Allergen Bureau

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The VITAL® Program – a standardized allergen risk assessment

Food Allergen Management Workshop - Mars Global Food Safety Center, Beijing, China

Georgina Christensen
VITAL Coordinator - The Allergen Bureau

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Overview of this Presentation:

- Who is the Allergen Bureau?
- Why was the VITAL ® Program developed?
- The VITAL Program (and a little Allergen Management)
- Science behind the VITAL Program

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The Allergen Bureau

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The Allergen Bureau

- The Allergen Bureau is the **peak industry body** representing food industry allergen management in Australia and New Zealand
- The Allergen Bureau is a **membership based** organisation established to provide food industry with rapid responses to questions about allergen risk management in food ingredients and manufactured foods
- Established 2005, **pre-competitive**, '**not-for-profit**', industry volunteer Board

Full Members

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The Allergen Bureau – Our Vision and Mission

Vision

- The Allergen Bureau is a globally recognised and supported industry organisation promoting best practice food industry allergen management, risk review and consistent labelling to facilitate informed consumer choice

Mission

- To facilitate a globally accepted, consistent, science-based approach to food allergen risk assessment, management and communication that:
  - guides **industry** best practice
  - assists allergen sensitive **consumers** to make informed choices based on label information

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Allergen Bureau Management

Allergen Bureau ('Not for Profit')

The Board of Directors

- Kirsten Grinter (Nestlé)
- Caroline Gray (Danisco-DuPont)
- Debbie Hawkes (Hawkins Watts)
- Jasmine Lacis-Lee (DTS Food Assurance)
- David Henning (Invited Director)

Our support network

- VITAL® Coordinator /support (Georgina Christensen & Lisa Warren)
- Technical expertise (Simon Brooke Taylor & Rob Sherlock)
- VITAL® Scientific Expert Panel (VSEP)

Funded Secretariat

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Growing International Interest

- **Over 2500 registered organisations use the VITAL Program**
- **VITAL Online website visitors – Top 10**

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

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Why should the food industry manage food allergens?

- protect allergic consumers
- food safety necessity
- consumers depend on food that is labelled correctly
- legal requirement for declaring food allergens
- costly to have non-compliance, allergen issues with consumers, recalls, withdrawals, re-labelling

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FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

- Undeclared allergen recalls in 2016, 33 (46%), 34 (49%) in 2017 and 46 (46%) in 2018

- FSANZ identified the key causes for allergen related recalls,
  - Packaging errors
  - Supplier allergen verification
  - Lack of skills and Knowledge of labelling requirements
  - Accidental cross contamination

- As of 3/5/19 – 27 recalls (8 allergen recalls)

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Why was the VITAL Program developed?

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A quick understanding of Australian consumers!

- Food allergies are common! A food allergic person must avoid the food to which they are allergic
- Manufactured food (food in a packet) is as a large portion of the diet
- Half of all manufactured food has a Precautionary Allergen Label, for example: “May contain: *(insert allergens)*” . Is this safe for an allergic person? Limited diet.
- Food allergic patients are managed by their doctor or specialist – doctors are confused too!
- Many people avoid certain foods for (perceived) health (e.g. Gluten)

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Predominant Food Allergens (Western)

Children

- Peanut
- Tree nuts
- Soy
- Milk
- Eggs
- Wheat

Adults

- Peanuts
- Tree nuts
- Crustacea (shrimp, crab, lobster)
- Fish
- Sesame

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A quick understanding of Australian/New Zealand food allergen regulations!

- Intentionally added allergens must be declared
- Intentionally added allergens are usually declared in the ingredient list
- Intentionally added allergens include:
  ingredients
  compound ingredients
  additives
  processing aids

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A quick understanding of Australian/New Zealand food allergen regulations!

Mandatory Allergens:

- Added sulphites (10ppm or more)
- Cereals containing gluten
- Crustacea
- Egg
- Fish
- Peanuts
- Sesame
- Soybeans
- Tree nuts
- Lupin

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Why do we have cross contact allergens?

