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# VITAL<sup>®</sup> Activities ~ the priorities & challenges

Lisa Warren

VITAL Support, The Allergen Bureau

## Overview

- ~ Who is the Allergen Bureau
- ~ Allergen declaration requirements
- ~ Food allergen recalls
- ~ The VITAL<sup>®</sup> program
- ~ Current Allergen Bureau projects

# Who is the Allergen Bureau?

- The **peak industry body** representing food industry allergen management in Australia and New Zealand
- 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

# Allergen Bureau Organisation

## The Board of Directors

Kirsten Grinter (Nestlé Australia Ltd)

Caroline Gray (DuPont)

Debbie Hawkes (Hawkins Watts)

Karen Robinson (Invited Director)

David Henning (Invited Director)

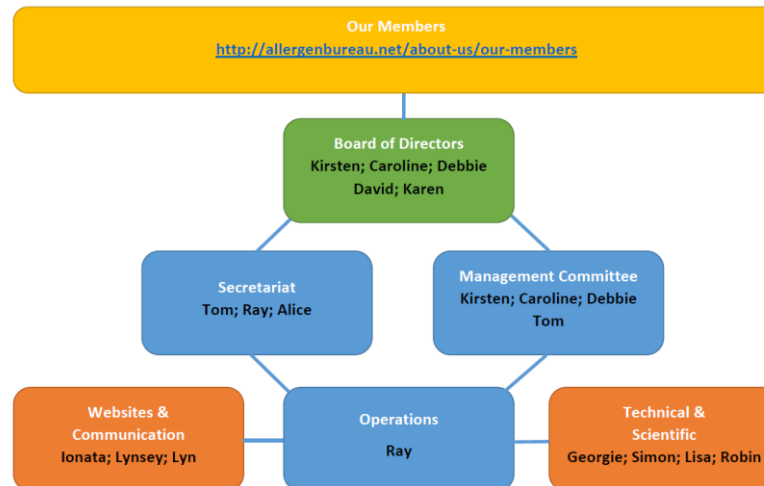
## Our support network

VITAL® Coordinator / Support  
(Georgina Christensen & Lisa Warren)

Technical expertise  
(Simon Brooke Taylor & Robin Sherlock)

VITAL® Scientific Expert Panel (VSEP)

## Funded Secretariat



## Top ten countries visiting Allergen Bureau website

Australia (3718 – 44%)

United States (684 – 8%)

New Zealand (646 – 8%)

United Kingdom (386 – 5%)

Germany (310 – 4%)

Netherlands (255 – 3%)

France (203 – 2%)

**India\*** (175 – 2%)

Belgium (140 – 2%)

Spain (138 – 2%)

Non-bounce sessions Jul – Dec 2017



# Foods & Substances that Require Mandatory Declaration

- ~ cereals containing gluten  
(wheat, rye, barley, oats, spelt,  
their hybridised strains) (incl.  
exemption)
- ~ crustacea
- ~ egg
- ~ fish (incl. exemption)
- ~ milk (incl. exemption)
- ~ peanuts
- ~ soybeans (incl. exemption)
- ~ sesame seeds
- ~ tree nuts (not coconut)
- ~ lupin
- ~ added sulphites (10mg/kg or  
more)

Food Standards Code Standard 1.2.3-4

# Mandatory and voluntary information

Ingredient List (mandatory)  
Bolding (voluntary)

Allergen Summary  
Statement (voluntary)

Precautionary Statement  
(voluntary)

## INGREDIENTS

**Wheat** Flour, Sugar, Butter (**Milk**), **Egg**,  
Raising Agents (339,341,450), Flavour

Contains cereals containing gluten, milk,  
egg

May be present: almond



# Not declaring allergens accurately is bad for business

## ~ Customer and consumer relationships

- ~ trust, confidence

## ~ Costs to the business

- ~ unsafe product
- ~ brand damage
- ~ food recall



### Serendipity Vanilla Bean Ice Cream

Sarric PTY Ltd trading as Serendipity Ice Cream

The presence of an undeclared allergens (milk and egg).



### Jimmy Brings Wine

Jimmy Brings

The presence of undeclared allergens (sulphites, milk and eggs).



### Seafood Salad

Kailis Bros Pty Ltd

Non-compliant labelling (some ingredients)



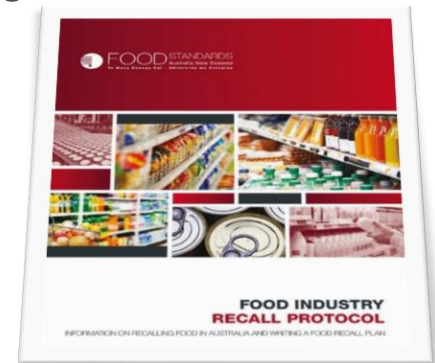
# Food recalls

When a food is unsafe, the food business must remove it from distribution, sale and consumption to protect public health and safety.

