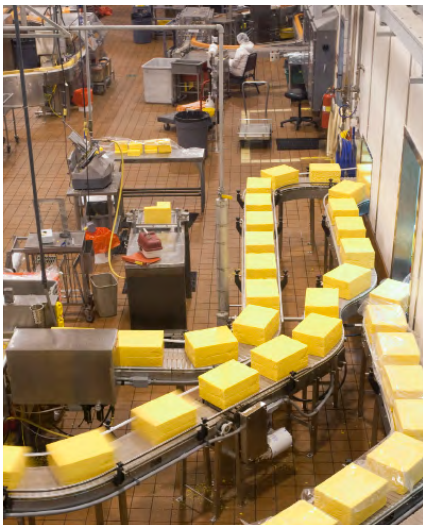
Allergen Bureau

informing the food industry

VITAL® Best Practice Labelling Guide

For Australia and New Zealand



VITAL®
an initiative of the Allergen Bureau

October 2016

Allergen Bureau *informing the food industry*

VITAL®

Disclaimer

The information contained in this document has been developed by the Allergen Bureau VITAL® Phase 2 – Risk Communication (Labelling) Working Group for, and on behalf of, the Allergen Bureau. It is intended that the guidance within this document shall provide the Australian and New Zealand food industry with the tools to achieve best practice allergen labelling, using the Voluntary Incidental Trace Allergen Labelling (VITAL) Program.

This VITAL Best Practice Labelling Guide contains allergen labelling recommendations for the Australian and New Zealand food industry. The labelling recommendations in this guide and the use of the VITAL Program support industry best practise, but do not guarantee compliance with the Australia New Zealand Food Standards Code (FSC) or other relevant legislation at Commonwealth or State or Territory level.

The VITAL Program and this guide may be updated over time as further scientific evidence in relation to allergens and reactions becomes available. It is your responsibility to keep up to date of such developments and to continue your education through all available resources, many of which are accessible on the Allergen Bureau website.

The information in this guide must not be relied upon as legal advice or used as a substitute for legal advice. You should ensure that you have full knowledge of the labelling requirements of the FSC and other legislation (including but not limited to state and territory Food Acts and the Australian and New Zealand consumer laws) and should obtain appropriate expert advice relevant to your particular circumstances.

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1 VITAL LABELLING BEST PRACTICE

1.1 PREFACE

This VITAL® Best Practice Labelling Guide (Guide) was developed by members of the food industry working closely with one of our key stakeholders, Allergy & Anaphylaxis Australia representing people with food allergy. This voluntary collaboration was initiated as the VITAL Phase 2 - Risk Communication (Labelling) Working Group, part of the Allergen Bureau priorities for 2014-2015. The purpose of the Working Group was to facilitate the food industry to move towards more accurate and consistent communication of food allergen information to consumers when using the VITAL (Voluntary Incidental Trace Allergen Labelling) Program.

The key objectives of the Working Group were to:

- Collate existing allergen labelling information to provide food industry with a single list of relevant information; and
- Review existing allergen labelling information and to further develop information that supports clarity and consistency of allergen labelling.

This Guide is for members of the food industry who are using the VITAL Program, have preferably received VITAL training, and who understand the food labelling requirements of the Australia New Zealand Food Standards Code. It is intended to provide the food industry with guidance for declaring allergens on a label, using the outcomes of a VITAL assessment, with the aim of providing clear and consistent information about the allergen status of the product and its suitability for the consumer with food allergy.

1.2 SCOPE

This Guide is made up of the following tools:

- Steps for composing an ingredient list that declares allergens clearly
- Five worked examples that show best practice for declaring food allergens on a label
- A list of definitions of key words used within this Guide
- A list of references to other materials that provide guidance on allergen declaration

This Guide is intended to be used with the VITAL Program and to be read in conjunction with the relevant legislation and guidance documents. These are referenced to support the specific topic being discussed. The core contents of this Guide are the worked examples that demonstrate the outcomes of a VITAL assessment for complex allergen labelling scenarios.

The information in this Guide relates to food products sold within Australia & New Zealand and the allergens listed in the Australia New Zealand Food Standards Code section *1.2.3-4 Mandatory declaration of certain substances in food*.

1.3 STEPS FOR COMPOSING A STATEMENT OF INGREDIENTS WITH CLEAR ALLERGEN STATUS

Step	Description	References/Resources
1	Obtain the product formulation/recipe including amounts of each ingredient.	
2	Obtain Product Information Forms (PIFs) and/or specifications for all ingredients. Ensure all sources of allergens as ingredients and cross contact allergens are identified and recorded.	✓ AFGC - Product Information Form (PIF)
3	Identify allergens in the product using the formulation and ingredient information, including: ✓ Ingredients ✓ Food additives ✓ Processing aids ✓ Compound ingredients ✓ Cross contact ingredients	✓ ANZ Food Standards Code Standard 1.2.3 ✓ AFGC - Product Information Form (PIF) ✓ Allergen Bureau - VITAL Guide (2012) ✓ Allergen Bureau - Unexpected Allergens in Food
4	Compose the ingredient list and declare the allergens formulated into the product.	✓ ANZ Food Standards Code Standard 1.2.3 ✓ AFGC – Allergen Guide ✓ Allergen Bureau - VITAL Best Practice Labelling Guide
5	Conduct a VITAL risk assessment to determine the presence of cross contact allergens from ingredients and processing.	✓ Allergen Bureau - VITAL Guide (2012) ✓ Allergen Bureau – VITAL Online (web-based calculator) ✓ Allergen Bureau – VITAL Q&As
6	Using the VITAL summary of labelling outcomes ✓ confirm the allergens in the ingredient list ✓ confirm the allergen summary statement, and ✓ compose the appropriate precautionary statement	✓ Allergen Bureau – VITAL Online (web-based calculator) ✓ AFGC – Allergen Guide ✓ Allergen Bureau - VITAL Best Practice Labelling Guide

Please note that the titles of some references and resources within this table have been shortened.

➲ Refer to Section 4 of this Guide for full titles and for further information.

1.4 ALLERGEN LABELLING FORMAT

The recommended labelling format for declaring food allergens is based on the Australian Food and Grocery Council 'Food Industry Guide to Allergen Management and Labelling' (AFGC - *Allergen Guide*) which should be considered a key document in understanding allergen labelling for the Australian and New Zealand jurisdictions. The AFGC - *Allergen Guide* establishes key allergen labelling principles upon which the recommendations in this document are based.

The recommended labelling format consists of:

- an ingredient list declaring, in **bold**, allergenic substances and their derivatives; and
- an allergen summary statement; and
- a precautionary statement.

The text size for the ingredient list and all printing on a label should comply with the requirements set by the Food Standard Code. As the allergen summary statement and the precautionary statement are voluntary, the AFGC – *Allergen Guide* recommends that the print size is to be the same size of type as the ingredient list information, or a minimum print size of 1.5mm.

In this Guide, the worked examples show ingredient and allergen declarations using the following format. These descriptors are used to make the text easier to follow, however this tabular format is not required on the label.

Ingredient List:	Mandatory statement that declares **ingredients including added allergenic substances and their derivatives** and must comply with the requirements of the FSC.
Allergen Summary Statement:	Voluntary statement that **summarises the allergens** present in the food due to intentional inclusion as part of the recipe.
Precautionary Statement:	Voluntary statement that declares those **cross contact allergens** which are required as per the VITAL® Program to be included in a precautionary allergen statement (i.e. Action Level 2).

