

# Allergen Bureau

## Allergen Labelling Reforms

9<sup>th</sup> Annual Food Law Forum 2021  
Kirsten Grinter

Informing the  
food industry



# Agenda

- About Us
- Vision and Mission
- Transition to Plain English Allergen Labelling (PEAL)
- PEAL Impact on PAL
- Best Industry Guidance
- The VITAL Program Update
- What the future may hold?
- Allergen Free Claims



# 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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# Allergen Bureau Strategies 2021-25

1. Evidence based science
2. Best practice allergen management guidance & resources
3. Key stakeholder acknowledgment
4. Global influence & brand recognition
5. Good governance and financial sustainability



# PEAL

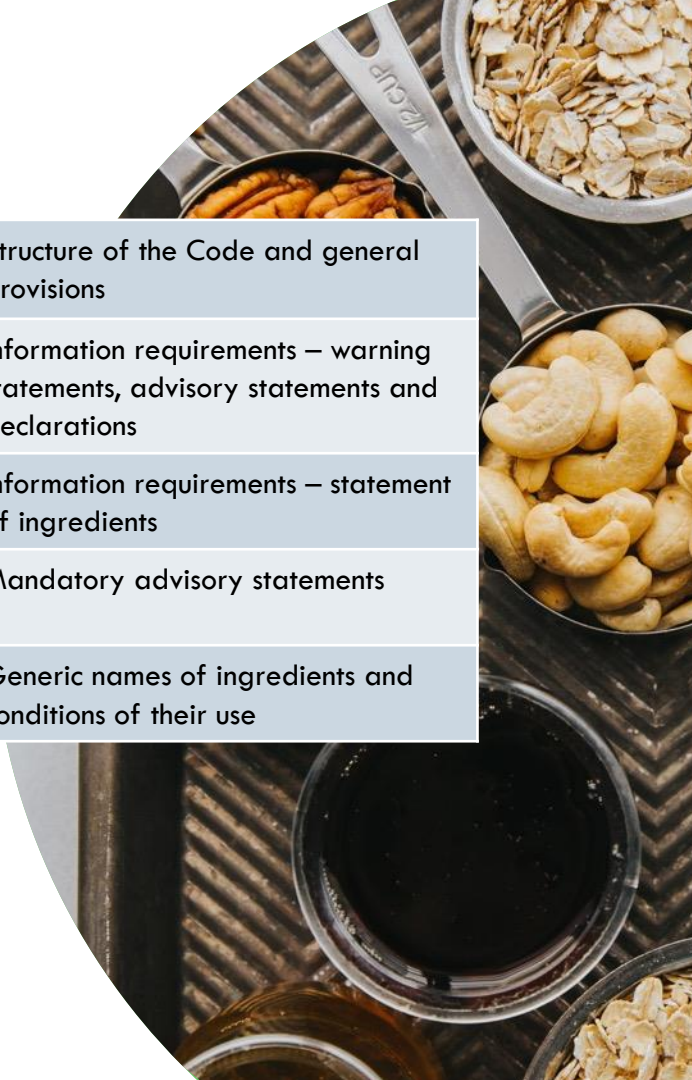
## Plain English Allergen Labelling

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# What is PEAL?

- PEAL is the Plain English Allergen Labelling variation to the Australia New Zealand Food Standards Code (the Code)
- sets out how to declare allergens to ensure that they are clear and consistent
- applies to all foods
- refer to the Code to ensure requirements are met



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



# How Much Time Do We Have?

Standard 1.2.3

Information requirements –  
warning statements, advisory  
statements and declarations

## Food Standards (Proposal P1044 – Plain English Allergen Labelling) Variation

Item [3] of the Schedule	197	F2021L00145 24 Feb 2021 FSC138 25 Feb 2021	Clause 4	Clause 4 a transitional arrangement for variations to the Code made by Item [3.1], [3.2], [3.3], [3.4] and [3.5] of the Schedule.  The transition period is the period of time that commences on 25 February 2021 and ends on 25 February 2024.  The post-transition period is the period of time that commences 26 February 2024 and ends on 26 February 2026.
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PEAL  
Updates

- PEAL regulation started 25 Feb 2021
- Food can be sold with either old or new allergen labelling up to 25 Feb 2024
- Food packaged & labelled with old allergen info before 26 Feb 2024 may still be sold until 26 Feb 2026
- see [www.foodstandards.gov.au](http://www.foodstandards.gov.au)

# 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



PEAL  
Updates

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# FAQ's that we receive

## Representation of Mandatory Information?

- What industry guidance is available (e.g., how to declare coconut milk with contains casein from milk?)
- What does “not present” mean for gluten in the cereals containing gluten?
- General format and labelling questions – this is a big change to regulations & it will take some time to digest the changes

## PEAL & PAL and Label Impacts

- How does PEAL affect PAL?
- Can I still say, “May be present: tree nuts”?