This process is known as a food recall.

FSANZ has a range of resources for food businesses including:

- The Food Industry Recall Protocol
- Food recall templates
- FAQs for food businesses



[www.foodstandards.gov.au/industry/foodrecalls](http://www.foodstandards.gov.au/industry/foodrecalls)

# Undeclared allergen recalls coordinated by FSANZ

Average 10 - 39 undeclared allergen recalls yearly

- ~ Increasing in last few years
- ~ 24 so far this year (Jan - Jun 2018)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Undeclared allergen	10	17	13	24	17	16	27	39	33	34	230

## Cause

- ~ Undeclared dairy (31%), peanut (20%), multiple allergens (15%)

## Common food types

- ~ Processed foods (33%), confectionary (15%), baked goods (11%), beverages (11%)

## Most common reasons for undeclared allergen recalls

- ~ lack of skills and knowledge
- ~ supplier verification issues e.g. ingredients
- ~ packaging errors
- ~ accidental cross contact in raw materials and finished product

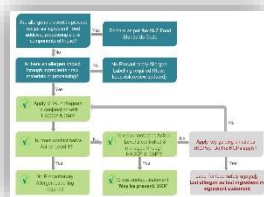
## The VITAL<sup>®</sup> Program

- ~ consistent approach to assessing cross contact allergen risk (defined level of risk based upon scientific principles)
- ~ encourages the elimination of cross contact allergens where possible within manufacturing or via material supplier
- ~ clear, consistent and accurate allergen declaration that assists consumers in making safer food choices (standardised precautionary allergen labelling statement)



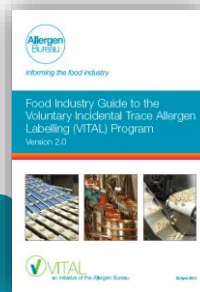


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Risk Review  
Anomalies

VITAL Program



Tools & Helpline



VSEP



Training  
Providers



VITAL Online



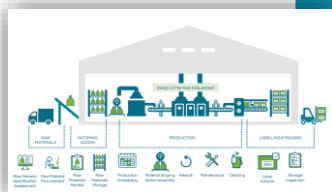
(WG2)  
Communication

Ingredient List	Water, potato, carrots, celery, brown rice, <b>oats</b> , <b>peanut</b> oil, yeast extract ( <b>barley</b> ).
Allergen Summary Statement	Contains cereals containing gluten, peanut.
The VITAL Preliminary Statement	May be present: wheat.

(WG3)  
Certification



(WG1) Risk  
Review



The  
**VITAL**®  
Framework

## The 10 Steps of VITAL<sup>®</sup>

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

<http://allergenbureau.net/vital/vital-downloads>

# The VITAL<sup>®</sup> Program tools

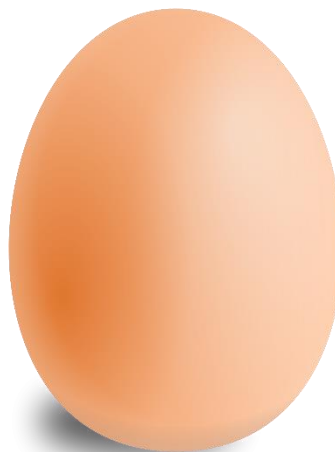
- ~ VITAL Procedure
- ~ Decision Tree
- ~ Interactive VITAL Action Level Grid
- ~ VITAL Online (Calculator)
- ~ VITAL training materials
- ~ Guidance documents & FAQs





## 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

# The VITAL<sup>®</sup> Scientific Expert Panel (VSEP)

**Dr Steve Taylor** (Chair of Panel) - Food Allergy Research & Resource Program (FARRP) (USA)

**Dr Joseph Baumert** Food Allergy Research & Resource Program (FARRP) (USA)

**Dr Geert Houben** Program Manager Food Safety, Netherlands Organisation for Applied Scientific Research (TNO) supported by **Mr Benjamin Remington** (NL)

**Dr Rene Crevel** RENE CREVEL Consulting Ltd (UK) (Formerly Allergy & Immunology, Unilever)

**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)



VITAL Science –  
<http://allergenbureau.net/vital/vital-science/>

# The VSEP overarching scientific approach

- ~ analysed existing published clinical data plus some unpublished data. Over 1800 clinical data points (in 2011) and growing each year
- ~ statistically based risk assessment, validated using probabilistic modelling for the population
- ~ scientifically and clinically sound, defensible and transparent
- ~ protection for vast majority of people with food allergy

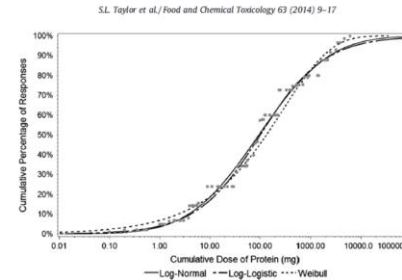


Fig. 1. Probability distribution models for individual peanut thresholds (expressed as mg protein).