The '**May be present: XXX**' statement is the only precautionary allergen statement to be used in conjunction with the VITAL Program and is an indication to the consumer of a sporadic, unavoidable cross contact with an allergen which may present a risk to the person with food allergy. This precautionary statement is used where a VITAL assessment has been applied and the labelling recommendation for the allergen is at Action Level 2.

1.5 ALLERGEN LABELLING SHOULD BE EASY FOR CONSUMERS TO UNDERSTAND

People with food allergy are challenged with their understanding, and trust, of the allergen information presented on food labels. Food companies can provide useful information by applying best practice as shown in this Guide, and also by considering the overall consistency of the information.
That is, asking: **Is the information clear and does it make sense?**

Consider the perspective of people with food allergy and the people who shop on their behalf. People with food allergy are usually advised to read the ingredient list, and where provided, the allergen summary statement and precautionary statement in their entirety every time the product is purchased. Often they have limited food choices so need to look at the labels of many different foods and brands to supplement their diet. This is done most easily, and with the least errors, where the information is presented in clear language and in a consistent format on each product.

Reviewing labels in detail is time consuming and may be confusing for allergic consumers, particularly when:

- Information in the ingredient list may not be consistent with what is in the allergen summary statement and/or the precautionary statement.
- Generalised allergen claims, such as 'No Known Allergens', are used. Such statements are not meaningful to consumers with food allergy or those shopping for them.
- Allergenic ingredients are described in an unclear way. It is important to remember that people with food allergy and people who shop on their behalf are not experts on ingredient and allergen terminology.

1.6 THE REGULATORY FRAMEWORK

The mandatory requirements for declaring food allergens, for foods sold in Australia and New Zealand, are set out in Standard 1.2.3 of the Australia New Zealand Food Standards Code (FSC). The FSC does not clearly define how to label intentionally added allergens, only that they must be declared. Common practice is to declare such allergens within the statement of ingredients. The FSC does not specify any requirements for declaring an allergen that is unintentionally present. In this instance the VITAL® Program can be used.

This Guide is not a legal document. The requirements for the mandatory declaration of food allergens are set out in the FSC which can be accessed through the Food Standards Australia New Zealand (FSANZ) website.

Other regulations should also be considered. Of particular relevance to allergen labelling is the Competition and Consumer Act 2011 (Aus) and Fair Trading Act 1986 (NZ) which require that products should not be misleading or deceptive.

1.7 THE VITAL PROGRAM

The VITAL® (Voluntary Incidental Trace Allergen Labelling) Program, is a standardised allergen risk assessment process for food industry. The VITAL Program provides a consistent methodology for the food industry to assess the impact of allergen cross contact from raw materials and the processing environment. It determines appropriate precautionary labelling based on risk by using Action Levels that are underpinned by scientific evidence. The VITAL Program can be used to assist food producers in presenting allergen labelling accurately and consistently for people with food allergy.

The VITAL Program consists of a range of tools including:

- VITAL Procedure
- Decision Tree
- Interactive VITAL Action Level Grid
- VITAL Online (web-based VITAL calculator)
- VITAL training materials
- Guidance documents

After applying the VITAL Program, a recommendation is given as to whether or not the cross contact allergen should be declared on the label. The VITAL Program does not provide specific guidance on how to declare cross contact allergens, other than the precautionary statement '**May be present: XXX**', which is the only statement to be used in conjunction with the VITAL Action Levels. Therefore, this Guide makes use of the information from the VITAL Program labelling outcomes and shows the best practice for declaring clear and consistent allergen information on a label.

The VITAL Program is not applicable to foods specifically formulated for infants or other population groups that may have heightened sensitivity to the presence of allergens. The VITAL precautionary statement '**May be present: XXX**' is not appropriate for foods for these population groups.

1.7.1 The VITAL Program and allergen free claims

For the purpose of this Guide, allergen free claims are claims stating that a food is free from an allergen and that the allergen will not be present, in any amount, including unintentionally added cross contact. Examples of free claims include 'milk free', 'wheat free' and 'egg free'. Free claims are regulated by consumer laws to prevent deceptive and misleading practices. Additional requirements to meet gluten free claims and lactose free claims are provided in the FSC *Schedule 4 Nutrition, health and related claims*.

The substantiation for each allergen free claim on a product should be rigorous. Substantiation may involve additional validation activities over and above those used to validate the assumptions applied in the VITAL Program. An example of an additional substantiation activity is analytical allergen testing of the finished product.

It is important to note that where cross contact from an allergen is identified using the VITAL Program (either at Action Level 1 or Action Level 2), a claim that this product is free of that allergen is unlikely to be appropriate.

2 WORKED EXAMPLES

The rationale applied for the best practice labelling recommendations are explained step by step under each of the following worked examples. Icons are used to indicate the information source, and where relevant, interesting facts have been included in the 'Did you know?' boxes.

 Industry best practice

 Regulatory requirement

 VITAL Program

 Did you know?

Each worked example shows a recipe set out in the following table format.

Ingredient	Quantity (%)	Allergen Information	Detailed Summary Report	VITAL Online finished product labelling outcome

- Provided by Table 4 and Table 6 of the VITAL Online Detailed Summary Report.
- Summarises the allergen status of each ingredient and the cross contact from processing sources.

- Provided by Table 1 of the VITAL Online Detailed Summary Report and the VITAL Online Short Summary Report.
- Lists the recommended labelling outcome after the application of a set of rules

The VITAL Online finished product labelling outcome rules are based on the following hierarchy:

Allergen Status	VITAL Online finished product labelling outcome
The allergen is present at Action Level 1	Action Level 1
The allergen is present at Action Level 2	Action Level 2
The same allergen is present at Action Level 1 and Action Level 2	Action Level 2
The allergen is present as cross contact in particulate form	Action Level 2
The same allergen is present at Action Level 1 and/or Action Level 2 and as cross contact in particulate form	Action Level 2
The allergen is intentionally added	Intentionally added
The same allergen is present at Action Level 1 and/or Action Level 2 and/or in particulate form and intentionally added	Intentionally added
Cereals containing gluten	based upon total protein concentration (ppm) of cereals containing gluten
Tree nuts	based upon the total protein concentration (ppm) of tree nut allergen

2.1 Wholegrain Soup

a. Overview

This worked example covers the following:

- Cereals containing gluten
  - added as ingredients and present from cross contact;
- An allergen present from more than one source
  - peanut oil present both as an ingredient and from cross contact due to processing;
- Particulates & readily dispersible materials

b. Recipe - Wholegrain Soup

Ingredient	Quantity (%)	Allergen Information	Detailed Summary Report	VITAL Online finished product labelling outcome
Water	40			
Potato	17			
Carrots	16			
Celery	10			
Brown rice	8			
Whole oats	6	• Allergen - **cereals containing gluten (oats)** • Intentionally added	Table 4 **Intentionally added**	**Cereals containing gluten (total)** **Intentionally added**
		• Allergen - **cereals containing gluten (wheat)** • Cross contact • Form - particulate	Table 4 **Particulate**	**Cereals containing gluten (total)** **Intentionally added**
Peanut oil	2	• Allergen - **peanut** • Intentionally added	Table 4 **Intentionally added**	**Peanut** **Intentionally added**
Yeast extract	1	• Source - grown on wort (malted barley) • Allergen - **cereals containing gluten (barley)** • Intentionally added	Table 4 **Intentionally added**	**Cereals containing gluten (total)** **Intentionally added**
Cross contact due to processing		• Source – cross contact due to other products run on same equipment • Cross contact - peanut oil • Allergen - **peanut** • Form - readily dispersible	Table 6 **9 ppm**	**Peanut** **Intentionally added**

c. Recommended ingredient list showing allergen declaration

Ingredient List:	Water, potato, carrots, celery, brown rice, **oats, peanut** oil, yeast extract (**barley**).
Allergen Summary Statement:	**Contains cereals containing gluten, peanut**.
Precautionary Statement:	**May be present: wheat**.

