



VITAL[®] BEST PRACTICE LABELLING GUIDE

For Precautionary Allergen
Labelling (PAL) Statements
Used In Conjunction With The
VITAL Program

For Australia and New Zealand

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**PEAL
updated**

Allergen Bureau

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Best Practice Labelling Guide For Precautionary Allergen Labelling (PAL) Statements Used In Conjunction With The VITAL® Program

1. SCOPE

This Guide demonstrates how to form an [ingredient list](#), using information from a risk assessment of a product using the [VITAL Program](#), which complies with the recommendations in the [Food Industry Guide to Allergen Management and Labelling \(FIGAML\)](#). This document focuses on precautionary allergen labelling (PAL) statements. PAL statements are voluntary and not included in the Australia New Zealand Food Standards Code (the Code).

This document is designed as a companion to the Voluntary Incidental Trace Allergen Labelling ([VITAL Program](#)) and [FIGAML](#), it should be referenced alongside these guides. The [VITAL Program](#) and [FIGAML](#) provide further information about the use of PAL statements and the [VITAL Program](#). The examples in this guide are set out in the same format as the outcomes from [VITAL Online](#).

Key components of this guide include:

- [A list of guiding principles for the declaration of allergens in a PAL statement;](#)
- Worked examples demonstrating 'best practice' for declaring food allergens in a PAL statement, specifically for a product assessed using the VITAL Program, and;
- [A list of references to other materials that provide further guidance on allergen declaration.](#)

This Guide uses the term '[ingredient list](#)' as a collective term to describe the mandatory statement of ingredients, the mandatory summary statement and the voluntary PAL statement. The document presents worked examples in a tabular format, including descriptors for each section; however, it is important to note that such formatting is not obligatory for a product's ingredient list.

Tabular Format In This Guide:

<i>Statement of ingredients:</i>	Wholegrain cereals (15%) (triticale (wheat, rye), oats , whole grain wheat), water, potato, carrots, celery, peanut oil.
<i>Summary Statement</i>	Contains: wheat, gluten, peanut.
<i>PAL Statement</i>	May be present: barley.

Actual Declaration:

Ingredients
Wholegrain cereals (15%) (triticale (wheat, rye), oats , whole grain wheat), water, potato, carrots, celery, peanut oil.
Contains: wheat, gluten, peanut.
May be present: barley.

The information in the guide should only be used by a food business operator (FBO) after they have implemented the VITAL Program. The only PAL statement recommended for use with the VITAL Program is '**May be present: allergen x, allergen y.**' Please use this PAL statement only in conjunction with products that have been assessed using the VITAL Program.

2. DECLARATION OF ALLERGENS IN PAL STATEMENTS

2.1 Guiding Principles For The Declaration Of Allergens In PAL Statements

Topic	Comments	Additional References
General	<p>Ensure the PAL statement is logically consistent and is not contradictory to the statement of ingredients or summary statement.</p> <p>For example, a PAL statement should not include an allergen which has been listed in a “free” claim, the statement of ingredients or the summary statement.</p> <p>Where there are no cross contact allergens, or all cross contact allergens are present at Action Level 1, then there is no requirement to have a PAL statement. Do not use a statement such as “Nil cross contact allergens” or “No known cross contact allergens” as such statements may imply a “free” claim to consumers.</p>	<p>Section 4.1.11 Precautionary Allergen Labelling of FIGAML</p> <p>Refer to FIGAML for examples of ingredient lists which do not have a PAL statement.</p>
Format	<p>The PAL statement should be printed in the following format:</p> <p>May be present: allergen x, allergen y.</p> <p>where “allergen x” and “allergen y” are cross contact allergens identified at Action Level 2 in a risk assessment of a product using the VITAL Program.</p> <p>Use the same typeface and text size as any required name in the statement of ingredients.</p> <p>Declare the cross contact statement in bold font.</p>	<p>Section 4.1.11 Precautionary Allergen Labelling of FIGAML</p> <p>Refer to FIGAML for examples of how to format an ingredient list.</p>
Location	<p>Display the PAL statement separately from but next to the summary statement.</p> <p>The preferred location is below the allergen summary statement on a separate line.</p> <p>The PAL statement cannot be located such that it prevents the summary statement from being directly next to the statement of ingredients (for example it cannot be between the statement of ingredients and the summary statement).</p> <p>If a summary statement is not used because there are no allergens in the statement of ingredients, display the PAL statement where the summary statement would usually be located.</p>	<p>Section 4.1.1 Recommended Allergen Labelling Format Figure 2 - The Allergen Labelling Elements of an ingredient list of FIGAML</p> <p>Section 4.1.11 Precautionary Allergen Labelling of FIGAML</p>

