is an allergen in Japan and Korea.

The Code requires the mandatory allergen declaration of ten (10) food allergens and sulphites (refer to [Table 2: Mandatory declaration requirements for certain foods or substances in Australia and New Zealand](#) in this Guide). 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<sup>6</sup> 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."<sup>7</sup>

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<sup>8</sup>. 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<sup>9</sup>. A small number of people with asthma can experience wheezing, chest tightness and coughing<sup>10</sup> 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 food company needing information on 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)<sup>11</sup>.

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 including the mandatory declaration of allergens.

### Packaged and Non-packaged Foods Allergen Labelling Requirements

A food for sale in a package must bear an attached label which specifies the allergen status of the food. This includes packaged food sold to caterers.

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 item of food not in a package must be accompanied by labelling stating the allergens present in the food.

### Mandatory Allergen Declaration Requirements

The Code sets out the mandatory declaration requirements for foods and substances that are allergens. Standard *1.2.3 Information requirements – warning statements, advisory statements and declarations* requires the mandatory declaration of certain foods or substances in food where the food or substance 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 or food used as a processing aid or an ingredient or component of such a substance or food.

The allergens (when present as described above) that are required to be declared are listed in Table 2.

**Table 2: Mandatory declaration requirements for certain foods or substances in Australia and New Zealand**

Food or substances that ...		Further Information
<b>require mandatory declaration</b>	<b>are exempt from mandatory declaration</b>	<i>Note: Columns 1 and 2 are based on the Code Section 1.2.3—4 Mandatory declaration of certain foods or substances in food. For column 3, where applicable, the Code is referenced. If not referenced, the information is guidance.</i>
<b>Added sulphites in concentrations of 10 mg/kg or more</b>	NIL	Unlike true food allergens which are usually proteins, sulphites are a mineral and are widely used as a food additive.  Further information about sulphites is discussed below this table.
<b>Cereals containing gluten, namely wheat, rye, barley, oats and spelt and their hybridised strains, and their products</b>	where these substances are present in beer and spirits; or  alcohol distilled from wheat; or  glucose syrups that are made from wheat starch and that:  (a) have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable; and  (b) have a gluten protein content that does not exceed 20 mg/kg.	Within a statement of ingredients, where the generic name “cereals” or “starch” is used, the specific name of the cereal or source of the starch must be declared where the cereal is wheat, rye, barley, oats or spelt or a hybridised strain of those cereals [Schedule 10-2 of the Code].
<b>Crustacea and crustacea products</b>	NIL	Within a statement of ingredients, where the generic name “fish” is used, the specific name of the crustacea must be declared [Schedule 10-2 of the Code].  Examples of crustacea include crabs, prawns, lobsters
<b>Egg and egg products</b>	NIL	This should include all avian (bird) eggs.
<b>Fish and fish products</b>	isinglass derived from swim bladders and used as a clarifying agent in beer or wine	Within a statement of ingredients, the generic name “fish” can be used [Schedule 10-2 of the Code].  Refer to the earlier section of this table for further information about crustacea.  Further information about fish is discussed below this table.
<b>Milk and milk products</b>	alcohol distilled from whey	This should include the mammary secretion of all milking animals [Section 1.1.2—3 of the Code].  Further information about milk is discussed below this table.

Continued...Table 2: Mandatory declaration requirements for certain foods or substances in Australia and New Zealand

Food or substances that ...		Further Information
<b>require mandatory declaration</b>	<b>are exempt from mandatory declaration</b>	<i>Note: Columns 1 and 2 are based on the Code Section 1.2.3—4 Mandatory declaration of certain foods or substances in food. For column 3, where applicable, the Code is referenced. If not referenced, the information is guidance.</i>
<b>Peanuts and their products</b>	NIL	Within a statement of ingredients, where the generic name “fats or oils” is used, and the source of the fat or oil is peanut, the peanut source must be declared. Additionally, where the generic term “nuts” is used, the specific name of the nut must be declared [Schedule 10-2 of the Code]
<b>Soybeans and their products</b>	soybean oil that has been degummed, neutralised, bleached and deodorised; or  soybean derivatives that are a tocopherol or a phytosterol	Within a statement of ingredients, where the generic name “fats or oils” is used, and if the source of oil is soybeans and the oil has not been degummed, neutralised, bleached and deodorised, the soybean source must be declared [Schedule 10-2 of the Code]
<b>Sesame seeds and their products</b>	NIL	Within a statement of ingredients, where the generic name “fats or oils” is used, and the source of the fat or oil is sesame, the sesame source must be declared [Schedule 10-2 of the Code].
<b>Tree nuts, and their products</b>	coconut from the fruit of the palm <i>Cocos nucifera</i>	Within a statement of ingredients, where the generic name “nuts” is used, the specific name of the nut must be declared [Schedule 10-2 of the Code].  Further information about tree nuts is discussed below this table.
<b>Lupin and their products</b>	NIL	Within a statement of ingredients, where the generic name “fats or oils” is used, and the source of the fat or oil is lupin, the lupin source must be declared [Schedule 10-2 of the Code].