d. Tips / Reasoning

2.1.1 Cereals containing gluten

The FSC section *1.2.3-4(1)(b)* requires the mandatory declaration of cereals containing gluten and their products when present in a food (unless an allergen labelling exemption applies). Additionally FSC *Schedule 10 Generic names of ingredients and conditions for their use* requires that the specific name of the cereal (wheat, rye, barley, oats or spelt or their hybridised strains) is declared.

The AFGC – *Allergen Guide* recommends that each specific added cereal (gluten source) is identified in the ingredient list. In the allergen summary statement, if there is more than one ingredient derived from a cereal containing gluten, the general term 'cereals containing gluten' can be used. Alternatively, the specific name of the cereal can be used in brackets after the general 'cereals containing gluten' term, as this clarification may be useful to consumers.

Did you know?

Individuals may be allergic to a particular cereal containing gluten but not to gluten.
So it is important to **clearly specify the cereal source.**
Using terms such as '*cereals containing gluten*' or '*contains gluten*' without further clarification will not always provide enough information for consumers who need to know the specific type of cereal.

In this Wholegrain Soup example, cereals containing gluten are present both as ingredients and cross contact allergens. The ingredient list clearly states the individual cereals - therefore they do not need to be qualified in the allergen summary statement. The wheat is identified as a cross contact allergen (in particulate form) and is a different cereal type to the cereals declared in the ingredient list. [Note: If the wheat cross contact was present in readily dispersible form, it will be identified in the VITAL Online Detailed Summary report by its concentration in ppm.] To clearly specify the source of the cereal cross contact, the specific name 'wheat' is declared in the precautionary statement.

In the Snack Bar example, there is only one gluten containing cereal requiring mandatory declaration, therefore the allergen summary statement does not include the general term 'cereals containing gluten'. In the Mayonnaise in a sachet example, the allergen summary statement includes the general term 'cereals containing gluten' and qualifies each cereal. This is because the sachet is a small package and does not include an

ingredient list, yet is required to fulfil the mandatory declaration requirements of the FSC.

- Refer to worked examples 2.2 Snack Bar and 2.4. Mayonnaise in a sachet.

2.1.1.1 Declaring specific cereal varieties

Some cereals containing gluten have a varietal name, or other description, that may not clearly show a consumer the cereal origin. For example, there are a number of varieties of wheat (including spelt, khorasan, farro and durum), and wheat products (including bulgar and semolina), where the wheat origin may not be obvious.

Some examples for how the wheat can be declared are:

- spelt (**wheat**)
- durum **wheat**
- **wheat** semolina

Did you know?

Cross breeding two strains of cereal results in a hybridised strain. An example is triticale which is a hybrid of wheat and rye.

2.1.2 An allergen present from more than one source

Sometimes an allergen may be added to a food from more than one source (i.e. more than one ingredient, or from an ingredient and due to cross contact). The FSC does not set requirements for declaring the same allergen when present in a food more than once.

The AFGC – *Allergen Guide* recommends declaring the allergen each time it appears in the ingredient list. It is important, however, that the information is not confusing. An example of this may be if the same allergen is declared in the ingredient list, the allergen summary statement and (because the same allergen is present due to cross contact) in the precautionary statement. That is, consumers may find it confusing to see an allergen declared as present as well as declared as '**May be present**'.

If an allergen is intentionally added, and the same specific allergen is present as a result of cross contact, it is not necessary to declare that allergen again in the precautionary statement, because it is already declared in the ingredient list and the allergen summary statement. This is shown in this Wholegrain Soup example, for peanut.

2.1.3 Particulate and readily dispersible materials

Cross contact allergens, assessed using the VITAL Program, can be present either in readily dispersible or particulate form. In this Wholegrain Soup example, the 'whole oats' ingredient contains whole wheat grains as a result of cross contact. The wheat grains are considered cross contact in a particulate form. Unlike a cross contact allergen in a readily dispersible form, the wheat protein is not evenly distributed across the production batch. A significant amount of allergenic protein could be consumed in a single mouthful (a single wheat grain) which creates risk of an adverse allergic reaction in a sensitive consumer.

In the VITAL Program, a particulate cross contact allergen will provide a labelling recommendation of Action Level 2. However, if the same allergen is intentionally added, the finished product labelling recommendation will follow the labelling hierarchy rules

➲ Refer to Section 2 labelling hierarchy

Allergens that are identified to be at Action Level 2 (in this case particulates) are included in the '**May be present: XXX**' precautionary statement, as per the VITAL Program.

2.2 Snack Bar

a. Overview

This worked example covers the following:

- Tree nuts
  - when present as an ingredient and as a cross contact allergen;
- The VITAL Program and tree nuts;
- Coconut;
- Honey;
- Highly refined ingredients and allergen labelling exemptions

b. Recipe - Snack Bar

Ingredient	Quantity (%)	Allergen Information	Detailed Summary Report	VITAL Online finished product labelling outcome
Oats	64	• Allergen - **cereals containing gluten (oats)** • Intentionally added	Table 4 **Intentionally added**	**Cereals containing gluten (total)** **Intentionally added**
Glucose syrup	15	• Source - derived from wheat (supplier advises that it is highly refind glucose syrup and contains less than 20 ppm gluten protein) • Allergen - **cereals containing gluten (wheat)** • Intentionally added	Table 4 **Intentionally added**	**Cereals containing gluten (total)** **Intentionally added**
Almond meal	10	• Allergen - **tree nut (almond)** • Intentionally added	Table 4 **Intentionally added**	**Tree nuts (total)** **Intentionally added**
		• Allergen - **tree nut (cashew)** • Cross contact • Form - readily dispersible	Table 4 **30 ppm**	**Tree nuts (total)** **Intentionally added**
Honey	6			
Coconut	5			
Cross contact due to processing		No cross contact due to processing		

c. Recommended ingredient list showing allergen declaration

Ingredient List:	**Oats**, glucose syrup, **almond** meal, honey, coconut.
Allergen Summary Statement:	**Contains oats, tree nuts (almond)**.
Precautionary Statement:	**May be present:** other **tree nuts (cashew)**.

d. Tips / Reasoning

2.2.1 Tree nuts

The FSC section *1.2.3-4(1)(b)* states that it is mandatory to declare tree nuts and tree nut products other than coconut from the fruit of the palm *Cocos nucifera*. Additionally, the FSC *Schedule 10* requires the specific name of the tree nut to be declared. The *FSC Schedule 22 Foods and classes of foods* lists tree nuts as: 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 nuts; walnuts.

➲ * Refer Section 2.2.2 as to why coconut is a 'tree nut' that does not require mandatory declaration.