Topic	Comments	Additional References
VITAL Labelling Hierarchy	The VITAL Program uses a labelling hierarchy to determine the labelling outcome where the same allergen is present from multiple sources or in different forms (particulate or readily dispersible form).	Appendix 1: The VITAL Program Hierarchy <ul style="list-style-type: none"> Wholegrain Soup Example Snack Bar Example Mayonnaise Example Pork and Prawn Curry Rice Example
Terminology for the Precautionary Allergen Label (PAL) statement	The terminology to declare cross contact allergens in the PAL statement is explained in FIGAML and examples are listed in Section 2.3 of this document.	2.2 Recommended Terminology for PAL Statements <ul style="list-style-type: none"> Wholegrain Soup Example Snack Bar Example Section 4.1.3 Allergens and Required Names and; Section 4.1.11 Precautionary Allergen Labelling of FIGAML
Particulate & Readily dispersible	<p>Cross contact allergens in the VITAL Program are differentiated as readily dispersible or particulate cross contact allergens.</p> <p>The labelling outcome is Action Level 2 (PAL statement is required) for particulate cross contact allergens.</p> <p>The labelling outcome can be Action Level 1 or Action Level 2 for readily dispersible cross contact allergens depending on its concentration. The total concentration of readily dispersible cross contact allergens is summed and compared to the Action Level Transition point and may have an Action Level 1 (a PAL statement is not required) or Action Level 2 (a PAL statement is required).</p>	Appendix 1: The VITAL Program Hierarchy <p>2.7 Particulate Cross Contact Allergens of The VITAL Guide</p> <ul style="list-style-type: none"> Wholegrain Soup Example
Sulphites	<p>Added sulphites present at 10mg/kg and above are listed in the table to section S9-3 of the Code as a food for mandatory declaration. However, sulphites are not included in the allergen lists in VITAL Online. The guidance below covers sulphites as a cross contact allergen. Information about the declaration of sulphites as an intentionally added allergen is available in FIGAML.</p> <p>The presence of sulphites due to cross contact allergens should be considered. In the Code, sulphites are considered an allergen when the sulphites are present due to additives such as sulphur dioxide and sodium and potassium sulphites. Naturally occurring sulphites found in foods should not be considered as an allergen. Sulphites present due to cross contact from additives should be declared in a PAL statement where they are present at 10 mg/kg or above in the finished product. The presence of sulphites due to cross contact can be confirmed through analytical laboratory testing of finished product.</p>	<p>Standard 1.2.3 Information requirements - warning statements, advisory statements and declarations and Standard 1.2.4 Information requirements - statement of ingredients and Schedules 7, 8 and 9 of the Code</p> <ul style="list-style-type: none"> Pork and Prawn Curry Example <p>2.0 The VITAL Procedure of The VITAL Guide</p> <p>Section 4.1.3 Allergens and Required Names of FIGAML</p> <p>Allergen Bureau Food Allergen Analysis</p>

Topic	Comments	Additional References
Small packages	<p>Foods with a package with a surface area of less than 100 cm² require an allergen declaration which includes the required names from Column 4 of the table to section S9-3 of the Code. Format and location requirements do not apply.</p> <p>When required, PAL statements should be included in the ingredient declarations of small packages.</p>	<p>Standard 1.2.3 Information requirements – warning statements, advisory statements and declarations of the Code</p> <p>Table 3 Allergen Declaration Requirements for Various Foods Being Offered For Sale, 4.1 Allergen Declaration Requirements of FIGAML</p> <ul style="list-style-type: none"> • Mayonnaise Example

2.2 Labelling Outcomes From The VITAL Program

VITAL Online determines a labelling outcome for each allergen in the finished product, based on the allergen status of ingredients and the impact of a processing profile. The possible labelling outcomes are:

- **Intentionally Added**
the declaration of intentionally added allergens is regulated in Standard 1.2.3 Information requirements – warning statements, advisory statement and declarations of the Code. Intentionally added allergens are required to be declared using their required names, in a bold font, in the statement of ingredient and in the summary statement.
- **Action Level 1**
cross contact allergens at Action Level 1 are present at low levels and no PAL statement is required.
- **Action Level 2**
cross contact allergens at Action Level 2 are present at significant levels and are required in the [VITAL Program](#) to be declared in a PAL statement.

Refer to the definitions for intentionally added allergens and Action Levels in [Appendix 2](#).

