VITAL®

Allergen Bureau

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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Informing the food industry

allergenbureau.net

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 Labelling Guide demonstrates how to form an ingredient list which complies with the recommendations in the Food Industry Guide to Allergen Management and Labelling (FIGAML) by using information from the risk assessment of a product using the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program. 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 Food Industry Guide to the VITAL® Program and FIGAML and it should be referenced alongside these guides. These guides provide further information about the use of PAL statements and the VITAL Program. VITAL Online is the web-based calculator which assists in the implementation of the VITAL Program. VITAL Online is available by subscription through the Allergen Bureau website vital.allergenbureau.net.

The examples in this Best Practice Labelling Guide are set out in the same format as the outcomes that users of VITAL Online will see. Key components of this guide include the following:

- 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
- a list of references to other materials that provide further guidance on allergen declaration. The glossary with terms used can be found in the Food Industry Guide to the VITAL Program. Further resources, such as "Unexpected Allergens in Food", "Assessing Agricultural Cross Contact" can be found on the Allergen Bureau website.

This Guide uses the term "ingredient list" as a collective term to describe the following:

- the mandatory statement of ingredients
- the mandatory summary statement which lists allergens using the Required Name. Summary statements must begin with the word "Contains" and be in a **bold font**.
- 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.

Label

The information in this labelling guide should only be used by a food business operator (FBO) after they have implemented the VITAL Program. The 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.

Tabular Format In This Guide:

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

Actual Label Declaration:

INGREDIENTS

Vegetable oil [acid (330), antioxidant (306)], malt vinegar (**barley**), **milk** solids, **egg** yolk, water, salt, colour [150c (**wheat**)].

Contains: wheat, gluten, milk, egg.

May be present: peanut

2. DECLARATION OF ALLERGENS IN PAL STATEMENTS

2.1 Guiding principles for the declaration of allergens in PAL statements

Topic	Comments	Additional References
General	Ensure the PAL statement is logical, consistent and is not contradictory to the statement of ingredients or summary statement. For example, a PAL statement should not include an allergen which has been listed in a "free from" claim, the statement of ingredients or the summary statement. 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.	Section 4.1.11 Precautionary Allergen Labelling of FIGAML Refer to FIGAML for examples of ingredient lists which do not have a PAL statement.
Format	The PAL statement should be printed in the following format: **May be present: allergen x, allergen y.** 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. Use the same typeface and text size as any required name in the statement of ingredients. Declare the cross contact statement in bold font.	Section 4.1.11 Precautionary Allergen Labelling of FIGAML Refer to FIGAML for examples of how to format an ingredient list.
Location	Display the PAL statement separately from, but adjacent to the summary statement. The preferred location is below the allergen summary statement on a separate line. The PAL statement cannot be located such that it prevents the summary statement from being directly next to the statement of ingredients (for example it cannot be between the statement of ingredients and the summary statement). If a summary statement is not used because there are no allergens in the statement of ingredients, display the PAL statement where the summary statement would usually be located.	Section 4.1.1 Recommended Allergen Labelling Format Figure 2 - The Allergen Labelling Elements of an ingredient list of FIGAML Section 4.1.11 Precautionary Allergen Labelling of FIGAML

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 • 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 Best Practice Labelling Guide.	2.3 Recommended Terminology for PAL Statements • 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	Cross contact allergens in the VITAL Program are differentiated as readily dispersible or particulate cross contact allergens. Due to the definition of a particulate for the purpose of VITAL, the labelling outcome is Action Level 2 (PAL statement is required) for those particulate cross contact allergens which are matching the definition for both non-homogenously mixing as well as a relevant RfD. The labelling outcome can be Action Level 1 or Action Level 2 for readily dispersible cross contact allergens depending on its concentration. For allergens which are grouped together, 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).	Appendix 1: The VITAL Program Hierarchy 2.4 Particulate Cross Contact Allergens of Food Industry Guide to the VITAL® Program • Wholegrain soup example • Batter fryer example • Cashew kibble example

Topic	Comments	Additional References
Sulphites	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. The presence of sulphites due to cross contact 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 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.	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 • Pork and prawn curry rice example Chapter 2 of the Food Industry Guide to VITAL Section 4.1.3 Allergens and Required Names of FIGAML
Small Packages	Foods with a package with a surface area of less than 100 cm^2 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. When required, PAL statements should be included in the ingredient declarations of small packages.	Standard 1.2.3 Information requirements – warning statements, advisory statements and declarations of the Code Table 3 Allergen Declaration Requirements for Various Foods Being Offered For Sale, 4.1 Allergen Declaration Requirements of FIGAML • 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**
  Low concentration of the relevant allergen under evaluation, low chance of adverse reaction and no precautionary allergen labelling statement is required.
- **Action Level 2**
  Significant concentration of relevant allergen under evaluation, significant chance of adverse reaction and a precautionary allergen labelling statement is required (if legally permitted in the country of sale or the country of further manufacture).