The AFGC – *Allergen Guide* recommends the specific type of tree nut is declared in the ingredient list. In the allergen summary statement the term 'tree nuts' can be used, however the term 'nuts' should be avoided.

Did you know that peanuts and tree nuts are not the same?
Peanuts are legumes that grow underground, and they have different allergenic proteins to tree nuts.

In this Snack Bar example, tree nuts are present both as an ingredient (almond) and as a cross contact allergen (cashew). Tree nuts that are present as cross contact in readily dispersible form will be identified in the VITAL Online Detailed Summary report by a concentration in ppm. In this example, as the tree nut - almond is intentionally added, the finished product labelling recommendation will follow the labelling hierarchy rules.

➲ Refer to Section 2 labelling hierarchy.

To provide the consumer with useful information that more than one type of tree nut is present in the food, each tree nut is specified. Additionally, the term 'Other **tree nuts** (**cashew**)' is used in the precautionary statement instead of the shorter term 'tree nuts' to provide clear information.

Did you know?

Some people are allergic to one or more tree nuts but it is unusual to be allergic to all tree nuts. Cross reactivity is evident with tree nut allergy, meaning that a person who is allergic to a specific tree nut may also react to a different one. So it is important to **clearly specify which tree nuts** are present in a food wherever possible.

Tree nuts from the same botanical families have the strongest cross-reactivity. Cashew and pistachio are in the family Anacardiaceae; and walnut and pecan are from the family Juglandaceae.

2.2.2 Coconut

Despite being listed as a tree nut in the FSC Schedule 22, scientific literature indicates that coconut is not linked to severe allergic reactions. The FSC section *1.2.3-4(1)(b)* specifically excludes coconut from the fruit of the palm *Cocos nucifera* from the requirements of mandatory declaration.

Did you know?

Coconut milk may have unexpected allergens such as caseinates (milk proteins) due to intentional addition.

➲ Refer to Allergen Bureau - *Unexpected Allergens in Food* available on Allergen Bureau website.

Some international regulations include coconut within their definition of 'tree nuts', and in those countries, it is mandatory to declare coconut on the label when present. This is an example of where international food labelling laws and guidance may not align with Australian and New Zealand regulations.

2.2.3 The VITAL Program and tree nuts

The VITAL Program includes the following tree nuts within its Action Level Grid: almonds; Brazil nut; cashew nut; hazelnuts; macadamia nuts; pecan; pine nuts; pistachio nuts; walnut, as these are more commonly implicated in allergic reaction.

Although the FSC section *1.2.3-4(1)(b)* requires the declaration of tree nuts, it does not specify the tree nuts that are of clinical significance. Therefore it is important to be aware that beech nuts; chestnuts; hickory nuts; Japanese horse-chestnut; pili nuts; sapucaia nuts are not included within the scope of tree nuts in the VITAL Program.

➲ Refer to Allergen Bureau - *VITAL Q&As*

2.2.4 Honey

The FSC section *1.2.3-2(1)* and section *1.2.3-3* respectively require that if a food is bee pollen, propolis or royal jelly, or contains these as ingredients, the food must comply with the requirements for a mandatory advisory statement in the FSC *Schedule 9 Mandatory advisory statements* (bee pollen, propolis) and warning statement in section *1.2.3-3* (royal jelly).

Bee pollen may be naturally present in honey at very low levels, but as bee pollen is not added to honey as an ingredient, there is no requirement to declare it.

2.2.5 Highly refined ingredients and allergen labelling exemptions

For the purpose of this Guide, highly refined ingredients are those which have gone through a number of processing steps that result in a product that has no detectable, or extremely low, protein levels. If a food contains any products of the allergens listed in the FSC section *1.2.3-4(1)(b)*, even if highly refined, or if required by *Schedule 10*, the allergen source must be declared.

However, certain foods derived from allergenic sources (or products derived from them) have been shown, through scientific evidence, to be safe for people who are allergic to the original allergen source and are exempt from mandatory allergen declaration where specifically listed in the FSC.

The FSC section *1.2.3-4(1)(b)* includes a number of exemptions where the allergen source of some highly refined ingredients are not required to be declared. An example is isinglass derived from fish swim bladders and used as a clarifying agent in beer and wine. FSANZ consider exemptions on a case by case basis – continue to check the FSC to obtain the most current list of exemptions.

In cases when a food qualifies for an allergen labelling exemption, the allergen can still be declared voluntarily if manufacturer / supplier chooses to do so.

In this Snack Bar example, the glucose syrup is a highly refined ingredient that is a product of wheat. FSC section *1.2.3-4(1)(b)* states that refined glucose syrups that are made from wheat starch and contain a gluten protein content not exceeding 20 mg/kg are exempt from allergen declaration. Therefore, in this example, the glucose syrup does not include a declaration for wheat.

Did you know?

Wheat is a common allergenic food which is used to make highly refined ingredients. Mandatory allergen declaration applies to all derivatives of an allergen source (unless an exemption applies). Examples of ingredients derived from wheat include wheat flour, wheat starches (including thickeners and maltodextrin), wheat sugars (including glucose syrup and dextrose), wheat caramel colour, wheat grain alcohols and vinegars.

When declaring the allergen source of the food product, consider labelling in a way that provides the consumer with accurate and useful information.

Below are some examples showing how maltodextrin derived from wheat may be represented:

- Maltodextrin (**wheat**); or
- **Wheat** maltodextrin; or
- Maltodextrin (derived from **wheat**)
- Maltodextrin (product of **wheat**)

These formats help the consumer to understand the source from which the ingredient is derived.

Did you know?

Soybean oils that have been degummed, neutralised, bleached and deodorized are exempt from mandatory allergen labelling (FSC section *1.2.3-4(1)(b)*). If a soybean oil has not been processed as such (for example, cold pressed soybean oil) it does not qualify for the allergen labelling exemption and there is still a requirement to declare the soy allergen.

2.3 Fish Sauce

a. Overview

This worked example covers the following:

- Fish, crustacea, molluscs
  - fish added as an ingredient
  - crustacea present as cross contact due to processing;
- The VITAL Program and molluscs;
- Common names, generic names and specific names;
- Allergens within a compound ingredient
  - anchovy fillets as a compound ingredient added at less than 5% of the total recipe, with two allergens present;
- Ingredients derived from allergenic substrates
  - white vinegar and xanthan gum produced by fermentation of allergenic substrates

b. Recipe – Fish Sauce

Ingredient	Quantity (%)	Allergen Information	Detailed Summary Report	VITAL Online finished product labelling outcome
White vinegar	65	• Source - fermented from distilled whey alcohol • Allergen - **milk** (whey) • Intentionally added	Table 4 **Intentionally added**	**Milk** **Intentionally added**
Coconut milk	15	• Contains – coconut milk (98%), sodium caseinate (a derivative of casein) (2%) • Allergen - **milk** (casein) • Intentionally added	Table 4 **Intentionally added**	**Milk** **Intentionally added**
Sugar	12			
Anchovy fillets	4	• Contains - anchovies (65%), sesame oil (26%), salt (9%) • Allergen - **fish** (anchovy) • Intentionally added	Table 4 **Intentionally added**	**Finfish** **Intentionally added**
		• Allergen - **sesame** • Intentionally added	Table 4 **Intentionally added**	**Sesame** **Intentionally added**
Salt	3.8			
Xanthan gum	0.2	• Source - grown using soy (a microbial substrate) • Allergen - **soy** • Intentionally added	Table 4 **Intentionally added**	**Soy** **Intentionally added**
Cross contact due to processing		• Source – cross contact due to other products run on same equipment • Cross contact - shrimp • Allergen – **crustacea** • Form - readily dispersible	Table 6 **84 ppm**	**Crustacea** **Action Level 2**

c. Recommended ingredient list showing allergen declaration

Ingredient List:	White vinegar, coconut milk (sodium caseinate (**milk** protein)), sugar, **anchovy** (**sesame** oil), salt, stabiliser (415 (**soy**)).
Allergen Summary Statement:	**Contains milk, fish, sesame, soy**.
Precautionary Statement:	**May be present: crustacea (shrimp)**.