The rules for determining the labelling outcome for each allergen are included in the [VITAL Program Labelling Hierarchy](#) (Appendix 1).

Where VITAL Standard certification is achieved and is current, the VITAL Mark may be used on products and its related communications within the scope of the certification.

2.3 Recommended Terminology For PAL Statements

Declare cross contact allergens, when assessed at Action Level 2 in the VITAL Program, using the terminology below.

Food	Declaration On PAL Statement
Crustacea	Crustacean
Egg	Egg
Fish	Fish
Lupin	Lupin
Milk	Milk
Mollusc	Mollusc
Peanut	Peanut
Sesame seed	Sesame
Soybean	Soy, soya or soybean
Sulphites	Sulphites

i) Declaration of allergens in a PAL Statement

ii) Declaration of cereals in a PAL statement

Barley, rye and oats which do not contain gluten

The table to section 9-3 of the Code requires the mandatory declaration of barley, rye and oats if they contain gluten. All products of barley, rye, oats should be considered to contain gluten unless they have an assessment which determines that gluten is not present. This should be supported by a high standard of validation, which may include specialised laboratory analysis in addition to methods for quantitative allergen analysis and, where possible, consultation with an enforcement agency to ensure validation and verification approaches are adequate. A product of barley, rye or oats which does not contain gluten is not considered to be an allergen and is not required to be declared in the PAL statement.

Wheat and its hybrids which do not contain gluten

The table to section 9-3 of the Code requires the mandatory declaration of 'wheat' and also, the declaration of 'gluten' where gluten is present. Wheat products which do not declare gluten should have an assessment which determines that gluten is not present. This should be supported by a high standard of validation, which may include specialised laboratory analysis in addition to methods for quantitative allergen analysis. A product of wheat which does not contain gluten is required to declare 'wheat' in the PAL statement.

Group terms such as 'cereals containing gluten' and 'cereals'

Avoid the use of terms such as 'cereals containing gluten' or 'cereals' to describe a group of allergens. Where practicable, declare each cereal individually to assist consumers with food allergies to certain cereals.

There may be situations where, after a thorough risk review has been completed and opportunities to reduce or eliminate cross contact allergens have been exhausted, FBOs may need to apply a PAL statement that declares up to four cereals containing gluten. In this situation, the use of terms which describe a group of allergens may be appropriate.

Cereal	Declaration In Precautionary Allergen Labelling Statement
Any of the following cereals (including hybridised strains thereof) if they contain gluten: Barley Oats Rye	Barley, gluten Oats, gluten Rye, gluten
Wheat and its hybrids which contain gluten	Wheat, gluten
Wheat and its hybrids which do not contain gluten	Wheat

iii) Declaration of tree nuts in a PAL statement

Tree nut allergy

Some people are allergic to one or more tree nuts, but it is unusual to be allergic to all tree nuts. A person who is allergic to a specific tree nut may also react to a different one due to cross-reactivity. Tree nuts from the same botanical families have the strongest cross-reactivity. For example, people often have both a cashew and pistachio allergy as these tree nuts are both in the botanical family Anacardiaceae. Also, walnut and pecan allergy are often found together as they are from the same botanical family, Juglandaceae.

Group terms such as "tree nuts"

Where practicable avoid the use of terms such as 'tree nuts' to declare one or more tree nuts. However, there may be situations where, after a thorough risk review has been completed and opportunities to reduce or eliminate cross contact allergy have been exhausted, FBOs may need to apply a PAL statement that declares all (or virtually all) tree nuts. In this situation, the use of terms which describe a group of allergens may be appropriate.

Information that specifies which tree nut is present in a food is more helpful to people with a tree nut allergy than a broader statement like "tree nuts".

Tree Nut	Declaration in Precautionary Allergen Labelling Statement
Almond	Almond
Brazil nut	Brazil nut
Cashew	Cashew
Hazelnut	Hazelnut
Macadamia	Macadamia
Pecan	Pecan
Pine nut	Pine Nut
Pistachio	Pistachio
Walnut	Walnut

3. EXAMPLES

3.1 Wholegrain Soup Example

a. Overview - This worked example covers the below scenarios:

- Terminology for allergens declared in the PAL statement
- Declaration of cereals
 - triticale (wheat, rye) and oats present as ingredients
 - barley 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 cross contact allergens
 - barley is present as a particulate cross contact allergen
 - peanut is present as a readily dispersible cross contact allergen

b. Recipe - Wholegrain Soup

Ingredient	Quantity (%)	Intentionally Added Allergen	Cross Contact Allergen		Allergen Notes/ Assumptions
			Particulate	Readily Dispersible	
Water	40				
Potato	17				
Carrots	16				
Celery	10				
Triticale	8	Cereals (wheat and its hybrids which contain gluten & rye)			Triticale is a hybrid of wheat and rye.
Whole oats	4	Cereals (oats)	Cereals (barley)		
Whole wheat	3	Cereals (wheat and its hybrids which contain gluten)			
Peanut oil	2	Peanut			
Cross contact due to Processing	From shared production lines with products containing peanut oil.			Peanut	<ul style="list-style-type: none"> • Hang up quantity: 500g • Peanut in hang up: 2% • Protein in peanut: 1% • Batch size exposed to hang up: 1000kg
Reference Amount	100g			Yield	100%

c. VITAL Assessment Outcomes

Assessment Outcomes	
Recipe Name	Wholegrain Soup
Recipe Code	SOUP
Published	06 September 2021, 10:03:59 am
Legislation	Australia and New Zealand
Reference Amount	100 g
Intentionally Added	Oats, gluten Rye, gluten Wheat, gluten Peanut
Action Level 2	Barley Gluten
Action Level 1	

Substance	Intentionally Added	Cross Contact		VITAL Risk Assessment Labelling Outcome
		Particulate	Readily Dispersible	
Cereals (total)	✓	✓		Intentionally Added Action Level 2
Barley		✓		Action Level 2
Oats	✓			Intentionally Added
Rye	✓			Intentionally Added
Wheat and its hybrids which contain gluten	✓			Intentionally Added
Peanut	✓		✓	Intentionally Added

d. Recommended ingredient list

<i>Statement of ingredients:</i>	Wholegrain cereals (15%) (triticale (wheat, rye), oats , whole grain wheat), water, potato, carrots, celery, peanut oil.
<i>Summary Statement</i>	Contains: wheat, gluten, peanut.
<i>PAL Statement</i>	May be present: barley.

e. Tips / Reasoning for PAL

- Cereals containing gluten are present both as ingredients (wheat, rye, oats) and cross contact allergens (barley). **Barley** is a cross contact allergen, and it is declared in the PAL statement.
Note: declaring cereals individually, instead of using group terms such as 'cereals containing gluten' or 'cereals' in the PAL statement, is helpful to assist consumers with food allergies (see Section 2.3).
- The terminology for declaring the presence of barley in a PAL statement is "barley, gluten". However, gluten is listed in the summary statement, so it is not repeated in the PAL statement in this example.
- Peanut is present in peanut oil as an ingredient and as a cross contact from processing. The [VITAL Program Labelling Hierarchy](#) (Appendix 1) directs that it is only necessary to list peanut in the statement of ingredients and summary statement. In the example, it is not necessary to also list peanut in the PAL statement.

3.2 Snack Bar

a. Overview - This worked example covers the below scenarios:

- Declaration of tree nuts
 - when present as an ingredient and as a cross contact allergen
 - when multiple cross contact tree nuts are present

b. Recipe - Snack Bar

Ingredient	Quantity (%)	Intentionally Added Allergen	Cross Contact Allergen		Allergen Notes/ Assumptions
			Particulate	Readily Dispersible	
Oatmeal	64	Cereals (oats)			
Glucose syrup	15				Glucose syrup is derived from wheat (supplier advises that it is highly refined and contains <20 ppm gluten) This meets the exemption requirement to declare wheat as an allergen in Line 3, the table to section S9-3 of the Code .
Almond meal	10	Tree nuts (almond)			
				Tree nuts (hazelnut) 20 ppm	
				Tree nuts (macadamia) 20 ppm	
Honey	6				
Coconut	5				Coconut is not a substance required for mandatory declaration in the table to section S9-3 of the Code .
Cross contact due to Processing	None				
Reference Amount	40g			Yield	100%

c. VITAL Assessment Outcomes

Assessment Outcomes	
Recipe Name	Snack Bar
Recipe Code	SNACK BAR
Published	06 September 2021, 11:03:26 am
Legislation	Australia and New Zealand
Reference Amount	40 g
Intentionally Added	Oats, gluten Almond
Action Level 2	Hazelnut Macadamia
Action Level 1	