Cross contact due to ingredients

- Cross contact due to agricultural practices (shared harvesting garlic/peanuts, wheat/soy/lupin, shared harvesting and storage)
- Complex supply chains

Cross contact due to processing

- Complex manufacturing sites
- Cleaning challenges (dry blend or dark/milk chocolate)

How much allergen is too much & requires a label? How should this be declared to allergic consumers?

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Why was the VITAL Program developed?

- 2001 list of mandatory allergens was increased
- 2002 there was a meeting of the Australian Food & Grocery Council about food allergens
- Food industry met and planned to research food allergens and make their research publically available
- From this collaborative, industry process, the first version of the VITAL Program, and the Allergen Bureau were formed.

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Food regulations silent about cross contact allergens

- No information in Australia/New Zealand law (and most other jurisdictions) about how to label allergens which were present inadvertently – the Allergen Bureau counted 42 different statements
- Cross contact statements were applied to products with no consistency in wording or risk assessment
- Confusion for allergic consumers!
- Concern for food manufacturers!
- The industry needed a consistent way to identify, manage and label cross contact allergens

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Introduction to the VITAL Program

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Voluntary Incidental Trace Allergen Labelling

The VITAL® (Voluntary Incidental Trace Allergen Labelling) Program is a standardised allergen risk assessment process for food industry .

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

Developed by industry for industry and is adopted on a voluntary basis

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The VITAL® Program

The VITAL Program allows incidental allergens to be presented in a **single simple standardised precautionary statement** to assist allergic consumers and their carers

The VITAL precautionary statement is:

May be present: [insert cross contact allergens]

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VITAL® Program Objective

To ensure **manufactured food** is safe to consume for the vast majority of food allergic consumers by providing **consistent food labels** that declare the presence of allergens, due to documented, unavoidable and sporadic cross contact thus enabling allergic consumers and their carers to avoid purchasing foods that may present a personal risk.

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VITAL in a nutshell....

- **Risk assessment:** Quantify the amount of cross contact in the finished product
- **Science:** Compare this amount to scientifically determined amount threshold

Less than threshold - precautionary allergen label is not required

More than threshold - precautionary allergen label is required

"May be Present: XXX"

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Flourless Chocolate Cake Ref:Cake1

Recipe & Raw Material Allergen Status

Yield 85% (Water loss is 15%)
Serving size is 80g

			Allergen Status	
Reference	Raw Material	Ingoing %	Intentional	Cross Contact
RM1	Liquid whole egg	30	Egg	
RM2	Cooking fat	30		Milk (3ppm), fish (80ppm)
RM3	Sugar	30	None declared	
RM4	Dark compound chocolate	10	Soy	Peanut pieces (particulate)

Processing Cross Contact

Hang-up is 2kg
Batch size exposed to hang-up is 200kg
Raw Vegan Cake contains whole sesame seeds
Honey Almond Cake contains almond flour (40% almond in cake, 20.4% protein in almond)

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VITAL® Online

A web based calculator that uses the Reference Dose information in conjunction with the Reference Amount and provides Action Levels that set out a labelling recommendation for individual foods

vital.allergenbureau.net --- One Month Free Trial!