➲ Refer Section 2.3.5 as to why the milk allergen is not declared in association with the vinegar.

d. Tips / Reasoning

2.3.1 Fish, crustacea and molluscs

Fish is defined in the FSC section *1.1.2-3* as "*a cold-blooded aquatic vertebrate or aquatic invertebrate including shellfish, but not including amphibians or reptiles*". Under this definition 'fish' includes finfish, crustacea (such as prawns, crab and crayfish) and mollusc (such as abalone, oysters, clams, mussels, scallops and squid).

The FSC section *1.2.3-4(1)(b)* sets out the requirements for the mandatory declaration of crustacea and fish. The FSC *Schedule 10* states that the generic name 'fish' may be used, however the specific name of the crustacea must be declared.

FSANZ has recognised that there is a need to further clarify the definition of fish and crustacea in the mandatory declaration requirements. This is discussed in the FSANZ *Review of the regulatory management of food allergens (Dec 2010)*

The AFGC – *Allergen Guide* does not provide specific recommendations on how fish, molluscs and crustacea are declared; however, applying the same logic as for tree nuts and cereals containing gluten is appropriate. That is, declare the specific crustacea, and wherever possible the specific fish or mollusc in the ingredient list and the generic name can be declared in the allergen summary statement.

In this Fish Sauce example:

- the anchovy is declared in the ingredient list;
- the generic term 'fish' is used in the allergen summary statement; and
- the crustacea is declared (with specific crustacea name) in the precautionary statement '**crustacea (shrimp)**'.

2.3.2 The VITAL Program and molluscs

When using the VITAL Program, there is sufficient scientific evidence to set a Reference Dose for finfish and crustacea, however this is not the case for molluscs. Molluscs are excluded from the definition of fish in the VITAL Program, however the FSC requires the mandatory declaration of mollusc when present in a food.

Did you know?

The allergenic protein is different between finfish, mollusc and crustacea. Individuals may be allergic only to a specific fish, mollusc or crustacea so **clearly specifying the name** is important.

2.3.3 Common names, generic names and specific names

The FSC section *1.2.4-4* requires ingredients to be declared using either their common name; a name that describes the true nature of the ingredient; or a generic name as listed in the FSC *Schedule 10*. However, care must be taken to ensure that if generic names are used, the allergens are clearly declared.

In this Fish Sauce example, the coconut milk contains sodium caseinate which is a product of casein (a milk protein). As sodium caseinate may not be readily associated with milk allergy by consumers, including the common name 'milk' or 'milk protein' allows consumers to easily identify the allergen, shown here as 'Sodium caseinate (**milk** protein)'. An alternative description may also be 'Sodium caseinate (derived from **milk** protein)'.

The table below shows some of the generic names that are permitted to be used and describes how the allergens can be declared when present. The FSC *Schedule 10* provides further information.

Permitted generic names with potential allergen impact	Potential allergen	Best practice for using a generic name for an ingredient that contains an allergen.
Cereals	• Cereals containing gluten	Where the cereal is wheat, rye, barley, oats or spelt or their hybridised strains then the specific name of the cereal must be declared. e.g. Cereals **(oats, wheat, barley**)
Cheese	• Milk	e.g. Cheese (**milk**)
Fats or Oils	• Peanut • Soy • Sesame • Milk • Fish	Where the source of vegetable oil is peanut, sesame, or soy where an exemption does not apply, the specific source name must be declared. e.g. Vegetable oil (**sesame**)
Fish	• Fish • Crustacea • Mollusc	The specific name of the crustacea must be declared. e.g. **Crustacea (shrimp)** The specific name of the fish or mollusc should be declared. e.g. **Fish (hoki, oyster)**
Milk protein	• Milk	Proteins derived from milk such as whey or casein may be described as milk protein. e.g. **Milk** protein
Milk solids	• Milk	May be used to describe milk powder, skim milk powder, dried milk products or any two or more of the following ingredients: whey, whey powder, whey proteins, lactose, caseinates, milk proteins and milk fat. e.g. Lactose and milk fat together may be declared as **Milk** Solids
Nuts*	• Tree nuts • Peanuts	*The specific name of the nut must be declared. Best practice is for the generic name 'nuts' to be avoided altogether. e.g. **Almond, cashew** or **Tree nuts (almond, cashew)** Do not use the term 'nuts' for peanut.
Starch	• Cereals containing gluten	Where the source of the starch is wheat, rye, barley, oats or spelt, or their hybridised strains, the specific name of the cereal must be declared. The name 'starch' may be used for any unmodified starch or any starch which has been modified by either physical means or enzymes. e.g. **Wheat** Starch

2.3.4 Allergens within a compound ingredient

An ingredient of a food is a compound ingredient if it is itself made from two or more ingredients (FSC *Standard 1.1.2*). The requirements for declaring compound ingredients are set out in the FSC section *1.2.4-5(6)*. The presence of any allergens, in ingredients of a compound ingredient must be declared (FSC *section 1.2.3-4(2)*), even if added at less than 5% in the final food.

It is important to identify the presence of allergens within all components of ingredients and compound ingredients, including additives, and processing aids. Supplier specifications such as the AFGC - *Product Information Form (PIF)* should provide this information. It is the food industry's responsibility to verify the content of all ingredients, and where necessary clarify (and validate) the allergen status of ingredients used in their products.

Did you know?

Additives, processing aids and vitamins can contain carriers or diluents derived from allergenic substances.

➲ Refer to Allergen Bureau - *Unexpected Allergens in Food*.

In this Fish Sauce example, the anchovy fillet is a compound ingredient (less than 5% of the total sauce) which contains anchovies, sesame oil and salt. As both the sesame and fish are allergens, both must be declared, shown here as '**anchovy** (**sesame oil**)'.

[Note: The salt in the anchovy fillets is combined with the added salt ingredient in this example.]

2.3.5 Ingredients derived from allergenic substrates

The FSC provides no specific requirements relating to ingredients produced from fermentation processes other than the product of an allergen must be declared if present (FSC section *1.2.3-4(b)*).

Products derived from fermentation substrates can be separated into two categories:

1. The fermentation substrate is the food.

a. **Allergen labelling exemption does not apply:** If the food is the allergenic substrate, it should be declared as a product of the substrate. Examples include yoghurt from fermented milk products, tofu from fermented soy products and distilled alcohols and vinegars from fermented cereals containing gluten.

b. **Allergen labelling exemption applies:** In some cases, the fermentation substrate may be exempt from the requirements for mandatory declaration. In this Fish Sauce example, the white vinegar is a fermentation product of distilled whey alcohol (and whey is a product of milk). The milk allergen is not declared however, as it qualifies under the following allergen labelling exemption criteria.