## Further Information About Sulphites, Fish, Milk, Tree Nuts

**Sulphites** are substances used as a food additive that generally 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 in concentrations of 10mg/kg or more [Standard 1.2.3]. This should apply even when sulphite additives are not required to be declared in an ingredient list, such as 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].

**Fish** - Standard 1.2.3 requires the declaration of the presence of fish but does not provide specific information about which fish are to be declared. Fish, however, is defined in Standard 2.2.3 *Fish and fish products* as meaning:

*a cold-blooded aquatic vertebrate or aquatic invertebrate including shellfish, but not including amphibians or reptiles.*

For example, cold-blooded aquatic vertebrates may include bony and cartilaginous fish such as fin fish,

shark, rays and eels. Aquatic invertebrates may include molluscs such as clams, cockles, oysters, scallops, octopus, squid, cuttlefish, calamari, or sea cucumbers, sea urchins, jelly fish.

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 presence of either or both fish and crustacea is declared.

**Milk** is defined in Section 1.1.2—3 *Definitions – particular foods* of the Code as meaning:

- a) *the mammary secretion of milking animals, obtained from one or more milkings for consumption as liquid milk or for further processing, but excluding colostrums; or*
- b) *such a product with phytosterols, phytostanols and their esters added.*

Cow's milk is a common cause of food allergy in infants. In Australia and New Zealand, approximately 2% of infants are allergic to cow's milk. 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.<sup>12</sup>

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 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.

***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.***



**Tree Nuts** - Standard 1.2.3 of the Code requires the declaration of the presence of tree nuts other than coconut (from the fruit of the palm *Cocos nucifera*) but does not specify the tree nuts to be declared.

The Code provides a list of tree nuts in Schedule 22 under Nuts and seeds as follows:

*Almonds; Beech nuts; Brazil nut; Cashew nut; Chestnuts; Coconut; Hazelnuts; Hickory nuts; Japanese horse-chestnut; Macadamia nuts; Pecan; Pine nuts; Pili nuts; Pistachio nuts; Sapucaia nut; Walnuts*

It should be noted though that Schedule 22 describes foods and classes of foods for use by a select group of Standards in the Code, this group does not include Standard 1.2.3. As such this list should not be taken as a definitive representation of the types of allergenic tree nuts that are intended to be declared on food labels. Other nuts such as shea nuts and candle nuts may also need to be considered. Also, coconut (from the fruit of the palm *Cocos nucifera*) is included the Tree nuts list in Schedule 22 but is specifically excluded in Section 1.2.3-4 of the Code.

## 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.*

### Plain English Allergen Labelling (PEAL) (P1044)

Under Proposal 1044 (P1044), FSANZ is considering variations to the Code to provide clarity in allergen declaration requirements, and to require the use of plain English allergen labelling (PEAL) as a means of improving allergen information for consumers. PEAL is considered to be the use of clear and unambiguous terms in allergen declarations, primarily by reference to the specific source for the allergen.

**Reference:** [P1044](#)

## 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 labelled 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)<sup>13</sup> 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.

Suppliers and producers 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<sup>14</sup>). Therefore, a company 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 3 summarises the key principles and practices for best practice allergen management for facilities manufacturing, handling and packaging food products.





**Table 3: Key principles and practices for best practice allergen management for facilities manufacturing, handling and packaging food products**

Area	Key principles and practices for <i>best practice</i> 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 Plan	A documented food recall plan in place which has been tested through mock recall exercises.

For further detail about each area listed in Table 3, 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**



### 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 on food packaging is one of the most important means of communication for people with food allergy when deciding if a product is suitable and safe for them to consume. Increasing use of online shopping means that allergen information in electronic formats should also be accurate, clear and consistent with the allergen information on the food packaging.

