

# Allergen Bureau

## Overview of Allergen Management and Labelling in ANZ

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Informing the  
food industry



# Agenda

- About Us
- Vision and Mission
- Allergen Communication & Regulations
- Ensuring Compliance
- Evidenced based science & VITAL
- New work



# Food Allergen Management Guidance

*For industry, by industry*

The Allergen Bureau is the peak industry body representing best practice food industry allergen management globally.

**Become a member today.**

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# Allergen Bureau

- Membership based organisation established to provide food industry with rapid responses to questions about allergen risk management in food ingredients and manufactured foods
- Established in 2005, pre-competitive, 'not-for-profit', Allergen Bureau directors provide voluntary, unpaid services

Become a member

Global Member



Full Members



- ALDI Stores
- BBF Hull Limited
- SoFine Foods

# Vision & Mission

**Vision:** A trusted food supply for allergen sensitive consumers around the world.

**Mission:** Lead the global food industry in best practice allergen management, sharing information that builds trust and transparency that supports allergen sensitive consumers to make informed choices.

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# Australia & New Zealand Have High Rates of Food Allergy

Rapid increase in food allergic disease in last 30 years  
in mainly Western countries

## Food allergy affects\*

- 10 % infants (up to 12 months old)
- 4 - 8% children (up to 5 years)
- 2 % adults (approx.)

\*ASCIA [www.allergy.org.au](http://www.allergy.org.au)

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# Allergen Communication & the Regulations



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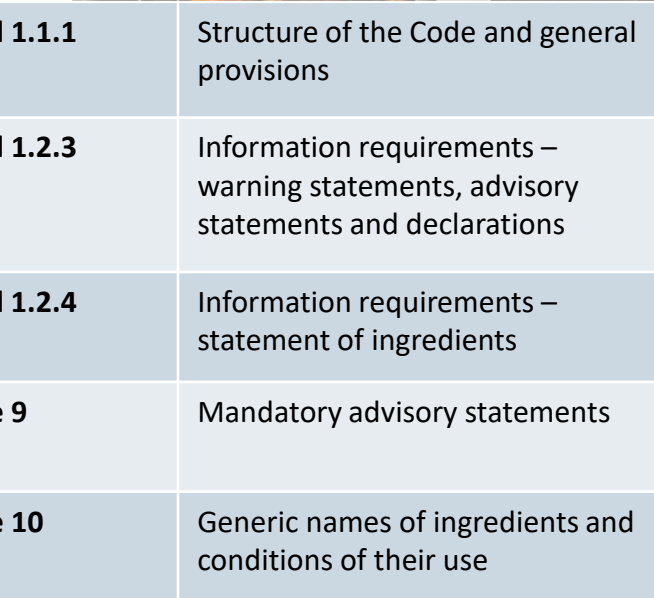
# Accurate & Consistent Allergen Declaration

- Allergen labelling is the key method to inform a consumer of the allergen status of a product
- Appropriate allergen declaration can:
  - help allergenic consumers choose foods which do not present a personal health risk
  - positively affect a consumer's relationship with a brand
  - avoid additional compliance costs
  - avoid allergen-related product recalls & other costs



# ANZ Allergen Labelling Regulations

- Australia New Zealand Food Standards Code [www.foodstandardscode.gov.au](http://www.foodstandardscode.gov.au)
- PEAL is the Plain English Allergen Labelling variation – currently in transition phase
- Sets out how to declare allergens to ensure that they are clear and consistent
- Applies to all foods



<b>Standard 1.1.1</b>	Structure of the Code and general provisions
<b>Standard 1.2.3</b>	Information requirements – warning statements, advisory statements and declarations
<b>Standard 1.2.4</b>	Information requirements – statement of ingredients
<b>Schedule 9</b>	Mandatory advisory statements
<b>Schedule 10</b>	Generic names of ingredients and conditions of their use

# Key Changes Due To PEAL

- Required names: mandatory specified names for allergens
- Molluscs & individual (specified) tree nuts to be declared
- Focus on wheat and gluten as substances of concern
- 'Contains' summary statement is required
- Format and location requirements for the allergen declaration

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PEAL  
Updates



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Figure 3. Examples of summary statement locations.