Substance	Intentionally Added	Cross Contact		VITAL Risk Assessment Labelling Outcome
		Particulate	Readily Dispersible	
Cereals (total)	✓			Intentionally Added
Oats	✓			Intentionally Added
Tree nuts (Almond, Brazil nut, Hazelnut, Macadamia, Pine Nut) (Total)	✓		3 ppm	Intentionally Added Action Level 2
Almond	✓			Intentionally Added
Hazelnut			2 ppm	Action Level 2
Macadamia			2 ppm	Action Level 2

d. Recommended ingredient list

<i>Statement of ingredients:</i>	Oatmeal (oats), glucose syrup, almond meal, honey, coconut.
<i>Summary Statement</i>	Contains: gluten, almond.
<i>PAL Statement</i>	May be present: hazelnut, macadamia.
<i>Alternative PAL Statement</i>	May be present: other tree nuts (hazelnut, macadamia).

e. Tips / Reasoning for PAL

- Tree nuts are present both as an ingredient (almond) and as a cross contact allergen (hazelnut, macadamia). Note the [VITAL Program Labelling Hierarchy](#) (Appendix 1) for grouped allergens where two allergens in the same group sum to [Action Level 2](#). The [Action Level transition point](#) is 2.5 ppm. The macadamia and hazelnut are both present at 2 ppm. When viewed individually, macadamia and hazelnut are present below the Action Level transition point. However, the hierarchy rules require that they are summed – and hence both have a labelling outcome of Action Level 2 in the VITAL Program.

Almond is also in the same group of allergens and is present as an intentionally added allergen. Hence, almond is declared as an intentionally added allergen (in the statement of ingredients and summary statement). Cashew and macadamia are Action Level 2, declared in the PAL statement.

- The preferred option for the PAL statement is to declare the possible presence of hazelnut and macadamia individually: **“May be present: hazelnut, macadamia.”**

An alternative PAL statement, that is **“May be present: other tree nuts (hazelnut, macadamia).”**, has been included in this example. The term “other” is used to emphasize the presence of additional tree nuts beyond those explicitly listed in the summary statement.

A statement like **“May be present: other tree nuts.”** is deemed inappropriate in this example. Primarily, it fails to specify the particular tree nuts that might be present, making it less informative for individuals with sensitivities to specific tree nuts. Such a statement should only be considered for use where the risk assessment identifies that all or virtually all (of the 9) tree nuts are potential cross contact allergens.

In this scenario, the use of “May be present: tree nuts.” could be misleading to consumers and **should not be used** because it could be interpreted that this referred to the intentionally added tree nuts (almond) and not the different cross contact tree nuts.

3.3 Mayonnaise

a. Overview - This worked example covers the below scenarios:

- cross contact allergen at Action Level 1
- ink jetted labels, i.e. where the requirement of food in small packages is met

b. Recipe - Mayonnaise

Ingredient	Quantity (%)	Intentionally Added Allergen	Cross Contact Allergen		Allergen Notes/ Assumptions
			Particulate	Readily Dispersible	
Vegetable oil (Canola)	50				Contains - canola oil, acid 330 (derived from maize), antioxidant (306 (derived from soy)) The soy meets the exemption for the requirement to declare soy as an allergen in Line 13, the table to section S9-3.
Malt vinegar	20	Cereals (barley)			Source - fermented from barley
Milk solids	12	Milk			Contains - milk proteins
Egg yolk	10	Egg			
Water	4				
Salt	3				
Caramel colour III	1	Cereals (wheat and its hybrids which contain gluten)			Source - derived from wheat
Cross contact due to Processing	From shared production lines with products containing sesame oil.			Sesame	<ul style="list-style-type: none"> • Hang up quantity: 1000g • Sesame in hang up: 1% • Protein in sesame: 1% • Batch size exposed to hang up: 2000kg
	From shared production lines with products containing peanut.			Peanut	<ul style="list-style-type: none"> • Hang up quantity: 1000g • Peanut in hang up: 100% • Protein in peanut: 28% • Batch size exposed to hang up: 2000kg
Reference Amount	40g			Yield	100%

c. VITAL Assessment Outcomes

Table 1: Assessment Outcomes

Assessment Outcomes	
Recipe Name	Mayonnaise
Recipe Code	M
Published	07 January 2022, 1:04:10 pm
Legislation	Australia and New Zealand
Reference Amount	40 g Mayonnaise
Intentionally Added	Barley, Gluten Wheat, Gluten Egg Milk
Action Level 2	Peanut
Action Level 1	Sesame

Substance	Intentionally Added	Cross Contact		VITAL Risk Assessment Labelling Outcome
		Particulate	Readily Dispersible	
Cereals (total)	✓			Intentionally Added
Barley	✓			Intentionally Added
Wheat and its hybrids which contain gluten	✓			Intentionally Added
Egg	✓			Intentionally Added
Milk				Intentionally Added
Peanut			140ppm	Action Level 2
Sesame			0.05ppm	Action Level 1

d. Recommended ingredient list

- i) Where the package does not meet the requirements for foods in small packages