- under FSC section *1.2.3-4(1)(b)* there is an allergen labelling exemption for alcohol distilled from whey;
- under FSC section *1.2.3-4(3)* there is no requirement to declare presence of a food/product that is derived from a food/product that is exempt from allergen labelling (in this example, the vinegar is a product of the alcohol distilled from whey).

2. The fermentation substrate is not the food.

Some ingredients are the product of the fermentation with microorganisms and a substrate (nutrient media). The substrate that is consumed by the food-producing organisms may contain protein from one or more food allergens. An example is xanthan gum, where microorganisms are grown on an allergenic substrate (wheat and/or soy) and produce xanthan gum. The wheat and/or soy may be fully digested, metabolised, physically removed or otherwise no longer present in the commercial form of the xanthan gum.

Substrates used in microbial fermentation are intentionally added [as ingredients, food additives or processing aids] during the manufacturing process. Therefore, if an allergen from a substrate is considered present in the food, allergen declaration as per the FSC Standard 1.2.3 is required.

If there is sufficient processing to ensure separation between the food and the substrate, allergen declaration is not required. Any determination that an allergenic substrate is no longer present in the food after fermentation (and therefore no allergen declaration is required) needs to be supported by objective evidence, arising from an assessment of the manufacturing process possibly supported by analysis.

This is shown by the questions asked in the AFGC - *Product Information Form (PIF)* and discussed further in the Allergen Bureau - *Unexpected Allergens in Food*.

If there is any doubt that the allergenic substrate is not fully removed or fully metabolised, then declaring the allergen is appropriate. In this Fish Sauce example, the supplier of the xanthan gum is unable to satisfactorily show that all of the soy fermentation substrate was fully removed, so the soy allergen is declared in the ingredient list, shown here as 'stabiliser (415 (**soy**))'.

Did you know?

The food additive xanthan gum is often produced using soy protein and/or wheat flour in the fermentation substrate. It is worth discussing with your ingredient supplier to determine the processes they use to remove allergenic substrates from ingredients. Ensure you fully understand whether a soy or wheat allergen declaration is required.

This determination should be done for each supplier of an ingredient from a fermentation substrate as different processes may result in different levels of separation from the substrate. If a decision is made that it is not appropriate to declare the allergenic substrate, ongoing evidence of protein monitoring should be included as part of the due diligence exercise.

2.4 Mayonnaise in a sachet

a. Overview

This worked example covers the following:

- Small package allergen labelling requirements;
- Food additives derived from an allergenic source
  - soy lecithin and caramel colour
  - vegetable oil as a compound ingredient containing a food additive derived from an allergen source

b. Recipe - Mayonnaise in a sachet

(where the surface area of the package is greater than 30 cm^2 but less than 100 cm^2)

Ingredient	Quantity (%)	Allergen Information	Detailed Summary Report	VITAL Online finished product labelling outcome
Vegetable oil (Canola)	50	• Contains - canola oil, acid 330 (derived from maize)*, antioxidant (306 (derived from soy))* *Has a technological function in the final food • Allergen - **soy** • Intentionally added	Table 4 **Intentionally added**	**Soy** **Intentionally added**
Malt vinegar	20	• Source - fermented from barley • Allergen - **cereals containing gluten (barley)** • Intentionally added	Table 4 **Intentionally added**	**Cereals containing gluten (total)** **Intentionally added**
Milk solids	12	• Contains - milk proteins, lactose • Allergen - **milk** • Intentionally added	Table 4 **Intentionally added**	**Milk** **Intentionally added**
Egg yolk	10	• Allergen - **egg** • Intentionally added	Table 4 **Intentionally added**	**Eggs** **Intentionally added**
Water	4			
Salt	3			
Caramel Colour III	0.5	• Source - derived from wheat • Allergen - **cereals containing gluten (wheat)** • Intentionally added	Table 4 **Intentionally added**	**Cereals containing gluten (total)** **Intentionally added**

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Soy lecithin	0.5	• Source - derived from soy (supplier advises that it is highly refined) • Allergen - **soy** • Intentionally added	Table 4 **Intentionally added**	**Soy** **Intentionally added**
Cross contact due to processing		• Source – cross contact due to other products run on same equipment • Cross contact - peanut oil • Allergen - **peanut** • Readily dispersible	Table 6 **120 ppm**	**Peanut** **Action Level 2**

c. Recommended ingredient list showing allergen declaration

Ingredient List:	Vegetable oil [acid (330), antioxidant (306)], malt vinegar (**barley**), **milk** solids, **egg** yolk, water, salt, colour (150c (**wheat**)), emulsifier (322 (**soy**)).
Allergen Summary Statement:	**Contains cereals containing gluten (barley, wheat), milk, egg, soy**.
Precautionary Statement:	**May be present: peanut**.

Recommended declaration for a package with a surface area greater than 30cm² but less than 100cm²

Allergen Summary Statement:	**Contains cereals containing gluten (barley, wheat), milk, egg, soy**.
Precautionary Statement:	**May be present: peanut**.

d. Tips / Reasoning

2.4.1 Small package allergen labelling requirements

A small package is defined as a package with a surface area of less than 100 cm² (FSC Standard *1.1.2*). In accordance with the FSC section *1.2.4-2(3)(c)* small packages do not require a statement of ingredients. However the FSC section *1.2.1 8 (3)* states that the presence of the allergens (FSC section *1.2.3-4*) must be declared on packages with a surface area of greater than 30 cm².

In this Mayonnaise in a sachet example, an ingredient list is provided for a package greater than 100cm², and for a small package, the allergen summary statement and the precautionary statement is provided.

Where label size constraints make it difficult to meet the recommended labelling format, the AFGC – *Allergen Guide* provides some alternatives for formatting and bolding. However the allergens present in the product must always be declared.

Did you know?

The labelling outcome of a VITAL assessment may be influenced by the Reference Amount (e.g. Serving Size). That is, there may be times when the maximum amount of food eaten in a typical eating occasion is not the same as the serving size on a Nutrition Information Panel. In this example, a typical eating occasion may include consuming the mayonnaise from two or more sachets. When assessing this product using the VITAL Program, it may be useful to consider setting an appropriate Reference Amount based on the likelihood that a consumer may eat more than one sachet of mayonnaise.

2.4.2 Food additives derived from an allergenic source

The FSC requires the mandatory declaration of the products of the allergens listed in the FSC section *1.2.3-4(2)*. The FSC also sets requirements for the declaration of substances used as food additives (FSC section *1.2.4-7*). The substance used as a food additive must be declared by its class name followed by the additive's prescribed name or code number in brackets. If the additive contains an allergen or is the product of an allergenic source, unless an exemption applies, it is mandatory to declare the allergen, regardless of the amount (percentage) of the additive in the finished product.

It is important to confirm the source of the food additive with the supplier. In this Mayonnaise in a sachet example, the lecithin emulsifier is derived from soy, the caramel colour is derived from wheat and the tocopherol antioxidant is derived from soy. In this example, the ingredient list shows how the food additives that are derived from an allergenic source may be expressed:

- colour (150c (**wheat**));
- emulsifier (322 (**soy**)).
- antioxidant (306) – in this case, the soy derivative from the antioxidant is not declared, as under FSC section *1.2.3-4(1)(b)* there is an allergen labelling exemption for soybean derivatives that are a tocopherol.