Preferred format - the summary statement is below, and c

**Ingredients**

Water, vegetable oil, vinegar, thickeners (1412), almonds, oil, flour, wheat, maltodextrin, s

Contains: egg, almond, milk

Alternative formats - the summary statement is next to, a

**Ingredients**

Water, vegetable oil, vinegar,

sugar, tomato paste,

capsicum, salt, egg yolk,

thickener (1412), almonds,

parmesan cheese (204),

garlic, wheat flour, flour,

maltodextrin, sesame

oil, antioxidant (202)

**Contains:**

egg,

almond,

milk,

wheat,

gluten,

sesame

Alternative format for labels with very limited space - is

INGREDIENTS: Water, vegetable oil, vinegar, sugar,

capsicum, salt, egg yolk, thickener (1412), al

parmesan cheese (204), garlic, wheat flour, flour,

maltodextrin, sesame oil, antioxidant (202)

Contains: egg, almond, milk, wheat, gluten, ses

**Terminology**

The required names for summary statements, except

for soybean and cereals containing gluten, are the

same as those in the statement of ingredients. These

are listed in Column 4 of the table to section 59-3.

The following example shows how the required name

can be presented in a statement of ingredients and

summary statement using the required names.

Example: Ingredient list for Frozen Green Vegetable

Mix.

**Ingredients**

Green beans, sugar snap peas, edamame

(soybean).

**Contains:** soy.

Note that soy, soya and soybean are required name

in the statement of ingredients, but not in the summa

statement where soy is the only permitted required

name.

2021  
Food Industry Guide  
to Allergen  
Management and  
Labelling  
For Australia and New Zealand



A partnership document of the  
Australian Food and Grocery Council and the Allergen Bureau

# Updated FIGAML 2021

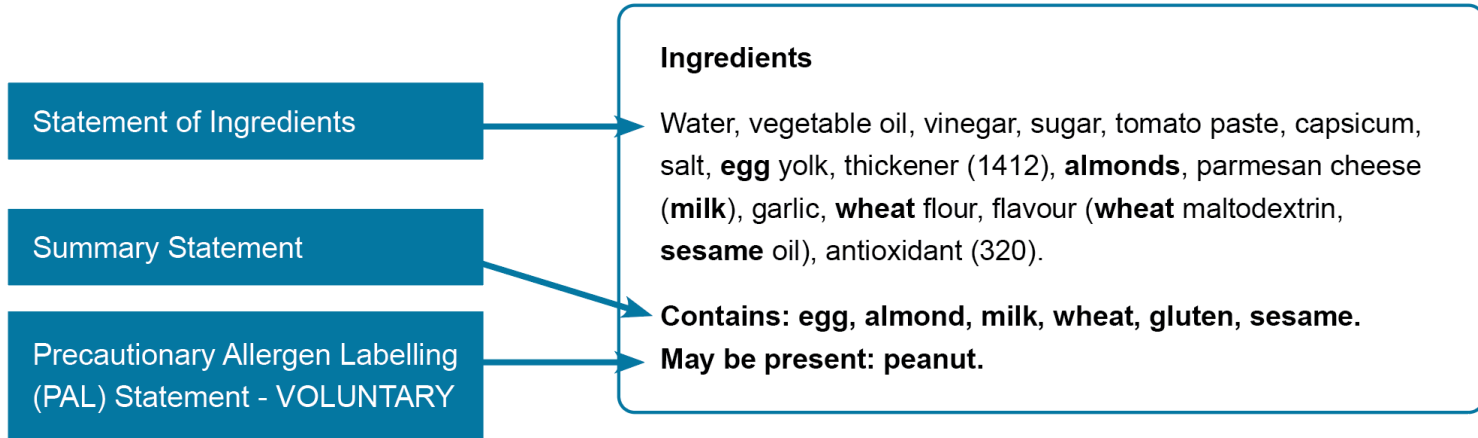
- 2021 edition contains updates for Plain English Allergen Labelling as shown by the orange PEAL logo.