Regardless of whether allergen declarations are on labels, provided on specifications, through verbal communication for unpackaged foods, or made available online, the process to determine the allergen status of a food is the same. In this Guide, [section 3.2 Allergen Risk Review](#) discusses the aspects of a thorough investigation of the allergen status of a food. After this information is collected, it can be transcribed into a format (usually an ingredient list) for consumers to access.

### This section of the Guide

- Describes allergen labelling best practice, which includes guidance for composing a voluntary allergen summary statement and voluntary precautionary allergen statement.
- Provides recommended allergen labelling formats for industry to adopt. Alternative labelling options are provided in recognition of constraints due to label size, legibility and other variables, while still promoting overall consistency and clarity of allergen information. In adopting one of these labelling formats, industry will assist consumers by providing greater consistency in the presentation, legibility and ease of identifying product allergen information.
- Describes the importance of clearly communicating the allergen status of foods and provides guidance on the management and communication of a change in allergen status of a food product. It also provides industry with guidance on the management of reports in relation to alleged allergic reactions to a food the company has supplied.



## 4.1 ALLERGEN LABELLING BEST PRACTICE

As described in this Guide (section 2.2 *Australia New Zealand Food Standards Code*), the Code sets out the mandatory declaration requirements for foods and substances that are allergens, but (other than legibility) does not specify formatting requirements for this information. For example, there is no requirement for the placement of the declarations, how food allergens should be declared and if and how precautionary allergen labelling statements should be made.

The allergen labelling guidance in this document is voluntary and represents industry best practice. It aims to assist the food industry with making allergen declarations and provide consumers with clear and consistent information.

### General Labelling Recommendations

The general allergen labelling recommendations are:

- All allergen information should be grouped together to be easily identified and not hidden amongst other labelling information.
- Allergens should be described using plain English terms consistent with the Code.
- Legibility requirements are specified in Section 1.2.1—24 of the Code.
- The print size should be big enough to be easily read, preferably at a minimum 1.5 mm sans-serif font, and the font colour should contrast distinctly from the background. The use of lower or upper case will depend on the overall presentation of labelling information.
- Product description and representation should provide an accurate expectation of the food and should not be misleading.
- Similar products with different allergens should be clearly and easily distinguishable.

### Describe Allergens in Plain English Terms

Consumers can potentially misunderstand allergen declarations when the terms used to describe the allergens are inconsistent or unfamiliar to them. For example, the ingredient sodium caseinate may not be recognised by a consumer as being a milk product.

When declaring food allergens, use descriptions that are in plain English and are consistent with the terminology used in Section 1.2.3—4 of the Code. For example, 'sodium caseinate (milk)'.

### Understand the Allergenic Nature of Ingredients

To declare ingredients that are (or contain) allergens accurately, manufacturers need to be aware of the nature of the ingredients they use in their products, and whether there are components in compound ingredients, additives and processing aids that are derived from an allergen.

Examples include:

1. Additives, processing aids and vitamins may be combined with carriers or diluents derived from allergens. Suppliers of ingredients, additives and processing aids have a responsibility to provide their customers with information on allergens contained in their products.
2. Some ingredients are grown on a fermentation substrate that may be an allergen. The Allergen Bureau describes some of the decisions required when assessing the allergen status of foods and food ingredients that are produced using bacteria, yeasts and other micro-organisms in a fermentation process in Appendix One of [Unexpected Allergens In Food](#). It is also discussed in the AFGC Product Information Form (PIF) V6.0 [User Guide](#) (Dec 2018)

The requirement to declare the presence of cereals containing gluten serves two purposes. People who are allergic to wheat can identify its presence and those who are gluten intolerant can identify the cereals that contain gluten. If the term 'gluten' or the term 'cereals containing gluten' is used, ensure that the individual cereal is also declared.



Although most food allergens are proteins, these proteins are usually not denatured under normal food processing conditions and are relatively resistant to digestion. It should not be assumed that normal food manufacturing processes will make a food less allergenic. Foods and ingredients that contain denatured proteins can still trigger an allergic reaction in a food allergic individual. An exception may be a food that has been extensively hydrolysed and then tested in robust clinical studies. In all cases, the allergen must still be declared unless it falls under an allergen labelling exemption.

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 is not detected using analysis, however the food is the product of an allergen source.