<i>Statement of ingredients:</i>	Vegetable oil [acid (330), antioxidant (306)], malt vinegar (barley), milk solids, egg yolk, water, salt, colour (150c (wheat)).
<i>Summary Statement</i>	Contains: wheat, gluten, milk, egg.
<i>Precautionary Statement</i>	May be present: peanut

- ii) Where the package meets the requirements for foods in small packages (as defined in Standard 1.1.2 - Definitions used throughout the Code of the Code)

<i>Summary Statement</i>	Contains: wheat, gluten, milk, egg.
<i>Precautionary Statement</i>	May be present: peanut.

e. Tips / Reasoning for PAL

- Foods in small packages (as defined in the Code) are required to have an allergen declaration and the guidance in this document is that the PAL statement should also be included in this declaration. The example shown for a small package could represent a sachet of mayonnaise included as part of a meal and frequently inkjet coding is used for this purpose. Note that it is difficult to apply bold font to inkjet text. Care should be taken to ensure that any allergen declarations made using inkjet coder can be clearly read. Refer to FIGAML for further information about allergen declarations using inkjet coders.
- Cross contact allergens with a labelling outcome of Action Level 1 are not required to be declared in a PAL statement. Sesame is present at Action Level 1 in this product and hence is not included in the PAL statement.

3.4 Pork And Prawn Curry Rice

a. Overview - This worked example covers the below scenarios:

- Listing of multiple allergens in the PAL statement
- The VITAL Program Action Levels
 - cross contact allergens at Action Level 1
 - cross contact allergens at Action Level 2
- Sulphites present as an intentionally added allergen (technically: food intolerance)
- Readily dispersible and particulate cross contact allergens

b. Recipe - Pork and Prawn Curry Rice

Ingredient	Quantity (%)	Intentionally Added Allergen	Cross Contact Allergen		Allergen Notes/ Assumptions
			Particulate	Readily Dispersible	
Cooked rice	50				
Pork	17	Milk			Contains - lactoperoxidase* (processing aid added at GMP levels) *Has no technological function in the final food
Prawns	11	Crustacean			
		Sulphites			Contains sodium metabisulphite (223) added to prawns at 90 mg/kg [equates to 10mg/kg added to this recipe]
Sugar	9				
Water	6.5				
Tapioca flour	4				
Curry powder	2.5				Coriander, turmeric, cumin seed, fennel seed, ginger
				Sesame (50ppm)	Sesame seeds are present as a particulate cross contact at harvest. During the process of making the curry powder, the mixture is finely ground and the sesame can be considered to be readily dispersible cross contact allergen.
				Cereals (wheat and its hybrids which contain gluten) (100ppm)	Wheat is present as a particulate cross contact at harvest. During the process of making the curry powder, the mixture is finely ground and the wheat can be considered to be readily dispersible cross contact allergen.
Cross contact due to Processing	From shared production lines with products containing peanut oil.			Peanut	<ul style="list-style-type: none"> Hang up quantity: 2000g Peanut in hang up: 5% Protein in Peanut: 1% Batch size exposed to hang up: 500kg
	From shared production lines with products containing soy.			Soy	<ul style="list-style-type: none"> Hang up quantity: 2000g Soy in hang up: 1% Protein in soy: 1% Batch size exposed to hang up: 500kg
Reference Amount	400g			Yield	100%

c. VITAL Assessment - Pork and Prawn Rice

Table 1: Assessment Outcomes

Assessment Outcomes	
Recipe Name	Pork and Prawn curry with rice
Recipe Code	r
Published	16 February 2022, 2:42:53 pm
Legislation	Australia and New Zealand
Reference Amount	400 g 1
Intentionally Added	Crustacean Milk
Action Level 2	Wheat, Gluten Peanut Sesame
Action Level 1	Soy

Substance	Intentionally Added	Cross Contact		VITAL Risk Assessment Labelling Outcome
		Particulate	Readily Dispersible	
Cereals (total)			2.5 ppm	Action Level 2
Wheat and its hybrids which contain gluten			2.5 ppm	Action Level 2
Crustacean	✓			Intentionally Added
Milk	✓			Intentionally Added
Peanut			2 ppm	Action Level 2
Sesame			1.25 ppm	Action Level 2
Soy			0.4 ppm	Action Level 1

d. Recommended ingredient list

<i>Statement of ingredients:</i>	Cooked rice, pork (processing aid milk), prawns (crustacean) (preservative (223) (sulphites)), sugar, water, tapioca flour, curry powder.
<i>Allergen Summary Statement</i>	Contains: milk, crustacean, sulphites.
<i>Precautionary Statement</i>	May be present: peanut, sesame, wheat, gluten.