2.5 Pork and Prawn Curry Rice

a. Overview

This worked example covers the following:

- Processing aids
  - allergen in a substance used as a processing aid that does not perform a technological function in the final food;
- Sulphites;
- The VITAL® Program Action Levels
  - cross contact allergens at Action Level 1 and Action Level 2

b. Recipe – Pork and Prawn Curry Rice

Ingredient	Quantity (%)	Allergen Information	Detailed Summary Report	VITAL Online finished product labelling outcome
Cooked rice	50			
Pork	17	• Contains - lactoperoxidase* (processing aid added at GMP levels) **Has no technological function in the final food* • Allergen - **milk** • Intentionally added	Table 4 **Intentionally added**	**Milk** **Intentionally added**
Prawns	11	• Allergen – **crustacea** • Intentionally added	Table 4 **Intentionally added**	**Crustacea** **Intentionally added**
		• Contains - sodium metabisulphite (223) added to prawns at 90mg/kg *[equates to 10mg/kg added to this recipe as a result of carry-over]*		
Sugar	9			
Water	6.5			
Tapioca Flour	4			

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Curry Powder	2.5	• Contains - coriander, turmeric, cumin seed, fennel seed, ginger • Intentionally added		
		• Contains - sesame present at harvest in particulate form but ground in with the curry powder • Allergen – **sesame** • Cross contact • Form - readily dispersible	Table 4 **9 ppm**	**Sesame** **Action Level 2**
		• Contains - wheat present at harvest in particulate form but ground in with the curry powder • Allergen – **cereals containing gluten (wheat)** • Cross contact • Form - readily dispersible	Table 4 **14 ppm**	**Cereals containing gluten (total)** **Action Level 2**
Cross contact due to processing		• Source – cross contact due to other products run on same equipment • Cross contact - peanut oil • Allergen – **peanut** • Form - readily dispersible	Table 6 **0.6 ppm**	**Peanut** **Action Level 2**
		• Source – cross contact due to other products run on same equipment • Cross contact - soy lecithin • Allergen – **soy** • Form - readily dispersible	Table 6 **2 ppm**	**Soy** **Action Level 1**

c. Recommended ingredient list showing allergen declaration

Ingredient List:	Cooked rice, pork (**milk**), **prawns** (preservative (**223**)), sugar, water, tapioca flour, curry powder.
Allergen Summary Statement:	**Contains crustacea (prawns), milk, sulphites**.
Precautionary Statement:	**May be present: peanut, sesame, wheat**.

d. Tips / Reasoning

2.5.1 Processing aids

The FSC section *1.2.3-4(2)* requires the mandatory declaration of allergens when present in a substance used as a processing aid or a component of a substance used as a processing aid.

In this Pork and Prawn Curry Rice example, the pork ingredient contains the milk based processing aid lactoperoxidase. The lactoperoxidase does not have a technological function in the final food and ordinarily would not require declaration. However, because it is derived from an allergen (milk), it meets the requirements for mandatory declaration of allergens.

For this Pork and Prawn Curry Rice recipe, some examples showing how to declare the presence of allergens from sustances used as processing aids are:

- pork (**milk**)
- pork,…other ingredients…, curry powder, processing aid: contains **milk**.
- pork, …other ingredients…, curry powder, **milk**.

Declaring the processing aid (allergen) only in the allergen summary statement and not also within the ingredient list is not recommended as it is confusing to consumers who are unable to identify where the milk originates from, and some may assume that it is an error.

2.5.2 Sulphites

The FSC section *1.2.3-4(1)(a)* requires the mandatory declaration of added sulphites in concentrations of 10 mg/kg or more when present in a food. This is a level that allows people who are sensitive to sulphites (e.g. people with asthma) to avoid particular foods. FSC section *1.2.4-7* sets out the requirements for the declaration of substances used as food additives and the FSC *Schedule 8 Food additive names and code numbers (for statement of ingredients)* lists the family of sulphite based food additives numbered from 220 to 228.

Did you know?

Sulphites can be naturally present in some foods, or created or destroyed during the food manufacturing process, however only added sulphites are part of the mandatory declaration requirements.

When establishing the sulphite concentration in a food, consider the cumulative total added sulphite component of individual ingredients, compound ingredients, processing aids and sulphite additives. Determining the total added sulphite level in a food can be done by calculation so it is important that each ingredient specification or AFGC - Product Information Form (PIF) contains this information. It may be appropriate to use analysis to confirm this value, or to help identify if processing or storage has an impact on the sulphite levels.

In this Pork and Prawn Curry Rice example, the total theoretical added sulphite quantity is 10mg/kg. The finished product is analysed for sulphites and the results support the theoretical value. As the sodium

metabisulphite added to the prawns is a substance used as a food additive, in this example, it is declared as per FSC section *1.2.4-7* and using the prescribed class name and then either the specific name or food additive number, shown as '**prawns** (preservative (**223**))'.

When declaring sulphites in the allergen summary statement, the generic name 'sulphites' may be used, if the information is useful, not confusing to consumers, and compliant with the FSC. Declaring sulphites in the VITAL precautionary statement '**May be present: XXX**' represents sulphites present in the form of cross contact only.

2.5.3 The VITAL Program Action Levels

The VITAL Program includes the VITAL Decision Tree for Cross Contact Allergens, which is a tool that provides guidance on the VITAL assessment process for determining when a precautionary statement is required. Allergens that fall into Action Level 2 require a '**May be present: XXX**' precautionary statement while allergens that fall into Action Level 1 do not require a precautionary statement.

➲ Refer to page 14 of Allergen Bureau - *VITAL Guide (2012)*

In this Pork and Prawn Curry Rice example, there are three cross contact allergens identified at Action Level 2, and one cross contact allergen identified at Action Level 1. The cross contact allergen soy lecithin is at Action Level 1 and does not need to be included in the precautionary statement.

Did you know?

The Reference Doses from the VITAL Program can be extremely useful in understanding how much product, when consumed in a single serve, could cause an adverse reaction in a consumer. This may help when training staff in allergen management, evaluation of Hang Up points in the manufacturing process, and ensuring the cleaning program minimises allergen cross contact.