Some ingredients undergo processes which remove most of the allergenic proteins. Unless that ingredient falls under 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/or have been assessed by FSANZ as safe and suitable for people who have allergies. These are generally known as allergen labelling exemptions, are listed in Section 1.2.3—4 of the Code, and do not require mandatory declaration. A summary of the allergen labelling exemptions currently listed in the Code is in [Table 2](#).

### 4.1.1 RECOMMENDED ALLERGEN LABELLING FORMAT

Allergen labelling information can consist of an ingredient list, an allergen summary statement and a precautionary allergen statement, of which some elements are mandatory and others voluntary. This is shown in Table 4.

**Table 4: Allergen labelling elements**

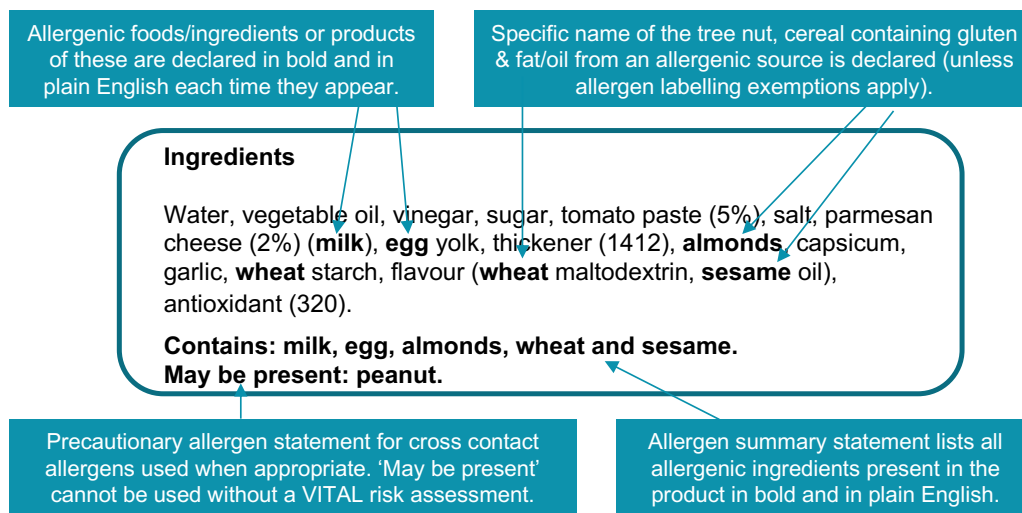
Element	Description	Mandatory/Voluntary
<b>Ingredient list</b>	A statement of ingredients including the allergens and their products when present in the food for sale.	Mandatory allergen declaration is required on the label of packaged food. This is usually located within the ingredient list.
<b>Allergen summary statement</b>	A statement that summarises the allergens and their products when present in the food. Summary statements begin with the word “Contains”.	Voluntary
<b>Precautionary allergen statement</b>	Statement of cross contact allergens.	Voluntary

A consistent approach in the presentation of allergen information will help consumers with food allergy more quickly and easily identify foods of concern, helping to minimise accidental consumption of unsuitable foods. The recommended best practice labelling format includes:

- an ingredient list declaring in **bold** the allergens and products of these;
- an allergen summary statement using the word 'contains'; and
- a precautionary allergen statement if required. The VITAL Program's "**May be present: allergen x, allergen y.**" is recommended after conducting a VITAL risk assessment.

Figure 2 sets out an example of a best practice allergen labelling format.

**Figure 2: Best practice labelling format**



Although some packaged foods do not require an ingredient list, allergens must still be declared when they are present. The allergens should be labelled in an easily identified format such as in an allergen summary statement.

Examples of some packaged foods that do not require an ingredient list include:

- individual portion packs with an outer package [Standard 1.2.1]
- foods in small packages [defined in Standard 1.1.2]
- foods where the name of the food is the allergen [Standard 1.2.4]
- packaged and labelled water [Standard 1.2.4]
- a standardised alcoholic beverage [Standard 1.2.4].