# PEAL Impact on PAL



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# The Food Standards Code Influences PAL Statements

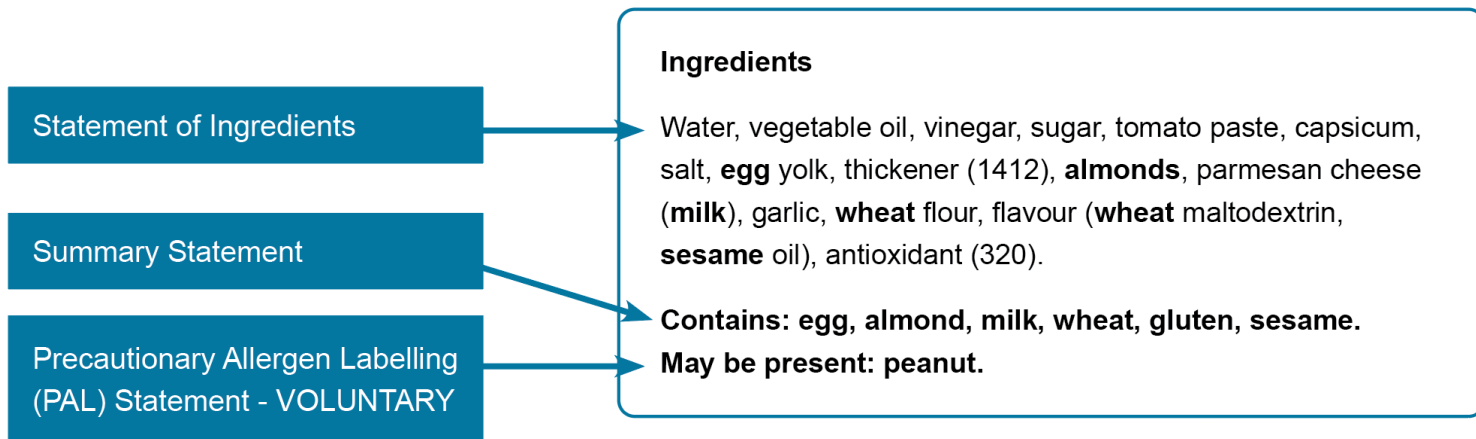
- ✓ Font and format
- ✓ Terminology
- ✓ Individually name cereals containing gluten and tree nuts
- ✓ Focus on gluten as a key substance

Examples shown in this presentation are to provide best practice guidance





# Recommended Labelling Format – FIGAML



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

- Incorporates mandatory requirements
- Additional guidance for consistency for how to set out an allergen declaration

# Recommended Labelling: PAL Statement

## Ingredients

Vegetable oil, vinegar, sugar, tomato paste, capsicum, salt, **egg** yolk, thickener (1412), **almonds**, parmesan cheese (**milk**), garlic, **wheat** flour, flavour (**wheat** maltodextrin, **sesame** oil), antioxidant (320).

**Contains: egg, almond, milk, wheat, gluten, sesame.**  
**May be present: peanut.**

## FORMAT of PAL:

- **May be present: allergen x, allergen y**
- Bold font
- Same typeface and text size as used for the required names in the Statement of Ingredients

## LOCATION OF PAL STATEMENT :

- Separately from, but next to, the summary statement
- Below the Summary Statement
- Where there is no Summary Statement, then place below the Statement of Ingredients

## TERMINOLOGY :

- Required names set out in Column 3 of the table to section S9-3 (FSC) + 'gluten' where present
- Declare individual allergens wherever possible
- Use singular terms

# Example 1: Barley stew

## Ingredients:

Water, potato, carrots, celery, **barley**, **oats**.

**Contains: gluten.**

**May be present: wheat.**

## NOTES:

- Gluten is in the Summary Statement
- Wheat cross contact – do not repeat ‘gluten’ in the PAL statement



# Example 2: Muesli bar

## Ingredients:

Oats, glucose syrup, almond meal, honey, coconut.