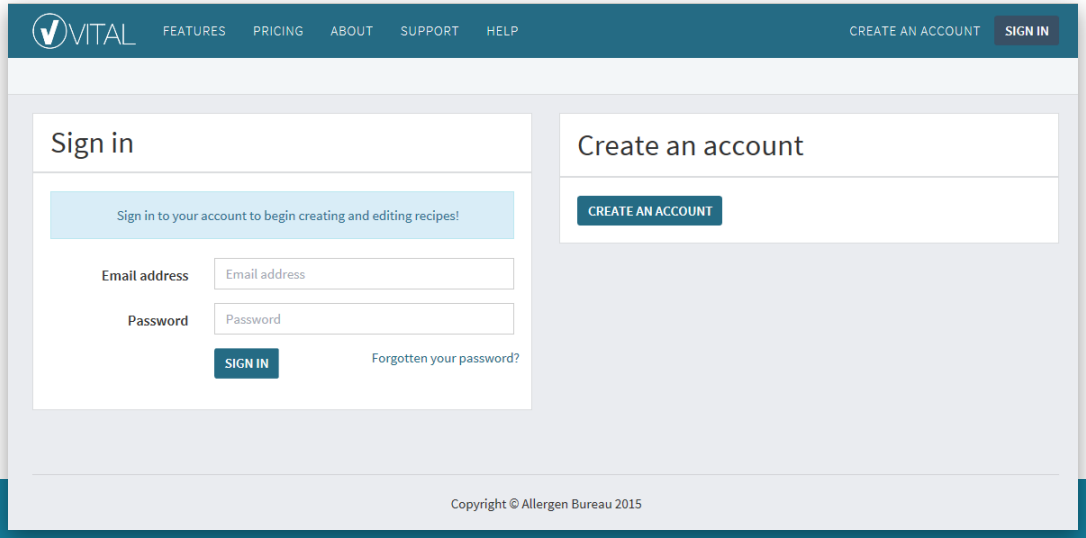

Table 1: Summary of labelling outcomes

Reference amount or serving size: 80g

Substances	Reference dose (mg)	Action level 1	Action level 2	Cross contact amount		Labelling outcome
				Particulate	Readily dispersible (ppm)	
Eggs	0.03	< 0.375 ppm	≥ 0.375 ppm			Intentionally added
Finfish	0.1	< 1.25 ppm	≥ 1.25 ppm		24	Action Level 2
Lupin						
Milk	0.1	< 1.25 ppm	≥ 1.25 ppm		0.9	Action Level 1
Peanut	0.2	< 2.5 ppm	≥ 2.5 ppm	yes		Action Level 2
Sesame	0.2	< 2.5 ppm	≥ 2.5 ppm	yes		Action Level 2
Shellfish/Molluscs						
Soy	1	< 12.5 ppm	≥ 12.5 ppm			Intentionally added
Sulphites						
Tree nuts (Total)	0.1	< 1.25 ppm	≥ 1.25 ppm		960	Action Level 2
Almonds					960	

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The VITAL® Program tools

- VITAL Procedure: how to implement the VITAL Program
- VITAL Online: tool for calculations and record information
- VITAL training materials: available to trainers
- Food Allergen Fundamentals presentation
- Conference Presentations
- Guidance documents & FAQs
- info@allergenbureau.net – free advice
- Risk Review Website

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The Risk Review interactive website

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The VITAL Program **IS NOT**:

- For INTENTIONALLY added allergens
- For infants and ‘foods for special medical purposes’ who have heightened sensitivity
- For “allergen-free” claims
- To justify poor allergen management practices (allergens must be controlled, even if they are declared in a precautionary allergen label)
- A government program
- Designed to be used with analytical analysis (it is designed to be used with physical risk assessment)

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The VITAL Program **IS**

- A tool
- Helpful to determine when a precautionary allergen label should be used

When a **precautionary allergen label** (i.e. May be Present) is used then
-The cross contact allergen should be present at the lowest practicable level; and
- be controlled at this level

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The science of the VITAL Program

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What is the science behind VITAL®?

The VITAL Program determines appropriate precautionary labelling based on risk by using Action Levels that are underpinned by **scientific evidence**

A collaboration of international food allergen experts established the science that underpins VITAL

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The VITAL® Scientific Expert Panel (VSEP)

- Dr Steve Taylor (FARRP) (USA)
- Dr Joseph Baumert (FARRP) supported by Mr Benjamin Remington (FARRP) (USA)
- Dr Geert Houben (Program Manager Food Safety, TNO) (NL)
- Dr Rene Crevel (Allergy & Immunology, Unilever) (UK)
- Dr Katie Allen (Paediatric Gastroenterologist / Allergist , Royal Children's Hospital, University of Melbourne), supported by Ms Jennifer Koplin (AUS)
- Dr Simon Brooke Taylor (Food Safety & Risk Analysis Consultant, Allergen Bureau) (AUS)

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Where does the data for thresholds come from?