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# Recommended Labelling Format – FIGAML



“May be present: allergen x, allergen y.” is recommend in conjunction with the VITAL Program

# The Food Standards Code Influences the VITAL Program Allergen Labelling Guidance

- ✓ Font and format
- ✓ Terminology
- ✓ Individually name cereals containing gluten and tree nuts, be as specific as you can
- ✓ Focus on gluten as a key substance

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# Ensuring Compliance



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# Allergen Management & Labelling Overview



## 1. ALLERGEN MANAGEMENT

The procedures, policies and practices put in place to manage allergens



## 2. ALLERGEN RISK REVIEW

Thorough investigation of the allergen status of a food including cross contact



## 3. ALLERGEN COMMUNICATION

Forming an ingredient list.





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Figure 3. Examples of summary statements

Preferred format - the summary statement

Ingredients:  
wheat,  
milk,  
soybean,  
egg,  
gluten,  
Contains:  
soy

Alternative formats - the summary statement

Ingredients:  
Water, vegetable oil, vinegar,  
yeast, tomato paste,  
sodium, salt, egg yolk,  
thickener (1412), almonds,  
parmesan cheese (milk,  
garlic, wheat flour, flavour  
[natural maltodextrin, sesame  
oil, antioxidant (E202)]

Alternative format for labels with very small text

INGREDIENTS: Water, vegetable oil,  
parmesan cheese (milk, garlic,  
maltodextrin, sesame oil), salt  
Contains: egg, almond, milk

#### Terminology

The required names for summary statements for soybean and cereals containing gluten are those in the statement of ingredients in Column 4 of the table. The following example shows how the information can be presented in a statement of ingredients using the required terminology.

Example: Ingredient list for Frozen Mince

Ingredients:  
Green beans, sugar snap peas, egg (soybean)

Contains: soy

Note that soy, soya and soybean are not used in the statement of ingredients, but are used in the statement where soy is the only allergen name.



2021  
Food Industry Guide  
to Allergen  
Management and  
Labelling  
For Australia and New Zealand

PEAL  
updated

A partnership document of the  
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# Essential Allergen Guidance For The ANZ Food Business Operator



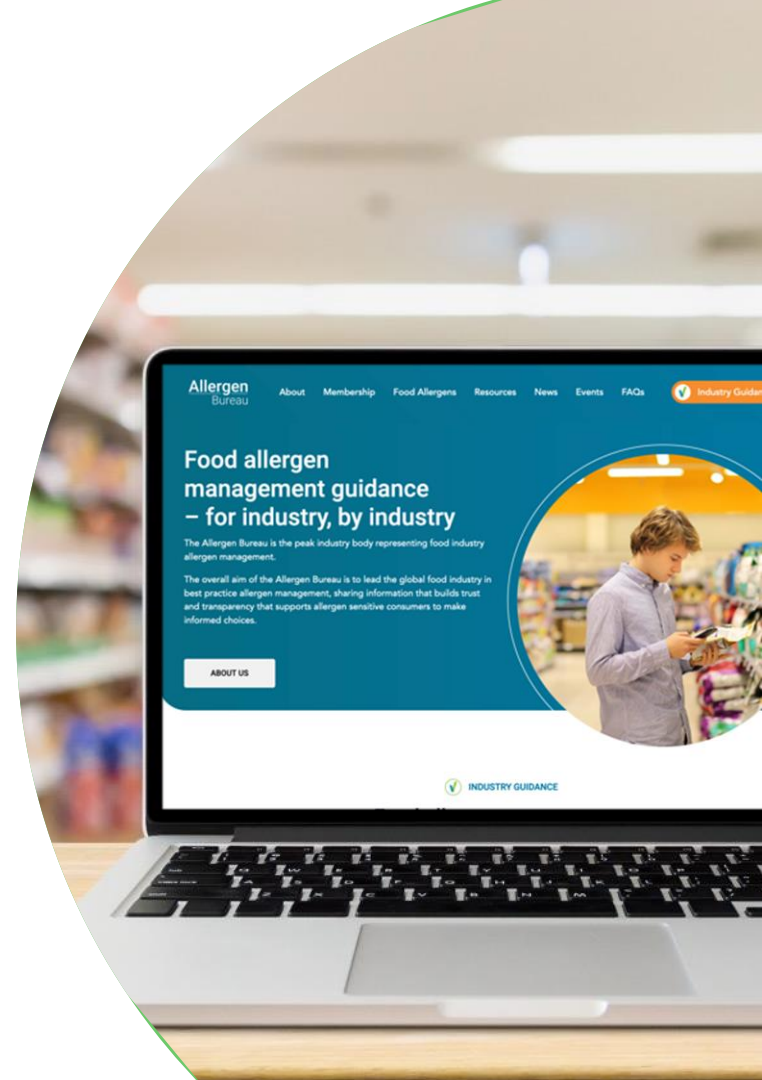
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# Allergen Management