### 4.1.2 COMPOSITION OF ALLERGEN LABELLING INFORMATION

Table 5 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 5: Process for composing an allergen declaration – packaged foods**

Step	Description	Reference/Resource
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.	<ul style="list-style-type: none"> <li>• AFGC - Product Information Form (PIF)</li> <li>• Allergen Bureau - Allergen Risk Review website</li> </ul>
3	Identify allergens in the product using the formulation and ingredient information, including: <ul style="list-style-type: none"> <li>• Ingredients</li> <li>• Food additives</li> <li>• Processing aids</li> <li>• Compound ingredients</li> <li>• Cross contact from ingredients</li> </ul>	<ul style="list-style-type: none"> <li>• ANZ Food Standards Code Standard 1.2.3</li> <li>• AFGC - Product Information Form (PIF)</li> <li>• AFGC &amp; Allergen Bureau– Food Industry Guide to Allergen Management and Labelling</li> <li>• Allergen Bureau - Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program</li> <li>• Allergen Bureau - Unexpected Allergens in Food</li> </ul>
4	Compose the ingredient list and declare the allergens formulated into the product.	<ul style="list-style-type: none"> <li>• ANZ Food Standards Code Standard 1.2.3</li> <li>• AFGC &amp; Allergen Bureau– Food Industry Guide to Allergen Management and Labelling</li> <li>• Allergen Bureau - VITAL Best Practice Labelling Guide for ANZ</li> </ul>
5	Conduct a VITAL risk assessment to determine the presence of cross contact allergens from ingredients and processing.	<ul style="list-style-type: none"> <li>• Allergen Bureau - Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program</li> <li>• Allergen Bureau – VITAL Online (web-based VITAL calculator)</li> <li>• Allergen Bureau – VITAL Q&amp;As</li> <li>• Allergen Bureau - Allergen Risk Review website</li> </ul>
6	Finalise allergen labelling: <ul style="list-style-type: none"> <li>• confirm the allergens in the ingredient list,</li> <li>• confirm the allergen summary statement, and</li> <li>• compose the appropriate precautionary allergen statement</li> </ul>	<ul style="list-style-type: none"> <li>• Allergen Bureau – VITAL Online (web-based VITAL calculator)</li> <li>• AFGC &amp; Allergen Bureau– Food Industry Guide to Allergen Management and Labelling</li> <li>• Allergen Bureau - VITAL Best Practice Labelling Guide for ANZ</li> </ul>



### 4.1.3 PRESENTATION OF AN INGREDIENT LIST

The general recommendations for declaring allergens in an ingredient list are:

- All allergenic foods/ingredients or products of these (as per Section 1.2.3—4 of the Code) are declared in the ingredient list each time an ingredient containing the allergen is listed.
- Allergens are declared in **bold** each time they appear in the ingredient list.
- The specific name of the allergenic components of ingredients are declared in bold e.g. Sodium Caseinate (**milk**).
- The specific name of the cereal containing gluten is declared.
- The specific name of each tree nut is declared, not the generic term nuts or tree nuts.
- Declare in bold any allergens present due to food additives and/or processing aids.
- Declare any sulphite ingredients, additives or processing aids as per Standard 1.2.4 of the Code, declare in bold when present in concentrations of 10mg/kg or more.

An example of this formatting is shown in [Figure 2: Best practice labelling format](#) of this Guide.

### Ingredient List Alternatives

To provide flexibility, alternative allergen labelling approaches are listed below. Refer to [Appendix 6.1 Alternative labelling formats](#) in this Guide for further information.

When an allergen summary statement is used in conjunction with the ingredient list:

- Bolding of the allergens in the ingredient list is optional (but is highly recommended).
- The specific name of each allergen does not have to be used within the ingredient list when the allergen summary statement uses the allergen terms described in the Section 1.2.3—4 and Schedule 10 of the Code.

An example of this formatting is shown in [Appendix 6.1 Figure 5: Alternative labelling format 1](#).

When there is no allergen summary statement following the ingredient list:

- Allergens should be declared in bold in the ingredient list.
- The specific name of the allergens should be declared using the terms described in Section 1.2.3—4 of the Code e.g. vegetable oil (soy) or soybean oil.
- When processing aids are allergens or components of allergens, they must be declared as per Section 1.2.3—4 of the Code. This may be a generic statement, such as 'processing aids contain allergen x, allergen y.' and should appear on a separate line at the end of the ingredient list.
- The use of ingredient substitution where one ingredient is an allergen and the other is not e.g. wheat or corn starch, should be avoided where possible. Where unavoidable, the declaration of substitute ingredients should highlight the allergen such as 'sunflower oil or **peanut** oil' or '**wheat** starch or corn starch', or 'hydrolysed vegetable protein (corn or **soy**)'.

An example of this formatting is shown in [Appendix 6.1 Figure 6: Alternative labelling format 2](#) of this Guide.