Clinical studies

- Known allergic patients fed increasing amounts of the allergen to which they are allergic
- Reactions are recorded
- Published and unpublished reviewed by VITAL Scientific Expert Panel
- Only appropriate data points used
- Statistical analysis to determine appropriate threshold

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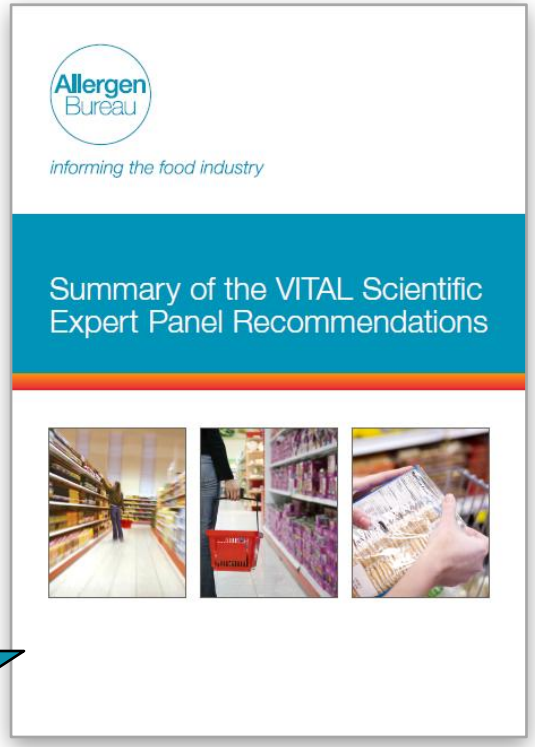
The VITAL® Scientific Expert Panel (VSEP) overarching scientific approach

- Analysed existing published clinical data and some unpublished data
- Statistical modelling to look at implication for the allergic population
- Scientifically and clinically sound, defensible and transparent
- Published papers (Taylor *et al* 2014, Allen *et al* 2014)
- Protection for vast majority of people with food allergy



VSEP meeting – 13 May, 2019: VITAL 3.0?

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The VSEP (VITAL 3.0?) Impacts for VITAL

- **Methodology** – Moved to Model Averaging
  - Defensibility – robust science is the key for all stakeholders

- **Reference Dose Recommendations -** ED01 or ED05?
  - ED01 = Reference Doses based on - 1 in 100 allergic consumers mildly reacting
  - ED05 = Reference Doses based on - 5 in 100 allergic consumers mildly reacting
  - Mildly reacting = mild, transitory & no pharmacological intervention
  - This means that the majority of allergic consumers can eat a normal diet (increase range of available when assessed using the VITAL Program)
  - VSEP still discussing ED01 vs. ED05

Allergen	VITAL 2.0	? VITAL 3.0 ?
Reference Dose – Increased		**Not yet adopted**
Egg	0.03	0.2 ?
Milk	0.1	0.2 ?
Shrimp	10	25 ?
Fish	0.1	1.3 ?
Reference Dose – Lowered		
Lupin	4.0	2.6 ?
Peanut	0.2	0.1 ?
Soy (Milk & Flour)	1.0	0.5 ?
Wheat	1.0	0.7 ?
Sesame	0.2	0.1 ?
Reference Dose – No change		
Hazelnut	0.1	0.1 ?
Mustard	0.05	0.05 ?
Reference Dose – NEW		
Cashew (Pistachio)	No ref dose	0.05 ?
Celery	No ref dose	0.05 ?
Walnut (Pecan)	No ref dose	0.03 ?

NOT CONFIRMED NOT CONFIRMED

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Key Concepts

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The key concepts of the VITAL® Program

Overview

- Action Levels
- Reference Dose
- Reference Amount or Serving Size
- Precautionary Labelling

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Action Levels guide labelling recommendations

Action Level 1

a low concentration of allergen protein and a low chance of adverse reaction.

No precautionary statement is required.

Action Level 2

a significant concentration of allergen protein and a significant chance of adverse reaction.

A precautionary statement is required.

