Allergen Bureau

Food Allergen Fundamentals

An introduction to the core allergen principles for the food industry

August 2021

Food Allergen Fundamentals

introduces the food industry to **core allergen principles** required to identify, manage and declare allergens in foods.

Refer to the guide (known as FIGAML) for more comprehensive information.

allergenbureau.net/industry-guidance

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Food Allergen Fundamentals

Core allergen principles
Food allergy & food intolerance
Regulatory requirements
Allergen management
Allergen labelling & communication

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Food allergy & food intolerance

This section describes

- food allergy
- anaphylaxis
- food intolerance
- Coeliac disease

Food allergy

A food allergy is an overreaction by the body's immune system to a certain food.

The body produces antibodies against a food protein and releases histamine and other chemicals causing inflammation.

An allergic reaction often occurs within minutes, though can take place up to two hours after ingestion.

Small amounts of an allergen can trigger a reaction and avoidance of the allergen is the only way to manage the condition.

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Food allergen

A normally harmless substance that triggers an allergic reaction. Most food allergens are proteins. A food may comprise of one or more allergenic proteins.

Cow's milk, for example, contains allergenic proteins in the whey fraction and different allergenic proteins in the casein fraction. Individuals may be allergic to only one milk protein or more.

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For this training, an 'allergen' is a food which requires a mandatory allergen declaration.

Food allergy

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

In Australia & New Zealand, food allergy occurs in approx. 10% of infants, 4-8% of children, and 2% of adults*

*ASCIA 2021
www.allergy.org.au

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Anaphylaxis

Anaphylaxis is a severe allergic reaction involving swelling of the airways and can be fatal if not treated with adrenaline within minutes.

In rare cases multiple organ systems are affected and death can occur in as little as ten minutes.

The incidence of anaphylactic reactions to food in allergic individuals is increasing.

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Individuals with food allergy may be at risk of anaphylaxis.

Impact of food allergy

There is currently no cure.

Sensitivity differs between individuals and depends on type of food, amount ingested and other activities at time of ingestion.

People with food allergy do not know when their next allergic reaction will occur or how severe it will be.

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Avoidance of the food is the only protection.

Foods of public health significance in ANZ with the potential to cause

allergic reactions

Wheat (of the genus *Triticum*, including spelt, and its hybridised strain such as triticale)

Any of these tree nuts
almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio, walnut

Crustacea

Lupin

Peanut

Egg

Milk

Sesame seed

Fish

Mollusc

Soybean

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Food intolerance

A food intolerance is an adverse reaction to a food but does not involve the immune system.

Often dose related, it includes reactions to non-protein substances in foods like carbohydrates, chemicals, food additives, toxins and irritants.

Unlike food allergy, symptoms can occur many hours after ingestion.

An example is lactose intolerance

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Foods of public health significance in ANZ with
the potential to cause non-allergic, hypersensitivity reactions. Also known as…

food intolerance

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Added sulphites in concentrations of 10mg/kg or more

Any of these cereals containing gluten wheat, barley, oats, rye and their hybrids

Lactose intolerance is due to a sugar naturally occurring in milk

Coeliac disease

Individuals diagnosed with coeliac disease have gluten intolerance.

It is a genetic immune disease caused by gluten, a protein in wheat, rye, barley, oats and their various subspecies and hybridised strains.

About 1 in 70 people in Australia and New Zealand are affected.

A gluten free diet must be strictly adhered to.

Wheat allergy & gluten intolerance are not the same.

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Lactose intolerance

A person who is lactose intolerant cannot digest the sugar component in milk. This is different to an allergy to milk protein. Declaring milk on a label informs individuals with milk allergy and those with lactose intolerance of the presence of the protein and the lactose.

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Sulphite intolerance

Sulphites are naturally found in some foods. They can also be added to a food (as an additive) to perform a technological purpose.

Sulphite intolerance can trigger asthma symptoms in individuals with underlying asthma.

Regulatory Requirements

This section describes

- ANZ food regulations
- ANZ mandatory allergen declaration requirements
- International food allergen regulation

Food business organisations who offer foods for sale in ANZ are required to declare certain allergens when present in a food.

ANZ food regulations

Food Acts & product liability laws require food to be safe, suitable and to comply with relevant laws including the Australia New Zealand Food Standards Code (the Code).

The Code sets out specific requirements including the mandatory declaration of allergens.

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The FSANZ website provides more information.
Go to www.foodstandards.gov.au

ANZ allergen labelling requirements

Most of the allergen declaration requirements are set out in Chapter 1 in the Code with additional information in Schedule 9 which lists the allergens to be declared.

The allergen declaration requirements are very comprehensive and apply to packaged foods, non packaged foods, foods offered for retail sale, foods for catering purposes and all other foods.

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The FSANZ website provides more information.
Go to www.foodstandards.gov.au

ANZ allergen labelling requirements

In general, certain allergens must be declared when present in a food as:

- an ingredient; or
- an ingredient of a compound ingredient; or
- a food additive (including its components/ ingredients); or
- a processing aid (including its components/ ingredients)

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The FSANZ website provides more information.
Go to www.foodstandards.gov.au

ANZ allergen labelling requirements

There are allergen labelling exemptions where some foods or substances have undergone processing steps and/or have been assessed as safe and suitable for people who have allergies. These do not require mandatory declaration.

See the Column 2 of the table to section S9-3 of Schedule 9 *Mandatory advisory statements and declarations* in the Code.

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The FSANZ website provides more information.
Go to www.foodstandards.gov.au

International food allergen regulation

Imported foods offered for sale in ANZ must comply with the Code and Food Acts.