e. Tips / Reasoning for PAL

- Where there are multiple substances listed in the PAL statement, they can be listed in any order - for example, alphabetical order. (Note, the recommendation in Section 4.1.6 Summary Statements of [FIGAML](#) for listing allergens in a summary statement is to list them in the order that they (first) appear in the statement of ingredients.) In this example, peanut, sesame and wheat are listed in alphabetical order. "Wheat" and "gluten" refer to the same cross contact so they are declared together.
- Sulphites are present in this product as part of a compound ingredient - they are defined as 'intentionally added' in the VITAL Program. The Code states that added sulphites present at 10mg/kg or above are required to be declared. Hence in this example the sulphites are declared in a bold font in the statement of ingredients and summary statement. If added sulphites were present at less than 10mg/kg, then the declaration of sulphites as an allergen is not required and the declaration should follow requirements for the labelling of additives.
- The curry powder contains wheat and sesame seed particulate cross contact allergens. In this case, the product has been ground and this has transformed the cross contact from a particulate form to a readily dispersible form. This example highlights that each cross contact allergens should be carefully assessed to understand their form ([readily dispersible](#) or [particulate](#)). There are also examples where due to the aggregation of readily dispersible cross contact allergens (clumping), a readily dispersible cross contact allergen must be considered as a particulate cross contact allergen in the VITAL Program.

Appendix 1 - The VITAL Program Labelling Hierarchy

Allergen Status	VITAL Online Finished Product Labelling Outcome
Allergen is intentionally added	Intentionally added
Allergen is present at Action Level 1	Action Level 1
Allergen is present at Action Level 2	Action Level 2
Same allergen is present at Action Level 1 and Action Level 2	Action Level 2
Allergen is present as cross contact in particulate form	Action Level 2
Same allergen is present at Action Level 1 and/or Action Level 2 and as cross contact in particulate form	Action Level 2
Same allergen is present at Action Level 1 and/or Action Level 2 and/or in particulate form and intentionally added	Intentionally added
<p>Grouped Allergens have additional hierarchy rules in VITAL Online. The groups based on rationale from related scientific groupings are not relevant for the process of creating a label declaration. The grouped allergens in VITAL Online are:¹</p> <ul style="list-style-type: none"> • Cereals (includes barley, oats, rye, wheat & its hybrids which contain gluten, and wheat & its hybrids which do not contain gluten). • Tree nuts (cashew & pistachio) • Tree nuts (pecan & walnut) • Tree nuts (almond, Brazil nut, hazelnut, macadamia, pine nut) 	
Two or more allergens in a group are Action Level 1 and sum to Action Level 1	Action Level 1 for each allergen present in the food from the group
Two or more allergens in a group are Action Level 2	Action Level 2 for each allergen present in the food from the group
Two or more allergens in a group are Action Level 1 and sum to Action Level 2	Action Level 2 for each allergen present in the food from the group
Particulate and one or more other cross contact allergen from the group in readily dispersible form	Action Level 2 for allergen present as a particulate plus the outcome of Action Level 1 or Action Level 2 depending on the sum of the other cross contact allergens in the group as per the rules above
Intentionally added allergen and one or more other cross contact allergen(s) from the group in readily dispersible form	Intentionally added allergen plus the outcome of Action Level 1 or Action Level 2 depending on the sum of the other cross contact allergens in the group per the rules above

¹ Tree nuts are divided into 3 groups. These groups are valid only for determining whether specific tree nuts are in Action Level 1 or Action Level 2 and these groups have no meaning as a labelling descriptor.