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Action Levels

Are the concentrations (of protein) which define the labelling outcomes from a cross contact allergen

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

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

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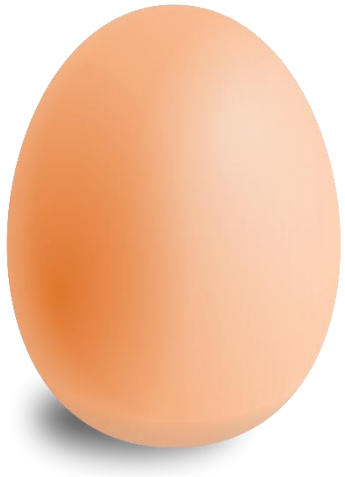
Reference Dose

The total protein from an allergic food below which only the most sensitive individual (between 1 and 5% depending on the quality of the data) in the allergic population are likely to experience an adverse reaction



Approx. 8900mg protein in a 70g raw whole egg

Greater than 0.03mg of egg protein may trigger an allergic reaction

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Reference Doses are available from the Allergen Bureau website

Allergen	**Reference Dose** (mg of total protein)
Peanut	0.2
Milk	0.1
Egg	0.03
Tree nuts	0.1
Soy	1
Wheat	1
Mustard	0.05
Lupin	4
Sesame	0.2
Crustacea (shrimp)	10
Fish	0.1

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Reference Amount

The maximum amount of a food eaten in a typical eating occasion (never the 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?

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Action Levels

Are the concentrations (of protein) which define the labelling outcomes from a cross contact allergen

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

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

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Example ~ Calculating Action Levels for product with peanut cross contact

Peanut Reference Dose = 0.2 mg protein

5g Reference Amount or Serving Size:

(Transition = 0.2 x 1000/5 = 40ppm)

Action Level 1:<40ppm

Action Level 2:≥40ppm

50g Reference Amount or Serving Size:

(Transition = 0.2 x 1000/50 = 4ppm)

Action Level 1 :<4ppm

Action Level 2 :≥4 ppm

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Implementation

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The VITAL® Procedure

1. Determination of relevant allergens
2. Identification of intentionally added allergens
3. Identification and quantification of cross contact allergens due to ingredients
4. Identification & quantification of cross contact allergens due to processing
5. Calculation of total cross contact allergen in finished product
6. Determination of Action Levels
7. Review of labelling recommendations and sources of cross contact
8. Recording of Assumptions
9. Validation of VITAL assessment
10. Ongoing Monitoring

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Why do allergen risk assessment?

Carrying out a VITAL® risk assessment using the tools provided ensures a food company understands

- the allergen status of its ingredients
- impact of allergen cross contact from processing
- the allergen status of its finished products

Allergen risk assessment contributes towards due diligence

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VITAL® and legal protection

VITAL does not directly offer any legal protection

HOWEVER, the proper implementation of VITAL provides evidence that a company has used best practice in regard to managing allergens

It is the application of due diligence that allows a defence or at least mitigation in product liability actions

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VITAL® and legal protection

Including an allergen precautionary statement on the label **does not mean** that you no longer have to control that allergen

Allergen management procedures should be followed to eliminate (or when that is not possible reduce) the possibility allergen cross contact

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VITAL® and legal protection

Using a precautionary statement, or indiscriminately using a precautionary statement, in lieu of appropriate allergen management are examples of the INCORRECT application of VITAL

The proper implementation of VITAL is where allergens are managed and are either eliminated or controlled at levels as low as practicable

Table : Summary of labelling outcomes

Reference amount or serving size: 80g

Substances	Reference dose (mg)	Action level 1	Action level 2	Cross contact amount		Labelling outcome
				Particulate	Readily dispersible (ppm)	
Celery						
Cereals containing gluten (Total)	1	< 12.5 ppm	≥ 12.5 ppm			
Barley	1	< 12.5 ppm	≥ 12.5 ppm			
Oats	1	< 12.5 ppm	≥ 12.5 ppm			
Rye	1	< 12.5 ppm	≥ 12.5 ppm			
Spelt						
Wheat	1	< 12.5 ppm	≥ 12.5 ppm			
Crustacea	10	< 125 ppm	≥ 125 ppm			
Eggs	0.03	< 0.375 ppm	≥ 0.375 ppm			Intentionally added
Finfish	0.1	< 1.25 ppm	≥ 1.25 ppm		24	Action Level 2
Lupin						
Milk	0.1	< 1.25 ppm	≥ 1.25 ppm		0.9	Action Level 1
Mustard						
Other						
Peanut	0.2	< 2.5 ppm	≥ 2.5 ppm	yes		Action Level 2
Sesame	0.2	< 2.5 ppm	≥ 2.5 ppm			
Shellfish/Molluscs						
Soy	1	< 12.5 ppm	≥ 12.5 ppm			Intentionally added
Sulphites						
Tree nuts (Total)	0.1	< 1.25 ppm	≥ 1.25 ppm			