#### 4.1.4 PRESENTATION OF AN ALLERGEN SUMMARY STATEMENT

The general recommendations for declaring allergens in an allergen summary statement are:

- List the allergens present in the food using the terms set out in Section 1.2.3—4 of the Code.
- Declare as '**Contains: allergen x, allergen y.**' and position directly beneath the ingredient list on a separate line in bold.
- Use the same text size as the ingredient list, or at a minimum print size of 1.5mm.
- Apply to the packaging of single ingredient foods where the product name does not include the name of the allergen e.g. For a pack of Edamame beans, the allergen summary statement could be '**Contains: soy.**'
- Declare each specific cereal containing gluten, alternatively use the general term 'cereals containing gluten' if there is more than one cereal containing gluten present, and the individual cereals are specified in the ingredient list.
- Declare the specific name of the tree nut, alternatively use the general term 'tree nuts', if there is more than one tree nut present, and the individual tree nuts are specified in the ingredient list. The term 'nuts' should not be used at any time.
- Declare any allergens present due to food additives and/or processing aids.
- The allergens stated in the allergen summary statement should align with the information in the ingredient list.

An example of this formatting is shown in [Figure 2: Best practice labelling format](#) of this Guide.

#### Allergen Summary Statement Alternatives

- The summary statement may be declared as 'Ingredients contain...' or 'Contains allergens from...' or words of similar intent.
- A summary statement may be omitted if the allergens are declared in the ingredient list and qualified using the terms listed in Section 1.2.3—4 of the Code and are declared in bold.

An example of this formatting is shown in [Appendix 6.1 Figure 6: Alternative labelling format 2](#) of this Guide.

The allergen summary statement should be limited to declaring the presence of allergens in the product and should not be used to indicate other features e.g. 'contains 10% milk fat'. Allergen summary statements should be clear and any other 'contains' statement should be separated from the allergen information.

#### 4.1.5 PRECAUTIONARY ALLERGEN LABELLING (PAL)

Allergen cross contact occurs when a residue or other trace amount of an allergen is unintentionally incorporated into another food. Clear and consistent labelling of cross contact allergens assists consumers with a food allergy and their carers to identify foods that are safe for them to eat, and those that they should avoid. 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.

Inconsistent use of PAL statements can lead to consumer distrust of the product label and are sometimes seen as ‘manufacturers 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.

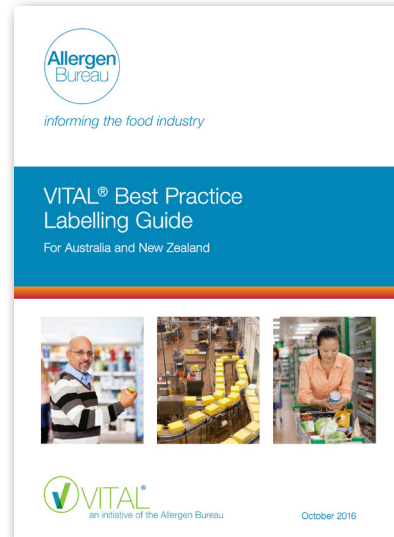
However, when PAL is applied after a robust scientific risk-based assessment process, which involves the reduction and/or elimination of cross contact allergens wherever possible, and is described in a clear, accurate and consistent manner, it enables consumers to trust the information provided.

#### Presentation of a Precautionary Allergen Labelling (PAL) Statement

The general recommendations for declaring allergens in a PAL statement are:

- List the cross contact allergens using terms set out in Section 1.2.3—4 of the Code.

- When a VITAL risk assessment has been applied (refer to this Guide, section 4.1.6 *The Voluntary Incidental Trace Allergen Labelling (VITAL®) Program*), declare the cross contact allergens as “**May be present: allergen x, allergen y.**” refer to the [VITAL Best Practice Labelling Guide for Australia and New Zealand](#) for further information.



- The PAL statement is positioned below the allergen summary statement on a separate line in bold.
- Ensure the PAL statement makes sense and is not contradictory to the ingredients list or allergen summary statement. For example, if a product contains added soy which is declared in the ingredient list and the allergen summary statement, do not also include soy in the PAL statement.
- Use the same text size as the ingredient list, or at a minimum print size of 1.5mm.

An example of this formatting is shown in [Figure 2: Best practice labelling format](#) of this Guide.