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition
Action Levels	Action Levels are the concentrations (of protein) which define the labelling outcomes for each concentration of cross contact allergen in a VITAL assessment. They are determined using the Reference Dose and the Reference Amount. • *Action Level 1*: Low concentration of the relevant allergen under evaluation, low chance of adverse reaction and no precautionary statement required. • *Action Level 2*: Significant concentration of relevant allergen under evaluation, significant chance of adverse reaction and a precautionary statement is required.
AFGC - Allergen Guide	Australian Food and Grocery Council's Food Industry Guide to Allergen Management and Labelling.
AFGC PIF also AFGC - Product Information Form (PIF)	The Product Information Form (PIF) is a standard specification form for ingredients and foods developed by the Australian Food and Grocery Council (AFGC) and voluntarily adopted by the food industry.
Allergen	Referred to in this Guide as the substances that are listed in the FSC section *1.2.3 - 4*
Allergen Bureau	A not for profit organisation, established in 2005 as an initiative of the Australian Food & Grocery Council Allergen Forum, to share information and experience within the food industry on the management of food allergens.
Allergen Summary Statement	A voluntary statement summarising the allergens that require mandatory declaration and that are present in the food due to intentional inclusion as part of the recipe. The statement should start with *'Contains…'*
Cereals containing gluten	Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains as listed in the FSC section *1.2.3 - 4(1)(b)*.
Compound ingredient	The FSC section *1.1.2-2* defines this as a food ingredient made up of two or more ingredients.
Consumer law	Laws protecting consumers from misleading or deceptive conduct. Of particular relevance to allergen labelling is the Competition and Consumer Act 2011 (Australia) and Fair Trading Act 1986 (New Zealand).
Cross contact allergen	A residue or other trace amount of an allergenic food that is unintentionally incorporated into another food. For the purpose of the VITAL program, cross contact sources can be from raw materials or processing. **Cross contact from raw materials** refers to allergens which may be incorporated during the supply chain of ingredients (e.g. shared harvesting/storage/packing and processing of the ingredient) prior to the addition of the raw material to the product to be assessed. **Cross contact due to processing** is the unintentional incorporation of allergens during production of the product to be assessed due to shared manufacturing lines, equipment, tools and/or people.
Crustacea	A group of aquatic arthropods which include crabs, lobsters, crayfish, shrimps and prawns. The FSC *Schedule* 22 provides a list of crustacea.

Term	Definition
Exemptions (also Allergen labelling exemptions)	Certain foods derived from allergenic sources (or products derived from them) have been shown, through scientific evidence, to be safe for people who are allergic to the original allergen source and are exempt from mandatory allergen declaration.
Fermentation substrate	The nutrient medium used to support the growth of microorganisms. The substrate may be the actual food ingredient (e.g. whey which is fermented into vinegar) or the medium on which the ingredient is grown (e.g. molasses that baker's yeast is grown on).
Fish	Defined in the FSC section *1.1.2-3* as a cold-blooded aquatic vertebrate or aquatic invertebrate including shellfish, but not including amphibians or reptiles. The collective term fish includes fish, crustacea and mollusc. The VITAL Action Level Grid defines fish as finfish (excludes mollusc and crustacea)**.**
Food additives	The FSC section *1.1.2-11* defines substances used as a food additive.
Food Standards Code (FSC)	The Australia New Zealand Food Standards Code is comprised of Standards which are the legislative instruments with which the Australian and New Zealand governments regulate food production and food suitable for retail sale.
FSANZ	Food Standards Australia New Zealand is a bi-national Government agency who develops and administers the Australia New Zealand Food Standards Code.
Gluten	A mixture of two proteins (gliadin and glutenin) present in some cereal grains.
Infant	Defined in the FSC section *1.1.2-2* as a person under the age of 12 months.
Intentionally added allergen	Any ingredient (or intrinsic part of the ingredient) of the recipe which contains an allergen, and includes all allergens which require mandatory declaration.
Mollusc	A group of aquatic invertebrates of the phylum Mollusca which include abalone, oysters, clams, mussels, scallops, octopus and squid. The FSC *Schedule 22* provides a list of molluscs.
Particulate	Defined in the VITAL Program as a separate and distinct particle of material which either • does not mix homogenously with other parts of the food; or • may consist of, or are likely to aggregate into an entity which contains a level equal to or greater than the relevant Reference Dose.
Peanut	The seed from the plant *Arachishypogaea* which is from the legume family Fabaceae. Also known as a groundnut.
PIF (Product Information Form)	See AFGC PIF
ppm	parts per million
Precautionary Statement	A voluntary statement listing all allergens that are present as a result of cross contact and at Action Level 2 as per the VITAL program. The only precautionary statement recommended for use with the VITAL Program is **'May be present: XXX.'**
Processing aid	The FSC section *1.1.2-13* defines substances as used as a processing aid.
Readily dispersible form	Defined in the VITAL Program as a powder or liquid in homogenous form that is of a uniform size and easily distributed throughout a food product e.g. milk powder, soy flour. A readily dispersible cross contact allergen which is considered homogenously distributed in the final product.

Term	Definition
Reference Amount	Defined in the VITAL Program as the maximum amount of food eaten in a typical eating occasion (may be the same as the serving size).
Reference Dose	Defined in the VITAL Program as the protein level (total protein in milligrams from an allergenic food) below which only the most sensitive individuals (between 1% and 5% depending on the quality of the data set available) in the allergic population are likely to experience an adverse reaction.
Sulphites	Sulphites are a group of substances used as food additives used to preserve food quality and appearance. Sulphites can trigger asthmatic symptoms, and can cause medically reproducible allergy-like reactions, however they are not typical allergens.
Tree nuts	The collective term for tree nuts and tree nut products. Tree nuts are described as such to differentiate them from ground nuts. The FSC *Schedule 22* lists 16 tree nuts including almonds; beech nuts; Brazil nut; cashew nut; chestnuts; coconut (from the fruit of the palm *Cocos nucifera* and exempt from mandatory allergen labelling in the FSC); hazelnuts; hickory nuts; Japanese horse-chestnut; macadamia nuts; pecan; pine nuts; pili nuts; pistachio nuts; sapucaia nut; walnuts. The VITAL Action Level Grid includes nine tree nuts known to be significant allergens: almonds; Brazil nut; cashew nut; hazelnuts; macadamia nuts; pecan; pine nuts; pistachio nuts; walnuts.
VITAL Guide	The Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program Version 2.0 developed by the Allergen Bureau.
VITAL Program	The VITAL (Voluntary Incidental Trace Allergen Labelling) Program is a standardised allergen risk assessment process for food industry.

4. REFERENCES AND RESOURCES

Current as of September 2016

Source		Reference / Resource
Australia and New Zealand		
	Allergen Bureau	Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program Version 2.0 (2012) *In this Guide this document title is abbreviated to : Allergen Bureau - VITAL Guide (2012)*
	Allergen Bureau	Unexpected Allergens in Food (18 April 2011 Version 1)
	Allergen Bureau	VITAL Online (web-based calculator) *Available by subscription through the Allergen Bureau website*
	Allergen Bureau	VITAL - Q&As
	Australian Food and Grocery Council	AFGC - Product Information Form
	Australian Food and Grocery Council	AFGC Resource October 2015 Allergen Management Resources: Summary Of Guidance Documents

Source		Reference / Resource
	Australian Food and Grocery Council	Australian Food and Grocery Council's Food Industry Guide to Allergen Management and Labelling *In this Guide this document title is abbreviated to : AFGC - Allergen Guide*
	Food Standards Australia New Zealand	Review of the regulatory management of food allergens (Dec-2010)
	Food Standards Australia New Zealand	Australia New Zealand Food Standards Code *In this Guide this document title is abbreviated to: FSC*
	New Zealand Ministry for Primary Industries	Identifying allergens in foods
	Food Standards Australia New Zealand	Plain English Allergen Labelling, Final Report – W1070 (2016)
International		
	British Retail Consortium & Food and Drink Federation	BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011
	Food Drink Europe	Guidance on Food Allergen Management for Food Manufacturers (January 2013)
	Food Standards Agency (UK)	Allergy: What to consider when labelling food (March 2015)
	Food Standards Agency (UK)	Guidance on Allergen and Miscellaneous Labelling Provisions (March 2011)
	U.S. Food and Drug Administration	Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labelling and Consumer Protection Act of 2004 (Edition 4)

Allergen Bureau

informing the food industry

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