- The procedures, policies and practices put in place to manage allergens
- Allergen management is a fundamental element of a food safety plan and Good Manufacturing Practice (GMP)
- Use a HACCP plan with allergens included as an independent category of food hazard
- Include the “life-cycle” of the product from raw materials, every step of production, and labelling & packing
- Establish systems to prevent unintentional cross contact for allergens to other products



# Allergen Risk Review and Website

- The Allergen Risk Review website (ARRW) is a freely available interactive factory map designed to assist the food industry with understanding the allergen status of its products.
- Includes 15 different areas which can impact on the status of a food.
- Here you can find detailed information about assessing allergen risk at every stage of the process to make food.
- Can help inform your own allergen control plan.



[info.allergenbureau.net](http://info.allergenbureau.net)

# Example 1: Cleaning



## Production Step 9 of 15 Cleaning

Cleaning equipment, preparation areas and the production lines of a food manufacturing site is necessary to eliminate allergen residue and the potential for cross contact. As facilities can vary in complexity, food materials, the allergen type, number, and nature, equipment type, and food contact surfaces, cleaning parameters may be unique to each process or site.

Hang Up



Cleaning controls and trouble spots



Cleaning validation and verification



Risk review considerations



Allergen Management Program (AMP)



prev step

next step



### Performing physical risk review

1. Assemble a cross-functional team
2. Consider all areas of the production line
3. Perform a physical audit by inspecting the processing equipment
4. Identify Hang Up points and other cross contact points
5. Consider the form of the cross contact (readily dispersible or particulate)
6. Quantify any cross contact that is present

### Further information

See Step – [Design of Premises & Equipment](#)

See Step – [Analysis & Testing](#)

# Transferring the Risk Assessment to Label - The VITAL Program

- Your due diligence - understanding the risk of cross contact allergens from ingredients and the manufacturing process
- Your commitment to consumers
- Your commitment to consistent risk review and allergen labelling across industry

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# The VITAL Program

# What is the VITAL Program?


The VITAL Program provides a consistent methodology for food industry to **assess the impact of allergen cross contact** and provide appropriate precautionary allergen labelling on their products



VITAL is managed by the  
Allergen Bureau

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The VITAL Program can be used to assist food producers in presenting allergen advice accurately and consistently for allergic consumers using a **single simple standardised precautionary allergen statement (PAL)**



The VITAL precautionary statement is:  
**May be present: allergen x, allergen y.**

# What do you need to Implement the VITAL Program?

An Allergen Management Plan includes the procedures, policies and practices contributing to the control of allergens within a food business.