#### PAL Alternatives

- Alternative PAL statements might be used when VITAL risk assessment has not been applied.
- 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 manufacturer's responsibility to take the above requirements into account when determining an appropriate alternative precautionary allergen statement.

#### 4.1.6 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<sup>15</sup> that are underpinned by scientific evidence. The VITAL Program can be used to assist food producers 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<sup>16</sup>. The "May be present" statement is placed below the ingredient list and the allergen summary statement on a separate line in bold.

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.

Food companies implementing VITAL must refer to 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 Bureau [website](#). This guidance is specific to dark chocolate only and cannot be transferred to other ingredients or food simply because cleaning and GMP practices impinge on allergen management best practice.

## 4.2 LABEL ARTWORK APPROVAL & SIGNOFF

Each food business 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 may only require an allergen summary statement, however, a package that has a front of pack label, back of pack label, neck label and print on the cap, may require considerations for the placement of the allergen declaration, and clarity and consistency of other information.

**Table 6. Packaging considerations**

Packaging aspect	Consideration
Ingredient list	Does it declare allergens present in the food?
Allergen summary statement	Does it align with the information in the ingredient list?  Is it clear? Does it make sense? Are there any contradictions that can be removed or corrected?
Precautionary allergen 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?

## 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 6 should be considered.

## 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 a sub-ingredient, or as a food additive or processing aid (including as an additive or processing aid in a sub-ingredient) 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 distributors 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 6.2 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<sup>17</sup>. 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.

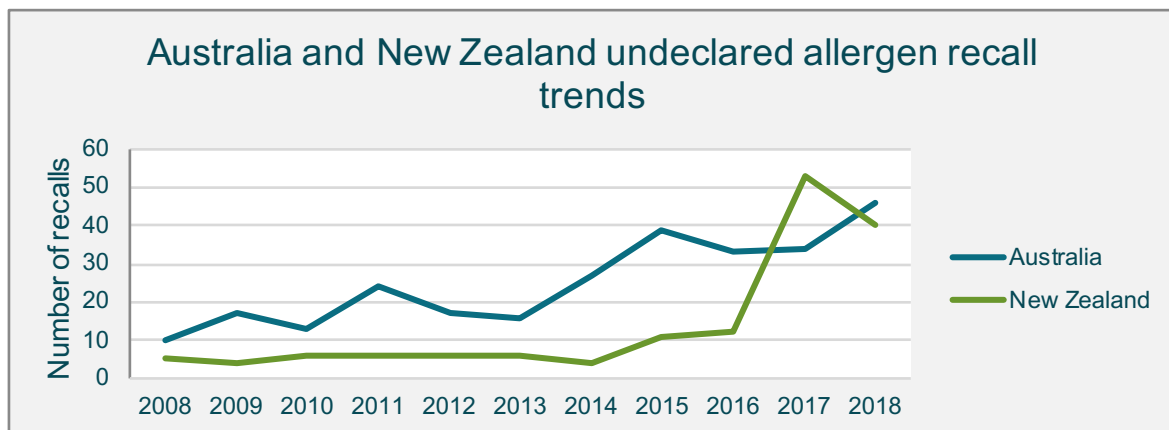
The most common reasons for undeclared allergen recalls coordinated by FSANZ are:

- 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

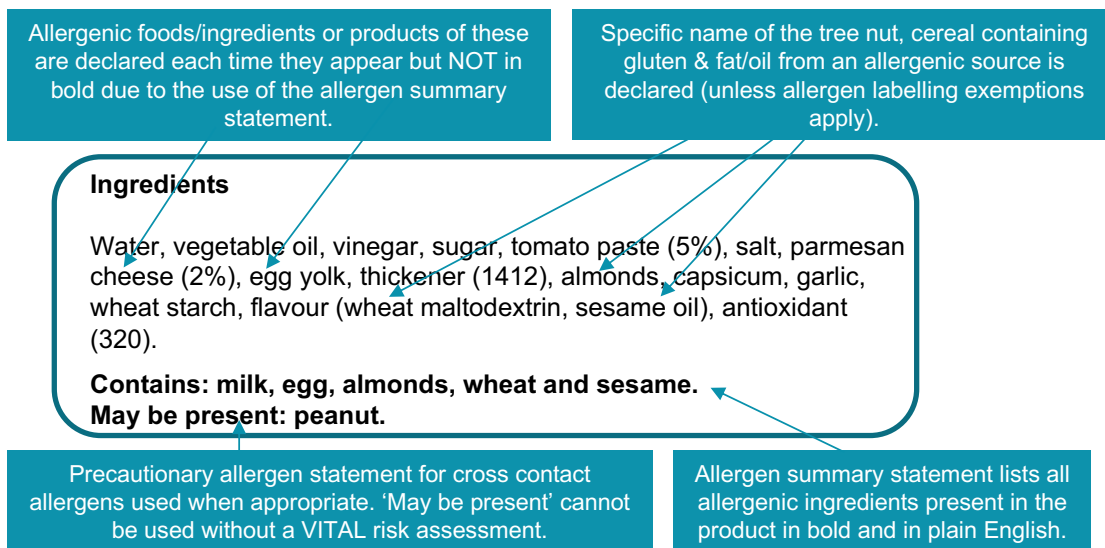
### 6.1 ALTERNATIVE LABELLING FORMATS

In this Guide, section 4.1 *Allergen Labelling Best Practice* describes the best practice allergen labelling format. It lists the general recommendations and some alternatives for declaring allergens in an ingredient list, and an allergen summary statement and if required a PAL statement. This section also provides guidance on recommended labelling alternatives from the best practice format. Alternative allergen labelling approaches provide flexibility where label size constraints and other variables do not permit the use of the best practice labelling format, while ensuring the goal of providing accurate consumer information.

Recommended labelling alternatives are shown in the following figures.

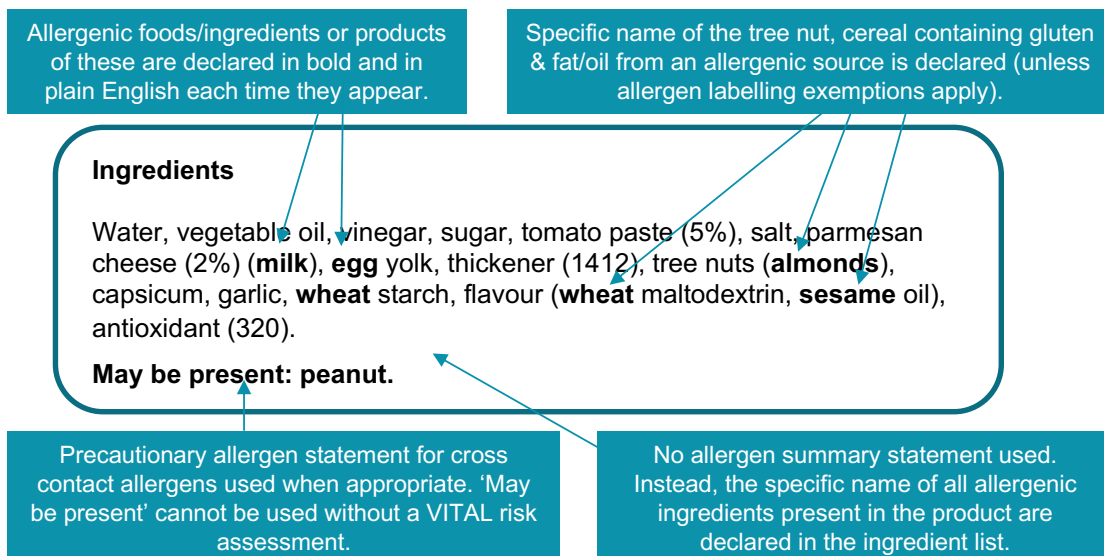
**Alternative labelling format 1:** Bolding and qualifying allergen in the ingredient list is optional when an allergen summary statement is present.

**Figure 5: Alternative labelling format 1**



**Alternative labelling format 2:** When an allergen summary statement is not present, allergens are bolded and qualified within the ingredient list.

**Figure 6: Alternative labelling format 2**



## 6.2 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.

## 6.3 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 ASCIA <https://www.allergy.org.au/patients/food-allergy/cows-milk-dairy-allergy>. Accessed 30 June 2018.
- 13 FARRP is based at the University of Nebraska-Lincoln
- 14 US Food & Drug Administration [Food Allergen Labeling and Consumer Protection Act of 2004 \(FALCPA\)](#).  
Accessed 14.04.19
- 15 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.
- 16 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.
- 17 FSANZ <http://www.foodstandards.gov.au/industry/foodrecalls/Pages/default.aspx>. Accessed 11.04.19