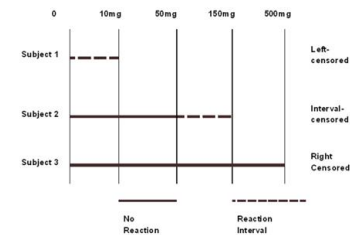


Figure 5 – Diagram of the Interval-Censoring Survival Analysis and how it assigns censoring values. Sample dosing schedule progresses from 10 mg – 50 mg – 150 mg – 500 mg.

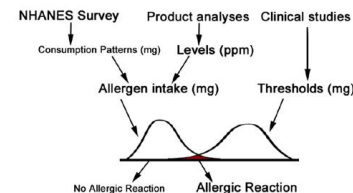


Figure 8 – Probabilistic risk assessment model for food allergens in the U.S., figure adapted from Spanjerberg et al. (2007).



## VITAL<sup>®</sup> Training

- ~ Global partners and collaborations to support and facilitate VITAL implementation
- ~ Critical to long term success (global consistency)
- ~ Ongoing industry engagement & connection

### 19 endorsed Training Providers

Australia and New Zealand  
North and S.E Asia  
Pacific region  
Africa  
Europe  
USA & Canada  
Mexico & S. America

### Virtual & Online training

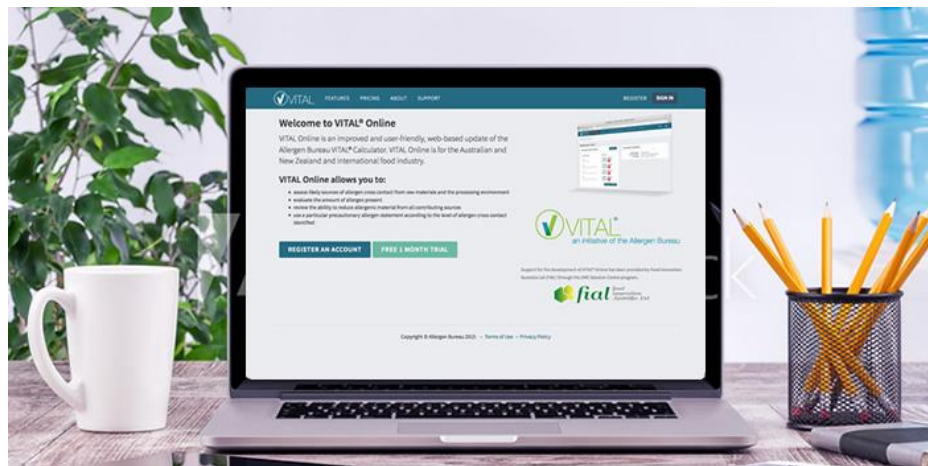
Over 2,500 people trained in  
VITAL version 2.0

Australia & New Zealand 2,150  
participants

Other countries  
350 participants

# VITAL<sup>®</sup> Online

- ~ The user-friendly, web-based VITAL Calculator
- ~ Input the results of a VITAL risk assessment
- ~ Output a finished product labelling outcome





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an initiative of the Allergen Bureau

# VITAL<sup>®</sup> Online (vital.allergenbureau.net)

The screenshot shows the 'ADD INGREDIENTS' section with a list of ingredients: Sugar (RM3, 30.000000%), Cooking fat (RM2, 30.000000%), Liquid whole eggs (RM1, 30.000000%), and Dark compound Chocolate (RM4, 10.000000%). A progress bar indicates '100.000000% of ingredients entered'. The 'Ingredient as a percentage of recipe\*' field is set to 30.000000. The 'Allergens & their products' section lists 'Gluten containing cereals' and 'Tree nuts'. The 'Help and Support' section provides instructions on adding ingredients and allergens.

Use this field for products sold to consumers

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

The 'Create recipe' form includes fields for 'Recipe name' (Flourless Chocolate Cake), 'Recipe code' (Cake1), and 'Reference Amount' (80 g). The 'Reference Amount' field is highlighted with a blue arrow pointing to the text 'Use this field for preparing a PIF for a customer, or when combining recipe components'. The 'Reference Amount assumptions' section states 'Represents one slice of cake'. The 'Legislation' dropdown is set to 'Australia and New Zealand', and the 'Legislation description' is 'ANZFSC Allergens'. A 'NEXT STEP' button is at the bottom right.