## ALLERGEN MANAGEMENT PLAN



A robust allergen management plan is a pre-requisite before considering implementing the VITAL Program



# Key Components of the VITAL Program

- Identify & Quantify Cross Contact Allergens
- Reference Dose
- Reference Amount
- Action Levels
- Precautionary Allergen Labelling (PAL)



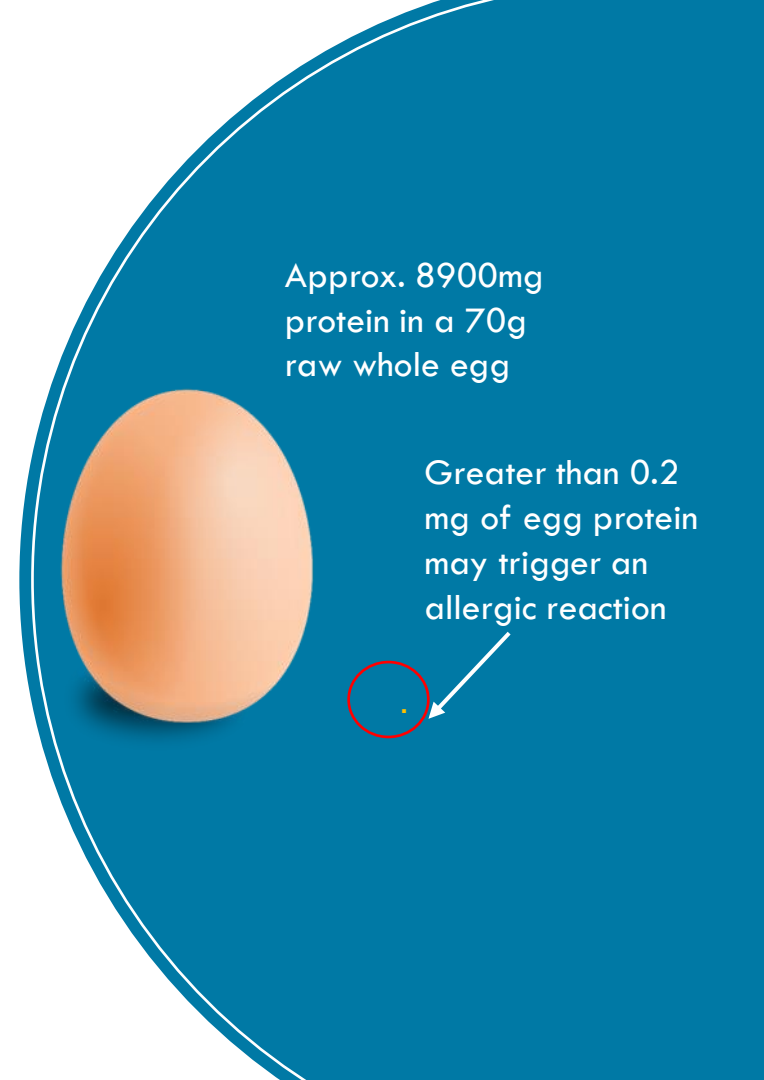


## Cross Contact Allergens

- Residues or an amount of an allergenic food **unintentionally** incorporated into another food that is not intended to contain that allergen
- May be present despite Good Manufacturing Practice
- Can enter a product at any point of the supply chain (harvesting, handling, storage, production, etc.)
- Should be controlled and managed to the lowest practicable level
- How should cross contact allergens be declared? How do you know when to declare cross contact allergens when they are present at trace amounts?

# Reference Dose

- Is the milligram protein level (total protein from an allergenic food) below which only the most sensitive (1%) of individuals in the allergic population are likely to experience an adverse reaction.
- If reactions to (unlabelled) allergens do occur from exposure below the Reference Dose they will be mild and transient, requiring no emergency medical intervention.



# The VSEP Today

The objective being to review the underpinning science around food allergen thresholds.

## Members of the VSEP

- **Dr Steve Taylor** (Chair of Panel) – Food Allergy Research & Resource Program (FARRP) (USA)
- **Dr Joseph Baumert** – Food Allergy Research & Resource Program (FARRP)
- **Dr Geert Houben** – Program Manager Food Safety, Netherlands Organisation for Applied Scientific Research (TNO) (NL)
- **Dr Rene Crevel** (RENE CREVEL Consulting Ltd) (UK) (formerly of Allergy & Immunology, Unilever)
- **Dr Simon Brooke Taylor** (Food Safety & Risk Analysis Consultant, Allergen Bureau) (AUS)
- **Dr Benjamin Remington** – Food Allergy Research & Resource Program (FARRP) and Remington Consulting Group B.V. (NL)