Refer to the definitions for intentionally added allergens and Action Levels in Food Industry Guide to the VITAL® Program.

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

Where products have current VITAL Standard certification, the VITAL Certification Mark may be applied along with any related communications within the scope of the certification.

2.3 Recommended terminology for PAL statements

2.3.1 Declaration of allergens in a PAL Statement

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

Food	Declaration in PAL Statement
crustacea	crustacean
egg	egg
fish	fish
lupin	lupin
milk	milk
mollusc	mollusc
peanut	peanut
sesame seed	sesame
soybean	soy, soya or soybean

2.3.2 Declaration of cereals in a PAL statement

Wheat and its hybrids

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. A product of wheat which does contain gluten is required to declare, "wheat, gluten" in the PAL statement.

Barley, rye and oats

The table to section 9-3 of the Code requires the mandatory declaration of barley, rye and oats, only 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.

Barley, rye and oats are not IgE mediated priority allergens, and individual quantification of these cereals is difficult to establish through sampling and testing (gluten tests do not differentiate between each cereal). For this reason labelling "gluten" in the PAL statement is recommended where there is a cross contact risk from barley, rye or oats alone or in combination.

Manufacturers are encouraged to record information on the known sources of gluten, as consumers with IgE-mediated allergies to rye, oats or barley may request more specific information regarding cross-contact sources.

Cereal	Declaration in PAL Statement
Any of the following cereals (including hybridised strains thereof) if they contain gluten: barley oats rye	gluten
Wheat and its hybrids which contain gluten	wheat, gluten
Wheat and its hybrids which do not contain gluten	wheat

A note of caution on gluten

Gluten can be defined as a combination of several proteins, prolamin and glutenin. Prolamins are described by different names in the different cereal species, the proportion of the protein varies between the cereals, as does the toxicity to those who suffer from coeliac disease.

There is a common misconception that oats do not contain gluten. In Europe and USA, oats can be labelled as 'gluten free' where there is no detectable contamination with wheat, rye, or barley. This is equivalent of oats labelled 'wheat free, oats (uncontaminated), pure oats' in Australia. (In addition, there are different regulatory requirements in EU and USA in relation to gluten free, where less than 20ppm of gluten from wheat, rye or barley is permissible).

Traditional analytical kits used to test for gluten were developed predominately in the EU and USA, where oats are not included in the mandatory allergen labelling legislation. These traditional kits have been designed to detect prolamins from wheat, rye and barley, but cannot identify avenin, the gluten protein in oats. Since 2020, a new kit has been introduced in Australia and New Zealand that can detect oat avenin, completing the gluten analysis puzzle and giving businesses the ability to verify and confirm the absence of all gluten types as required by The Code.

Labelling of cereals in PAL

The following table might assist with labelling cereals in PAL. Where it reads any of the following cereals, it is intended to read "the cereal and the hybridised strains thereof, and its products".

Ingredients (presence or absence)	Cross contact (presence or absence)	Summary Statement Label - Contains:	PAL Statement Label May be present:	Reason
wheat	-	wheat, gluten		As per the Code
wheat	barley or rye or oats	wheat, gluten	-	Gluten already stated
wheat, barley	rye or oats	wheat, gluten	-	Gluten already stated
wheat, rye	barley or oats	wheat, gluten	-	Gluten already stated
wheat, oats	rye or barley	wheat, gluten	-	Gluten already stated
wheat (no gluten)*	-	wheat	-	As per the Code
wheat (no gluten)*	barley or rye or oats	wheat	gluten	Gluten newly introduced
wheat (no gluten)*, barley	rye or oats	wheat, gluten	-	Gluten already stated
wheat (no gluten)*, rye	barley or oats	wheat, gluten	-	Gluten already stated
wheat (no gluten)*, oats	rye or barley	wheat, gluten	-	Gluten already stated
barley	-	gluten	-	As per the Code
rye	-	gluten	-	As per the Code
oats	-	gluten	-	As per the Code
barley	rye or oats	gluten	-	Gluten already stated
rye	barley or oats	gluten	-	Gluten already stated
oats	rye or barley	gluten	-	Gluten already stated
barley	wheat	gluten	wheat	Wheat is an allergen. Gluten already stated
rye	wheat	gluten	wheat	Wheat is an allergen. Gluten already stated
oats	wheat	gluten	wheat	Wheat is an allergen. Gluten already stated
barley (no gluten)*	-	-	-	As per the Code
rye (no gluten)*	-	-	-	As per the Code
oats (no gluten)*	-	-	-	As per the Code
oats (wheat free)**	-	gluten	-	As per the Code
barley (no gluten)*	rye or oats	-	gluten	Gluten newly introduced
rye (no gluten)*	barley or oats	-	gluten	Gluten newly introduced
oats (no gluten)*	rye or barley		gluten	Gluten newly introduced
oats (wheat free)**	rye or barley	gluten	-	Gluten already stated
barley (no gluten)*	wheat	-	wheat, gluten	Wheat and gluten newly introduced
rye (no gluten)*	wheat	-	wheat, gluten	Wheat and gluten newly introduced
oats (no gluten)*	wheat	-	wheat, gluten	Wheat and gluten newly introduced
oats (wheat free)**	wheat	gluten	wheat	Wheat is an allergen. Gluten already stated