Contains: gluten, almond.

May be present: cashew, walnut.

May be present: other tree nuts (cashew, walnut).

## NOTES:

- Thorough allergen risk assessment
- Declare individual tree nuts wherever possible in the PAL statement.
- Consider: is this clear for the consumer?



## Example 3: Salad sprinkle

### Ingredients:

Sesame seeds, pepitas, pine nuts, soy sauce.

Contains: sesame, pine nut, soy.

May be present: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pistachio, walnut.

### NOTES:

- Risk assessment has identified 8 tree nuts.
- Is the PAL statement clear for the consumer?





## Example 4: Salad sprinkle

**Ingredients:**

**Sesame seeds, pepitas, pine nuts, soy** sauce.

**Contains: sesame, pine nut, soy.**

**May be present: other tree nuts.**

**NOTES:**

Optional – using “tree nuts” may be appropriate to communicate the risk to the consumer.

The word “other” is used to indicate the possible presence of tree nuts other than the pine nuts that are an ingredient.



# Review Labels for Compliance

- PEAL means that a significant number allergen declarations will require review
- Check that your specifications/Product Information Forms (PIF) are up to date?
- Review the implementation of the VITAL Program
- Review allergen management plan
- *Refer to industry guidance to contribute to consistency in labelling across the food industry*





The  
VITAL  
Program

# 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 underpinning all that we develop





# The VITAL Program in Australia and New Zealand

- Adopted by food business operators on a **voluntary** basis – widely used in Australia & New Zealand
- The VITAL Program is well-known in Australia and New Zealand & acknowledged by regulatory agencies for its role as a voluntary industry guide
- Supported by the Product Information Form (PIF) – an industry-agreed questionnaire. The PIF is almost exclusively used in Australia as the source of information for legal and regulatory compliance



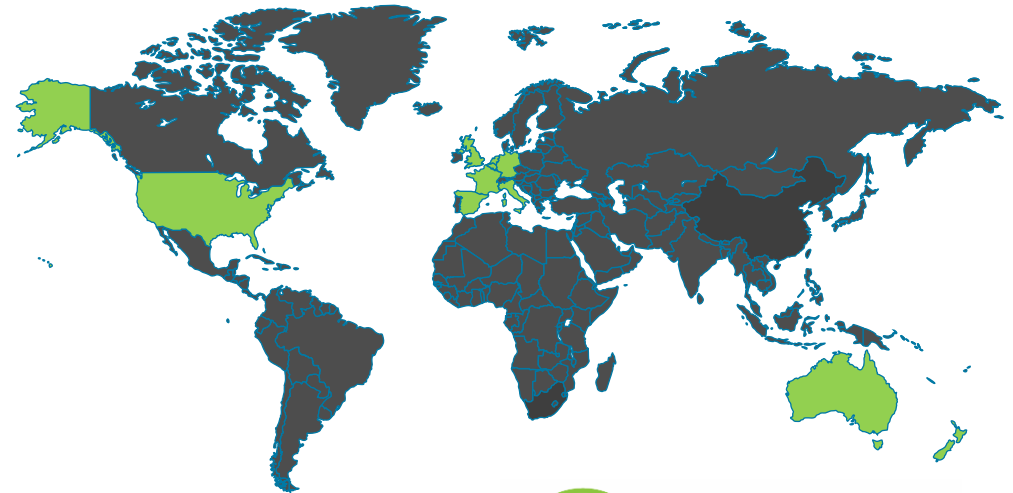


# Growing International Interest

Over 2500 registered organisations use the VITAL Program

TOP 10 VITAL Online website visitors

1. Australia (41%)
2. Netherlands
3. New Zealand
4. Germany
5. United Kingdom
6. France
7. Belgium
8. Spain
9. United States
10. Italy



# 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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## Cross Contact Allergens

- Residues or a small amount of an allergenic food **unintentionally** incorporated into another food that is not intended to contain that allergen
- May be present despite GMP
- Can enter a product at any point of the supply chain (harvesting, handling, storage, production, etc.)
- In the VITAL Program, it is necessary to control and manage **all** cross-contact allergens to the lowest practicable level