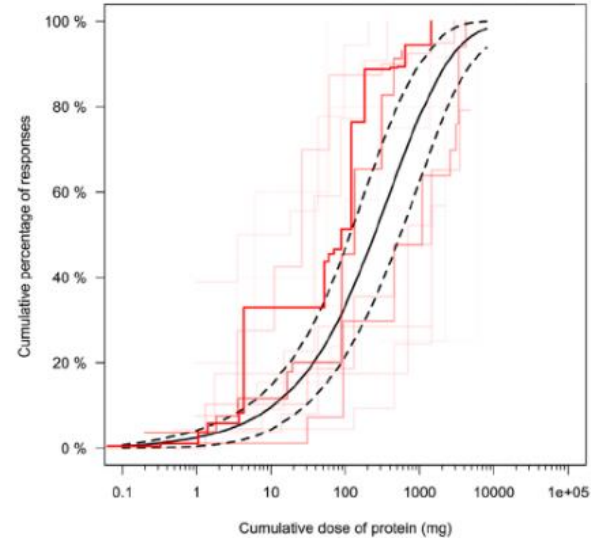
# Evidence Based Science

- Global acceptance of VITAL Science by the food industry, regulators, consumer organisations and other stakeholder groups
- Verified, auditable, food allergen risk assessment and decision-making process that incorporates relevant VSEP findings
- Scientifically robust resources



# The VSEP Expertise

- Over 3400 clinical data points were collated
- Used statistical modelling called “Stacked Model Averaging” which incorporated 5 different statistical models to produce a single “averaged” distribution
- Reference Doses are set using ED01 – the Eliciting Dose of an allergen at which 1% of the allergic population would be likely to react



Source: Wheeler et al (2021) Bayesian Stacked Parametric Survival with Frailty Components and Interval-Censored Failure Times: An Application to Food Allergy Risk, Risk Analysis, Vol. 41, No. 1, 2021.

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# VITAL 3.0 Reference Doses

Food	Reference Dose (mg)
Cereal containing gluten* (barley, oats, rye, wheat)	0.7
Crustacea	25
Egg	0.2
Fish	1.3
Milk	0.2
Peanut	0.2
Molluscs	None set
Sesame	0.1
Soy	0.5
Tree nuts (cashew, pistachio)	0.05
Tree nuts (walnut, pecan)	0.03
Tree nuts (almond, Brazil nut, hazelnut, macadamia nut, pine nut)	0.1

\*Action Level transition maximum point is 20ppm



# What Does the Future Hold?

## *FAO / WHO Expert Consultation on Risk Assessment of Food Allergens*

- Inform Codex Committee on Food Labelling
- Proposed changes to global priority allergens
  - Remove soy, lupin, mustard, celery, oats, molluscs, brazil nut, macadamia, pine nuts and sulphites
  - Consider region specific allergens
  - Pulses, insects and other foods (kiwi) added to “watch list”

<http://www.fao.org/3/cb4653en/cb4653en.pdf>

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# Reference Amount

The Reference Amount is the maximum amount of a food eaten in a typical eating occasion (never less than the serving size)


What is a typical eating occasion?

- One cake slice or two?
- One mini choc bar or a king size bar?
- Two scoops ice cream or more?



# Action Levels

Action Levels are the concentrations (of protein) which define the allergen cross contact labelling outcomes


$$\text{Action Level transition point* (ppm)} = \left( \text{Reference Dose (mg)} \times \frac{1000}{\text{Reference Amount (g)}} \right)$$

\* With the exception of cereals containing gluten where it is either the result from this formula or 20ppm, whichever is smaller

# Thresholds in the VITAL Program

## Action Level 1

low concentration of the relevant allergen under evaluation, low chance of adverse reaction

**no PAL statement is required**

## Action Level 2

significant concentration of the relevant allergen under evaluation, significant chance of adverse reaction

**PAL statement is required**

# Calculating Action Level: for a product with peanut cross contact

Peanut Reference Dose = 0.2 mg protein

**5g** Reference Amount or  
Serving Size:

(Transition =  $0.2 \times 1000/5$   
= 40ppm)