*no gluten: Please refer to Section 2.3.1 Barley, rye and oats

**oats: Products that contain oats cannot be labelled "gluten free". Refer to the following resources for more information: Allergen Bureau - making gluten free claims and Coeliac.org.au - oats commonly asked questions. Possible alternatives: oats (wheat free), oats (uncontaminated), pure oats.

2.3.3 Declaration of particulates in a PAL statement

For the purpose of VITAL, a particulate refers to a food material which:

- does not mix homogenously with other parts of the food; and
- consists of, or is likely to aggregate into, an entity which contains equal to or greater than the relevant Reference Dose

An ingredient that commences as a particulate, but is processed into an evenly dispersed material, is not considered a particulate as the process has changed the allergen form to homogeneous.

When selecting particulate, record your assumptions in the ingredient, recipe and/or processing profile. This may include recording the level of protein present in the particulate(s).

2.3.4 Declaration of tree nuts in a PAL statement

Tree nuts

For the purposes of allergen labelling, the relevant tree nuts are listed in the table to section S9-3 of the Code. These tree nuts are stated in the below table.

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" should be avoided

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".

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.

Tree Nut	Declaration in PAL 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

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**	• 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

Table 1: Assessment Outcomes

Assessment Outcomes	
Recipe Name	Wholegrain soup
Recipe Code	SOUP
Published	09 August 2024, 8:30:13 pm
Legislation	Australia and New Zealand
Reference Amount	100 g one pack
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 - wholegrain soup

Statement of ingredients:	Water, potato, carrots, wholegrain cereals (15%) (triticale (**wheat**, **rye**), **oats**, whole grain **wheat**), celery, **peanut** oil.
Summary Statement	**Contains: wheat, gluten, peanut.**
Precautionary Statement	(not required)

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, but gluten is already stated in the summary statement. The VITAL Program Labelling Hierarchy (Appendix 1) directs that it is only necessary to list gluten in the statement of ingredients and summary statement. In the example, it is not necessary to also list gluten in the PAL statement.
- VITAL is indicating that the source of gluten in a PAL statement is from barley. 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
  -

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 (**cashew**) 300 ppm	
				Tree nuts (**macadamia**) 280 ppm	
				Tree nuts (**hazelnut**) 100 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

Table 1: Assessment Outcomes

Assessment Outcomes	
Recipe Name	Snack Bar
Recipe Code	WG2 SNACK BAR
Organisation	Allergen Bureau
Published	09 February 2026, 12:28:19 pm
Published By	Squirrel@email.com
Jurisdiction	Australia and New Zealand
Reference Amount	40 g 1 bar
Intentionally Added	Oats, Gluten Almond
Action Level 2	Cashew Macadamia
Action Level 1	Hazelnut

Substance	Intentionally Added	Cross Contact		VITAL Risk Assessment Labelling Outcome
		Particulate	Readily Dispersible	
Cereals (total)	✓			Intentionally Added
Oats	✓			Intentionally Added
Tree nuts				
Almond	✓			Intentionally Added
Cashew			30 ppm	Action Level 2
Macadamia			28 ppm	Action Level 2
Hazelnut			10 ppm	Action Level 1

d. Recommended ingredient list - snack bar

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

e. Tips & reasoning for PAL

- Tree nuts are present both as an ingredient (almond) and as a cross contact allergen (cashew, 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 25 ppm. The cashew and macadamia are present at 10 ppm and 20 ppm respectively. When viewed individually, cashew and macadamia 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. Hazelnut on the other hand is in not in the same group of tree nuts and is therefore not summed with the other tree nuts.