Appendix 2 - Definitions

Term	Definition
Action Levels	<p>Action Levels are the concentrations (of protein) which define the labelling outcomes for each concentration of cross contact allergen in a VITAL risk assessment. They are determined using the Reference Dose and the Reference Amount.</p> <ul style="list-style-type: none"> • <i>Action Level 1</i>: Low concentration of the relevant allergen under evaluation, low chance of adverse reaction and no precautionary allergen labelling statement required. • <i>Action Level 2</i>: Significant concentration of relevant allergen under evaluation, significant chance of adverse reaction and a precautionary allergen labelling statement is required.
Action Level transition point	<p>The Action Level transition point (ppm) = Reference Dose (mg) x 1000 / Reference Amount (g)</p> <p>(except cereals containing gluten where the formula above is applicable or 20ppm, whichever is lower.)</p> <p>Source: The VITAL Guide</p>
Allergen	<p>Referred to in this Guide as the substances required for mandatory declaration that are listed in Column 1 of the table to section S9-3 of the Code.</p>
Allergen Bureau	<p>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.</p>
Cereals	<p>The table to section S9-3 of the Code has two separate categories which are:</p> <ul style="list-style-type: none"> • cereals (including hybridised strains thereof) if they containing gluten: barley, oats, rye; and • wheat (including its hybridised strain) irrespective of whether it contains gluten. <p>In the VITAL Program, the 'cereals' group is: barley, oats, rye, wheat and its hybridised strains which contain gluten, and wheat and its hybridised strains which do not contain gluten.</p>

Term	Definition
Cross contact allergen	<p>A residue or other trace amount of an allergenic food that is unintentionally incorporated into another food. For the VITAL program, cross contact sources can be from raw materials or processing.</p> <p>Cross contact is also be known as Unintentional Allergen Presence (UAP).</p> <p>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.</p> <p>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.</p>
Exemptions (also Allergen labelling exemptions)	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.
FIGAML	The Allergen Bureau and Australian Food and Grocery Council's (AFGC) Food Industry Guide to Allergen Management and Labelling.
FBO	Food Business Operator
Food Standards Code (the Code)	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 (the Code).
Ingredient List	<p>In this Guide an 'ingredient list' is a collective term which represents up to three labelling elements.</p> <ol style="list-style-type: none"> 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 (PAL) statement
Intentionally added allergen	<p>Any ingredient (or intrinsic part of the ingredient) of the recipe which contains an allergen, and</p> <p>includes all allergens which require mandatory declaration.</p>

Term	Definition
PAL statement	<p>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.</p> <p>The only PAL statement recommended for use with the VITAL Program is 'May be present: allergen x, allergen y.'</p>
Particulate cross contact allergen	<p>Defined in the VITAL Program as a separate and distinct particle of material which either</p> <ul style="list-style-type: none"> • does not mix homogeneously 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.
Readily dispersible cross contact allergen	<p>Defined in the VITAL Program as a powder or liquid in homogeneous 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 homogeneously distributed in the final product.</p>
Required names	<p>Mandatory declarations to be used when stating an allergen in a statement of ingredients or summary statement. Required names are listed in the table to Schedule 9-3 in the Code.</p>
Summary Statement	<p>A mandatory statement that summarises the required names of the allergens in the statement of ingredients. Summary statements must begin with the word 'Contains' and list allergens using the required name (from Column 4 of the table to section S9-3 of the Code) in a bold font. Standard 1.2.3 - <i>Information requirements - warning statements, advisory statements and declarations</i> of The Code outlines the format and location requirements for the summary statement.</p>
Tree nuts	<p>For the purposes of allergen labelling, the relevant tree nuts are listed in the table to section S9-3 of the Code. The tree nuts are: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio and walnut.</p>
VITAL	<p>Voluntary Incidental Trace Allergen Labelling Program</p>

Appendix 3 - Resources

Source	Reference / Resource
Australia and New Zealand	
Allergen Bureau	<p>Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program</p> <p>In this Guide this document title is abbreviated to “the VITAL Guide”</p> <p>VITAL Online is the web-based calculator which assists in the implementation of the VITAL Program, and is Available by subscription through the Allergen Bureau website vital.allergenbureau.net</p>
Allergen Bureau	<p>Unexpected Allergens in Food</p> <p>This document provides a list of foods, ingredients and raw materials that may unexpectedly contain allergens.</p>
Allergen Bureau	<p>Assessing Agricultural Cross Contact</p> <p>The guidance document provides the food industry with guidance on identifying and assessing agricultural commodities that may contain allergens due to cross contact events.</p>
Australian Food and Grocery Council and Allergen Bureau	<p>Australian Food and Grocery Council’s Food Industry Guide to Allergen Management and Labelling (FIGAML)</p> <p><i>In this Guide this document title is abbreviated to FIGAML.</i></p> <p>FIGAML provides:</p> <ul style="list-style-type: none"> • 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 Program for risk assessment and labelling of cross contact allergens. • 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.
Food Standards Australia New Zealand	<p>Australia New Zealand Food Standards Code</p> <p>In this Guide this document title is abbreviated to: ‘the Code’</p>

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