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.**



# The VSEP Today

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

## Members of the VSEP

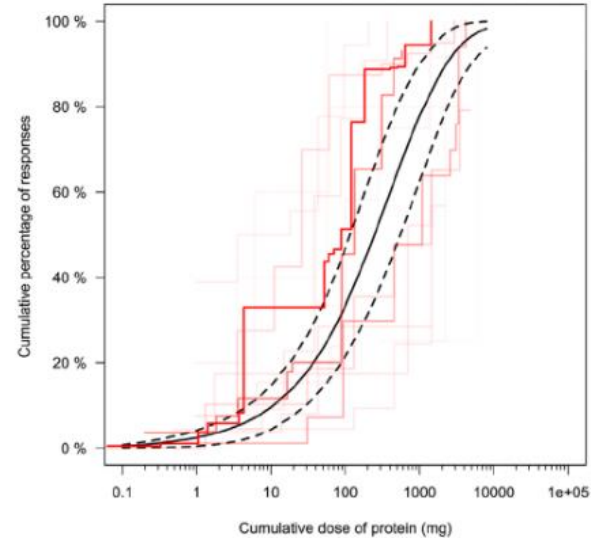
- **Dr Steve Taylor** (Chair of Panel) – Food Allergy Research & Resource Program (FARRP) (USA)
- **Dr Joseph Baumert** – Food Allergy Research & Resource Program (FARRP)
- **Dr Geert Houben** – Program Manager Food Safety, Netherlands Organisation for Applied Scientific Research (TNO) (NL)
- **Dr Rene 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)





# 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.

# 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

# VITAL – The Future

Ongoing developments & Learnings





# 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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# 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>

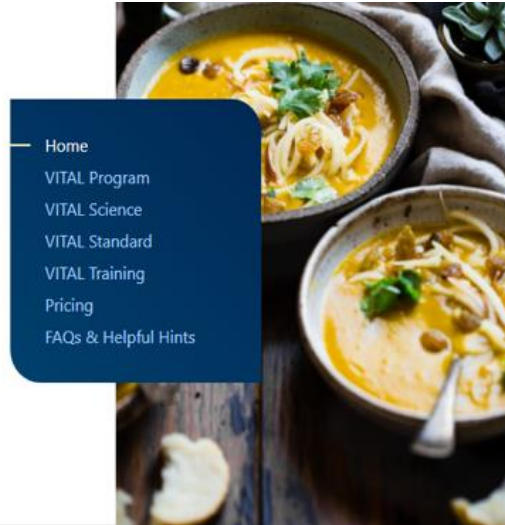
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# What Does the Future Hold?

## *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.

# What Does the Future Hold?

## *The consumer perspective*

- Question – Is PAL still helping the consumers?
  - Consumers see a proliferation of PAL
- A persistent view exists that PAL is applied indiscriminately
- Consumers don't find it useful – will regulation help?
- Proliferation of PAL may drive unsafe consumer behaviours - ignore PAL ?
- Non regulatory response is potentially – The VITAL Standard



# What Does the Future Hold?

## *The Industry Perspective*

- PAL is a risk communication statement
- Food industry allergen management is often very well informed and applied using experienced resources
- Clear and consistent PAL is VITAL
- It is the only way to communicate allergen risks
- Key to PAL being effective is robust allergen management risk assessment processes and inputs
  
- PAL stakeholder expectations?



# What Does the Future Hold?

## *Enforcement*

- Enforcement actions can be inconsistent for foods which have a PAL statement
- Sometimes actions focus on the end point labelling statement rather than the allergen management processes that drive good risk assessment
  - Limited investigation for a product with a PAL
  - Testing products to see if the PAL Statement is valid? (key - is adventitious cross contact)
- What and how could regulation help potentially? And what are the watch outs?



# Gluten Free Claims



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*Let's talk*  
**Gluten Free Claims**

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# Gluten Free Australia & New Zealand

- 'Gluten free' is a nutrition content claim with criteria in regulation
- No specific LOQ to substantiate 'nil detected' though generally LOQ of 5ppm is applied
- Allergen Bureau view is:
  - Use a validated/approved kit
  - Performed by an accredited laboratory and routinely as part of a proficiency program

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# Gluten Free Claims

- VITAL can be used to validate GF claims theoretically if the GF criteria is 20ppm (Internationally)
- AUS/NZ – the criteria is nil detected – testing is appropriate to substantiate GF
- Gluten Free claims should be supported by evidence
- The management processes applied are key - including storage, handling, manufacture & packing



# Allergen Free Claims

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A photograph of a woman and a young child with blonde hair looking down at a plate of food on a table. The woman is on the left, and the child is on the right. The background is a bright, modern kitchen.