  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 cashew and macadamia individually: "**May be present: cashew, macadamia.**"

  An alternative PAL statement, that is "**May be present: other tree nuts (cashew, macadamia)**.", has been included in this example. The term "other" is used to emphasise 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.

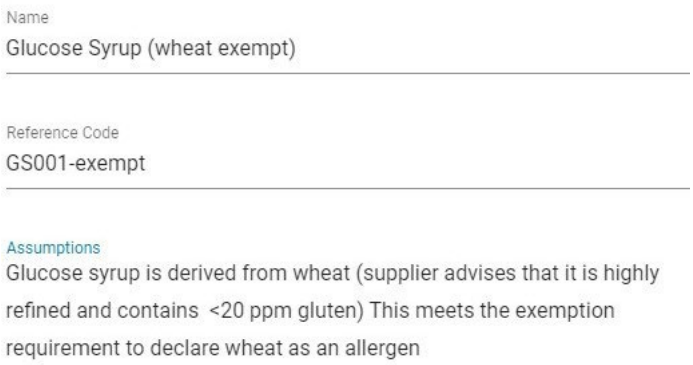
- As a minimum the relevant detailed allergen information such as exemptions should be stated within the Ingredient Assumption area.

  There are various options to improve visibility of assumptions/decisions in relation to allergen presence. This can be helpful for example when considering substitution of an ingredient and prevent missing the exemption when reviewing an ingredient/recipe.

  As reports are often disclosed to third parties, it is for consideration of the business on which option(s) to apply:

  1. State it within the ingredient Name
  2. State it within the ingredient Reference Code
  3. State it within the Recipe assumptions

  Example of logging the exemptions within the name, code and the Assumption area of the Ingredient information:



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**	• Hang up quantity: 1000g • Sesame in hang up: 1% • Protein in sesame: 22% • Batch size exposed to hang up: 2000kg
	From shared production lines with products containing peanut.			**Peanut**	• Hang up quantity: 1000g • Peanut in hang up: 60% • Protein in peanut: 25% • 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	MAYO1
Published	09 August 2024, 10:12:33 pm
Legislation	Australia and New Zealand
Reference Amount	30 g one sachet
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			75 ppm	Action Level 2
Sesame			1.1 ppm	Action Level 1

d. Recommended ingredient list - mayonnaise

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

Statement of ingredients:	Vegetable oil [acid (330), antioxidant (306)], malt vinegar (**barley**), **milk** solids, **egg** yolk, water, salt, colour [150c (**wheat**)].
Summary Statement	**Contains: wheat, gluten, milk, egg.**
Precautionary Statement	**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)

Summary Statement	**Contains: wheat, gluten, milk, egg.**
Precautionary Statement	**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.
- As a minimum the relevant detailed allergen information such as exemptions should be stated within the Ingredient Assumption area.

  There are various options to improve visibility of assumptions/decisions in relation to allergen presence. This can be helpful for example when considering substitution of an ingredient and prevent missing the exemption when reviewing an ingredient/recipe.

  As reports are often disclosed to third parties, it is for consideration of the business on which option(s) to apply:

  1. State it within the ingredient Name
  2. State it within the ingredient Reference Code
  3. State it within the Recipe assumptions

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 (250 ppm)	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**) (600 ppm)	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**	• Hang up quantity: 2000g • Peanut in hang up: 5% • Protein in Peanut: 25% • Batch size exposed to hang up: 500kg
	From shared production lines with products containing soy.			**Soy**	• Hang up quantity: 2000g • Soy in hang up: 1% • Protein in soy: 50% • Batch size exposed to hang up: 500kg
Reference Amount	400g			**Yield**	100%

c. VITAL assessment outcomes

Table 1: Assessment Outcomes

Assessment Outcomes	
Recipe Name	WG2 Pork Prawn Curry Rice
Recipe Code	WG2 PPCR001
Published	09 August 2024, 10:39:54 pm
Legislation	Australia and New Zealand
Reference Amount	400 g 090824
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)			15 ppm	Action Level 2
Wheat and its hybrids which contain gluten			15 ppm	Action Level 2
Crustacean	✓			Intentionally Added
Milk	✓			Intentionally Added
Peanut			50 ppm	Action Level 2
Sesame			6.25 ppm	Action Level 2
Soy			20 ppm	Action Level 1

d. Recommended ingredient list - pork and prawn curry rice

Statement of ingredients:	Cooked rice, pork (processing aid **milk**), prawns (**crustacean**) [preservative (223) (**sulphites**)], sugar, water, tapioca flour, curry powder.
Allergen Summary Statement	**Contains: milk, crustacean, sulphites.**
Precautionary Statement	**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.