It cannot be assumed that allergen information provided with imported foods and ingredients will automatically comply with ANZ requirements because allergen labelling requirements can differ across countries and regions.

All imported foods and ingredients should be checked carefully for compliance before being offered for sale.

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Refer to FIGAML on the Allergen Bureau website for more information. allergenbureau.net/industry-guidance

Allergen management

This section describes

1. Allergen management
2. Allergen risk review
3. Allergen analysis

The food industry uses this knowledge to identify and manage allergens within their facilities and to determine if cross contact allergens are to be declared.

Allergen management

The procedures, policies and practices contributing to the control of allergens within a food business.

This should be considered as a fundamental element of existing food safety management plans and processes including Good Manufacturing Practice.

HACCP Plans should be adapted to include allergens as an independent category of food safety hazard.

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Allergen management

BOTH

- are documented systematic approaches
- identify allergen risks & allergen challenges in manufacturing
- cover all aspects of the supply chain / supply matrix

BUT

although similar,
they are not the same

Allergen risk review

Allergen risk review

The process of thoroughly investigating the allergen status of food.

This begins with raw materials and continues throughout the manufacturing process until the food is packed and labelled.

The information collected in an allergen risk review can be used to inform both:

- an allergen management program
- a risk assessment

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Allergen Risk Review website

A web based interactive ‘Factory Map’ which

- provides detailed information & guidance for conducting an allergen risk review
- includes each aspect that an allergen risk review should address
- by clicking on each icon shows how a risk review impacts that production step

Resources!

allergenbureau.net/risk-review

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Food Allergen Analysis is useful to....

Establish the allergen status of ingredients

Target problem pieces of equipment

Inform the risk assessment

Confirm VITAL assumptions

Verify final product status in high-risk environments

Monitor effects of critical changes

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

Different types of analytical methods are available (i.e. ELISA, Lateral Flow Device and various others) - when choosing the method, it is important to ensure that it is fit for purpose and any limitations are well understood.

The wrong method selection could result in false negative or false positive results, putting your business and the consumer at risk.

Allergen Labelling & Communication

This section describes how FIGAML provides guidance on

- allergen labelling
- allergen communication
- VITAL Program

As well as declaring allergens clearly on packaging, there are several other ways that industry can communicate allergens clearly.

Allergen labelling

Consumers rely on the allergen information on labels – so it is important the information is clear and consistent.

FIGAML provides guidance on ‘allergen labelling best practice’ and effective allergen communication.

The following slides show some examples.

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Required names

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

FIGAML

- provides information about each allergen
- shows examples how a required name is declared

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Ingredient list format

1. Format, location & terminology requirements are set out in the Code.
2. FIGAML shows a preferred format for industry consistency.
3. In the statement of ingredients, declare allergens using required names in bold.
4. Summary statements are mandatory.
5. Precautionary allergen labelling (PAL) statements may be required when unavoidable cross contact is determined through a science based risk assessment process.

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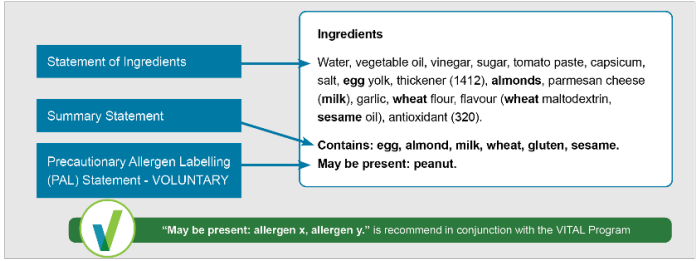
4.1.1 RECOMMENDED ALLERGEN LABELLING FORMAT

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

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

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

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



4.1.2 UNDERSTAND THE ALLERGENIC NATURE OF INGREDIENTS

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

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

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

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

Allergen communication

Industry should consider how a consumer can easily identify:

- when a food is reformulated and the allergens change
- that foods within a product range contain different allergens
- allergens in a food when shopping online or searching websites or using social media
- allergens in a food provided as part of in-store demonstrations

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Refer to FIGAML on the Allergen Bureau website for more information. allergenbureau.net/industry-guidance

Allergen cross contact

A residue or other trace amount of a food allergen that is **unintentionally** incorporated into another food.

Cross contact sources can be from

- agricultural co-mingling into a raw material
- carry-over due to using an ingredient that contains cross contact
- processes using shared manufacturing equipment or concurrent lines
- personnel
- inadequate cleaning of equipment

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The VITAL ® Program

A standardised allergen risk assessment process for food industry.

Provides a consistent methodology for food industry to assess the impact of allergen cross contact and provide appropriate precautionary allergen labelling on their products.

Developed **by** industry **for** industry and is adopted on a voluntary basis

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VOLUNTARY

INCIDENTAL

TRACE

ALLERGEN

LABELLING

The VITAL Program principles

Prerequisite: Allergen Management Plan

1. Identify cross contact allergens.
2. Eliminate cross contact allergens. If not possible reduce them to the lowest practicable level and manage and control them at this level.
3. Quantify cross contact allergens.
4. Compare with the thresholds in VITAL Program.
5. Use PAL where required.
   May be present: allergen x, allergen y.

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Visit the VITAL website to access more information about the VITAL Program.

vital.allergenbureau.net

Be prepared!

All food companies should have a documented Food Recall Plan.

Refer to FIGAML for:

- websites providing information about food recall plans
- information about product recalls and case studies showing how allergen mistakes can occur
- recommended actions for after a consumer contact about an allergic reaction is received

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Essential allergen guidance for the ANZ food business operator

Refer to the guide (known as FIGAML) shown here for more comprehensive information.

allergenbureau.net/industry-guidance

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