*Let's talk*  
**Allergen Free Claims**

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## Allergen Free Claims

- Criteria for allergen free claims such as 'dairy free' or 'peanut free' are not in regulation
- Free claims - Captured by Consumer Competition regulations
- In AUS/NZ 'allergen free' claims infer zero
- Allergen free claims can be made but – require evidence/due diligence & higher level of validation to substantiate

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# Allergen Free Claims

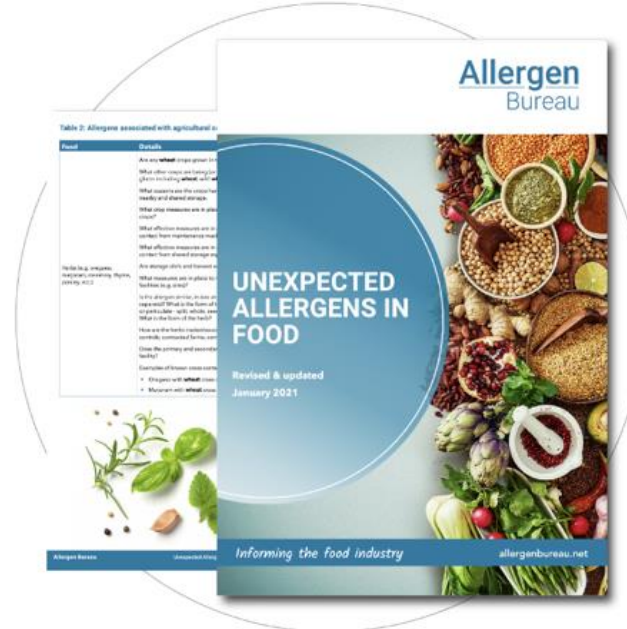
- There is no intrinsic reason why a production line that makes products containing an allergen cannot also make a product free of the allergen
- Specific validated cleaning steps at changeover should be part of the allergen management plan
- **Applying VITAL - a labelling outcome at Action Level 1 would be considered contradictory and incompatible with a free claim**





# Free Claims & Ag Co-Mingling

- Allergens present due to agricultural co-mingling do not fall under the requirements for mandatory labeling
- Co-mingling is a normal agricultural practice
- There is limited information about the level of risk caused through co-mingling
- Allergen Free representations are at significant risk of being incorrect if not managed well
- The important point - Know your Supply Chain



# Summary: GF & Allergen Free Claims

- **VITAL & Gluten Free claims** – can be used to validate (20ppm) criteria but not nil detected
  - Robust management practices must be implemented & ongoing confirmation that regulatory criteria is met
- **VITAL & Allergen Free claims** – we consider that Action Level 1 does not mean free
  - What is the consumer expectation of free?



# Our Resources



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# Industry Guidance

- encourages consistency in approach by industry
- confirms your understanding the Code
- assists in navigating the Code
- promotes discussion
- can approach subjects which are challenging to legislate to legislation – for example, precautionary allergen labelling (PAL)
- flexible to the needs of stakeholders





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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# 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.



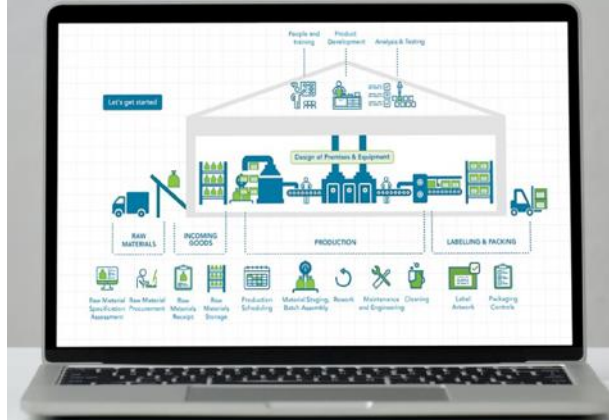
# Industry Guidance

- Food Industry Guide to Allergen Management and Labelling for Australia and New Zealand – PEAL updated edition
- Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program
- Allergen Risk Review Website



Assessing allergen risk at every stage of the process to make food.

*Find out more*



# The VITAL Standard

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



# 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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