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The 10 steps of VITAL®

Review of labelling recommendations and sources of cross contact

~ intentionally added allergens must be declared on the product label in the ingredient list

~ review cross contact allergens for opportunities to reduce or eliminate

~ precautionary labelling should only ever be used after a thorough assessment of risk

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Example of allergen labelling using VITAL®

Ingredient List

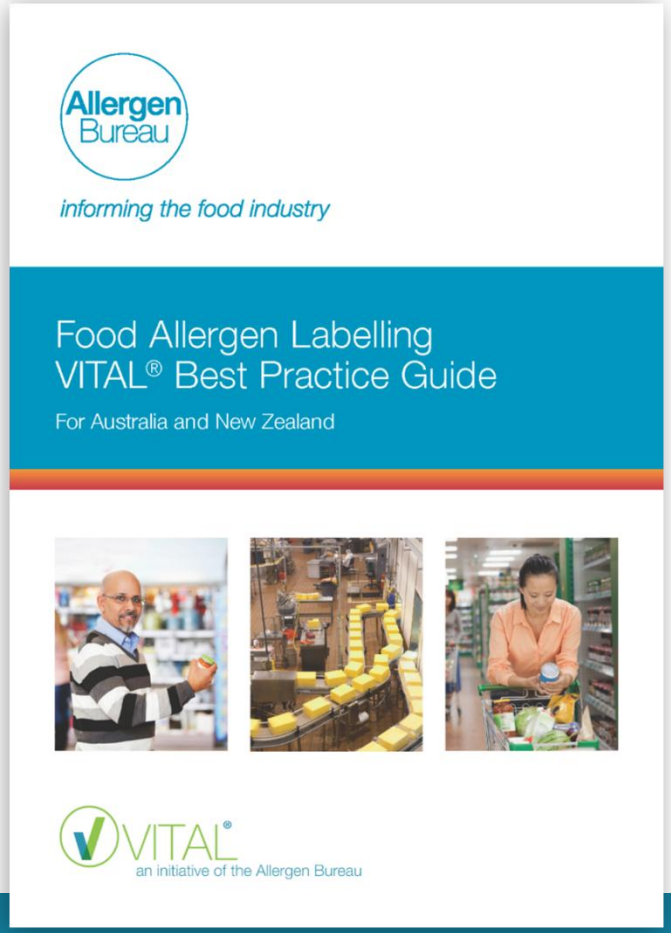
Water, potato, carrots, celery, brown rice, **oats**, **peanut** oil, yeast extract (**barley**).

Allergen Summary Statement

Contains cereals containing gluten, peanut.

May be present: wheat.

Precautionary Statement



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VITAL® Precautionary Statement

It is **only** to be used where allergen cross contact is:

~ Documented using the VITAL criteria;

~ Unavoidable; and

~ Sporadic

Removing all avoidable cross contact allergens is Good Manufacturing Practice

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VITAL® Working Group 3 – Certification

- VITAL Scheme under ISO 17065 has been drafted.
- Designed as an extra module for GFSI-recognised certified sites with HACCP based Allergen Management Programs.
- VITAL certification is product specific.
- Has been trialled by a few companies and Certification bodies to ensure it can be interpreted & applied consistently.
- Work in progress to determine resources to manage the VITAL Standard, including developing Industry & Auditor training, and providing required support and agreements for Certification bodies.
- VITAL Standard to be made publicly available soon.
  Application to JAS-ANZ for VITAL Scheme accreditation to be determined based on demonstration of industry need.

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What about allergen testing?

- If you use allergen testing, a laboratory specialising in allergen testing should be used
- Limitations of allergen testing are many E.g. only tests a tiny sample (one gram)
- When would you use allergen testing – validation of an assumption in your allergen management plan
  For example: to check cleaning of equipment between different products

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Further Engagement and Resources

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- Visit the website www.allergenbureau.net
- Subscribe to our free monthly Allergen Bureau eNews www.allergenbureau.net/news/
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