3.5 Batter fryer

a. Overview

This worked example covers the below scenarios:

- After an allergen risk review of a fryer used for battered products, it has been discovered that not all fryer matter can be filtered from the oil. The laboratory advises that oil cannot be tested for the presence of allergen by traditional methods as the matrix interferes with the reliability of the test. It is observed that the fryer matter is not distributed homogeneously in the oil.
- Collected oil shows particles ranging from fine dust to actual pieces. Over many production cycles it has been established that the largest piece of matter weighs 80mg.
- One of the batters used in the frying oil contains 30% milk. A dedicated line and tanks for oil storage is currently not possible.

b. VITAL assessment outcomes

In this case the following assessment can be applied to determine if the particulate should be declared in VITAL Online.

Weight of particulate (fried matter)	90mg
% of moisture lost during frying (concentration / yield)	yield =82% (water loss 18%)
Weight of original particulate prior to frying	110mg (90mgx100/82)
% Milk allergen that could be in the particulate (recipe)	30%
% milk protein in particulate prior to frying (recipe)	33 mg (30%x110mg)
% protein in milk	3.5%
Weight of milk protein in the particulate	1.15mg (3.5%x33mg)
RfD Milk (ED^{05})	2mg

c. Recommended ingredient list - Batter fryer

Precautionary Statement	(not required)

d. Tips & reasoning for PAL

- It is observed that the fryer matter is not distributed homogeneously in the oil, which means that part of the requirement of the VITAL particulate definition has been met. However, the worst-case particulate size does not contain an amount of protein greater than the RfD. Do not enter as a particulate in VOL.
- In cases where the worst-case size and the weight of particulates are estimated to contain insufficient protein to meet the VITAL definition, it is important to also consider their distribution in the finished product. This includes assessing the size and number of particulates likely to be consumed during a typical eating occasion, using available data or theoretical calculations, and evaluating the likelihood of such consumption.
- As a minimum the relevant detailed allergen information such as particulate calculations should be stated within the Ingredient Assumption area. There are various options to improve visibility of assumptions/decisions in relation to allergen presence. This can be helpful for example when considering substitution of an ingredient and prevent missing the exemption when reviewing an ingredient/recipe. As reports are often disclosed to third parties, it is for consideration of the business on which option(s) to apply:
    1. State it within the ingredient Name
    2. State it within the ingredient Reference Code
    3. State it within the Recipe assumptions Example of logging the exemptions within the name, code and the Assumption area of the Ingredient information:

3.6 Cashew kibble

a. Overview

This worked example covers the below scenarios:

- A cashew nut kibble is supplied for use in a muesli bar. The specification indicates the cashew nut kibble is between 2-4mm^3. Particle distribution analysis (sieve) verifies this result. The specification indicates an agricultural cross contact risk with peanut.

b. VITAL assessment outcomes

- The largest piece of peanut could be 4 mm^3 (largest size of sieve).
- The bulk density of peanut is on average 0.6g/cm^3.
- Peanut contains 25% protein (from Australian Composition Database).
- The 4 mm^3 piece of peanut contains therefore a protein weight of:

Size of particulate (largest size of sieve)	4mm^3
Bulk density of peanut	0.6g/cm3 (=0.6mg/ mm^3)
Weight of peanut piece	2.4 mg (=4 mm^{3}x0.6mg/mm^3)
% protein in peanut	25%
Weight of peanut protein in the 4 mm^3 peanut piece	0.6 mg (=25% of 2.4mg)
RfD peanut (ED^{05})	2.0mg

c. Recommended ingredient list - Cashew kibble

Precautionary Statement	(not required)

d. Tips & reasoning for PAL

- The peanut piece does not mix homogenously with other parts of the food, which means that part of the requirement of the VITAL particulate definition has been met. The reference dose for peanut is 2mg, therefore this size of particulate (0.6mg) does not contain a level of peanut protein requiring PAL labelling.
- Even while the calculation of a worst case scenario piece might not require a PAL, as part of the VITAL risk assessment, the business should challenge what the likelihood is of multiple pieces of the peanut entering the cashew kibble.

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 (as per VITAL particulate definition).	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
Grouped Allergens have additional hierarchy rules in VITAL Online. The groups based on rationale from related scientific groupings, based on endorsed Reference Dose, are not relevant for the process of creating a label declaration. The grouped allergens in VITAL Online are: • **Cereals** (includes barley, oats, rye, wheat & its hybrids which contain gluten, and wheat & its hybrids which do not contain gluten).	
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
Intentionally added allergen and one or more other cross contact allergen(s) from the group in readily dispersible form	Intentionally added allergen

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