Use this field for preparing a PIF for a customer, or when combining recipe components

# Example of a VITAL<sup>®</sup> Online Labelling Outcome Summary

VITAL labelling outcomes will appear like this

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			

# Growing International Interest

VITAL Online website  
top ten visiting countries

Australia  
Netherlands  
Belgium  
New Zealand  
France  
United States  
Germany  
United Kingdom  
South Africa  
Italy





# Expanding VITAL<sup>®</sup> Online to the world

## Benefits

- ~ a consistent approach to assessing cross contact allergen risk applied throughout the world
- ~ clear, consistent and accurate allergen declaration (and consistent level of risk) for all consumers

## Challenge

- ~ one size does not fit all



FOOD ALLERGENS	USA	CANADA	EU	AUSTRALIA/NZ	HONG KONG	CHINA	KOREA	TAIWAN*	ARGENTINA	THAILAND	BOLIVIA	BRAZIL	CHILE	COLOMBIA	COSTA RICA	CUBA	MEXICO	NICARAGUA	SOUTH AFRICA	VENEZUELA	MALAWI	SINGAPORE	JAPAN**	GSO***	ISRAEL (PENDING)	INDIA (IN DEVELOPMENT)
CRUSTACEAN SHELLFISH	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
EGG	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
FISH	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
MILK	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
PEANUT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
SOY	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
TREE NUTS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
WHEAT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
CEREALS W/ GLUTEN	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
BUCKWHEAT						X																	X			
CELERY		X																					X			
LUPIN		X	X																				X			
MOLLUSCAN SHELLFISH	X	X	X		X													X			X		X			
MUSTARD	X	X																					X			
SESAME	X	X	X																				X			
SULFITES	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
BEE POLLEN/ PROPOLIS				X																						
ROYAL JELLY			X																							
MANGO							X																			
PEACH						X																				
PORK						X																				
TOMATO						X																				
LATEX (NATURAL RUBBER)										X																

KEY:

\*Taiwan FDA released a new draft version of regulations on 12-11-2017 to include 11 proposed food allergens but they have not been finalized.

\*\*Voluntary labeling recommended for Abalone, Mackerel, Squid, Salmon, Salmon Roe, Cashew, Walnut, Matsutake Mushroom, Sesame, Soybean, Yam, Apple, Banana, Kiwifruit, Orange, Peach, Beef, Chicken, Gelatin, Pork.

\*\*\*GSO includes the countries of Saudi Arabia, UAE, Kuwait, Bahrain, Oman, Qatar, and Yemen

<https://farrp.unl.edu/IRChart>

## What Success Looks Like

- ~ The VITAL Program, with its tools, support material & services, it is **globally relevant**
- ~ The **science** that underpins the reference dose/action levels remains **current** through VSEP ongoing interaction
- ~ Growth through global partners and training collaborations
- ~ Continuous development of VITAL as the industry and the program evolves

## Finally

- ~ Allergen Bureau continues to respond to stakeholder needs
  - ~ Working groups
  - ~ Investment in development of resources to support allergen management and VITAL
  - ~ Awards for best practise allergen management
- ~ Collaborate with key stakeholders
  - ~ National Allergy Strategy, Allergen Collaboration
  - ~ FSANZ consultation pieces
  - ~ Codex consultation groups
- ~ International Collaboration FAMS2019

# FAMS2019 – 13th-16th May 2019, MELBOURNE. SAVE THESE DATES!!

by Imcleod / May 28, 2018 / Allergen Bureau News, Industry News, Training / 0



The 3rd Food Allergen Management Symposium – FAMS2019 – will be held at State Library Victoria, Melbourne from 13-16 May 2019.

Food industry, researchers, clinicians, dietitians, consumer groups, regulators and legislators with an interest in food allergy and food allergen management should attend FAMS2019.



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## For further engagement & information

- ~ Visit the Allergen Bureau website [www.allergenbureau.net](http://www.allergenbureau.net)
- ~ Join us & enjoy the benefits of the Allergen Bureau membership [www.allergenbureau.net/about-us/join-us/](http://www.allergenbureau.net/about-us/join-us/)
- ~ Subscribe to our free monthly Allergen Bureau eNews [www.allergenbureau.net/news/](http://www.allergenbureau.net/news/)
- ~ Access the free Allergen Bureau Helpline
  - email: [info@allergenbureau.net](mailto:info@allergenbureau.net)
  - Phone: +61 437 918 959 (International)