**Action Level 1** : <40ppm

**Action Level 2** :  $\geq 40$ ppm

**50g** Reference Amount or  
Serving Size:

(Transition =  $0.2 \times 1000/50$   
= 4ppm)

**Action Level 1** : <4ppm

**Action Level 2** :  $\geq 4$  ppm

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# Precautionary Allergen Labelling (PAL)

- To declare the possible presence of cross contact (a residue or an amount of a food allergen that is unintentionally incorporated into another food)
- Voluntary
- Important to help consumers know what food is safe for them to eat
- Most helpful when applied consistently across industry
- **May be present: allergen x, allergen y.**

May contain ...	May contain traces of ...	Packed in an environment where ... may be present	Made in a facility that also processes ...
Produced in a factory which handles ...	Produced on shared equipment that also processes ...	Made on the same production line as...	Made in a production area that also uses...
No nuts in ingredients, but cannot guarantee to be nut-free	Not suitable for ... allergy sufferers	Due to methods used in the manufacture of this product, it may occasionally contain ...	May be present: ...

# The VITAL Program: Ongoing Development



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# A New VITAL Online

We have responded to advances in web-based technology and embarked on a rebuild of the VITAL Online application to improve performance, manageability, and reliability of the VITAL Online platform.

You can now access the brand new VITAL Online website for the VITAL Online Calculator, as well as VITAL Science, VITAL Training, the VITAL Standard, and more, via the new VITAL Online portal.





# What Does the Future Hold?

## *FAO / WHO Expert Consultation on Risk Assessment of Food Allergens*

- Review and establish threshold levels for priority allergens – what will that mean for VITAL? ED01 and ED05 considerations
- Review and evaluate the evidence in support of precautionary allergen labelling
- Stakeholder discussion needed

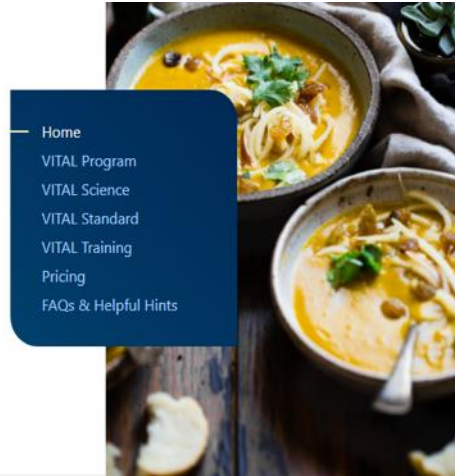
<http://www.fao.org/3/cb4653en/cb4653en.pdf>

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# Consumption Data May Inform Reference Amounts

- Food Category Consumption data rather than nominated Reference Amounts?
- Another level of consistency and robustness
- Working group activity



## Voluntary Incidental Trace Allergen Labelling

The Allergen Bureau's VITAL<sup>®</sup> (Voluntary Incidental Trace Allergen Labelling) Program is a standardised allergen risk assessment process for food industry.

# The VITAL Standard

- Voluntary
- Consumer visibility
- Cost effective
- Internationally recognised
- Robust
- Product specific
- Auditable



# Food Allergen Fundamentals

- Overview of food allergens to assist the food industry with the complex task of managing allergens.
- A free resource for people
  - New to the subject of food allergens in manufacturing
  - In the food industry who might benefit from a 'going back to the basics' refresher.



Download August  
21 Edition from  
our website Now

<https://allergenbureau.net/food-allergen-fundamentals-faf-updated-to-include-peal/>

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For the Food  
Industry

## Free resources available on our website

We have recently launched a new and improved corporate  
website

[allergenbureau.net](http://allergenbureau.net)

and a new platform for VITAL<sup>®</sup> Online

[vital.allergenbureau.net](http://vital.allergenbureau.net)

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# THANK YOU

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Don't forget to tell your ideas about this presentation and share it with us!

CONTACT US:



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[allergenbureau.net](http://allergenbureau.net)

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