



informing the food industry

Navigate the Science. Manage the Risk.

NZIFST Conference (4 Jul 2019)

Debbie Hawkes

Director, Allergen Bureau

(General Manager –Quality & Operations ANZ, Hawkins Watts)

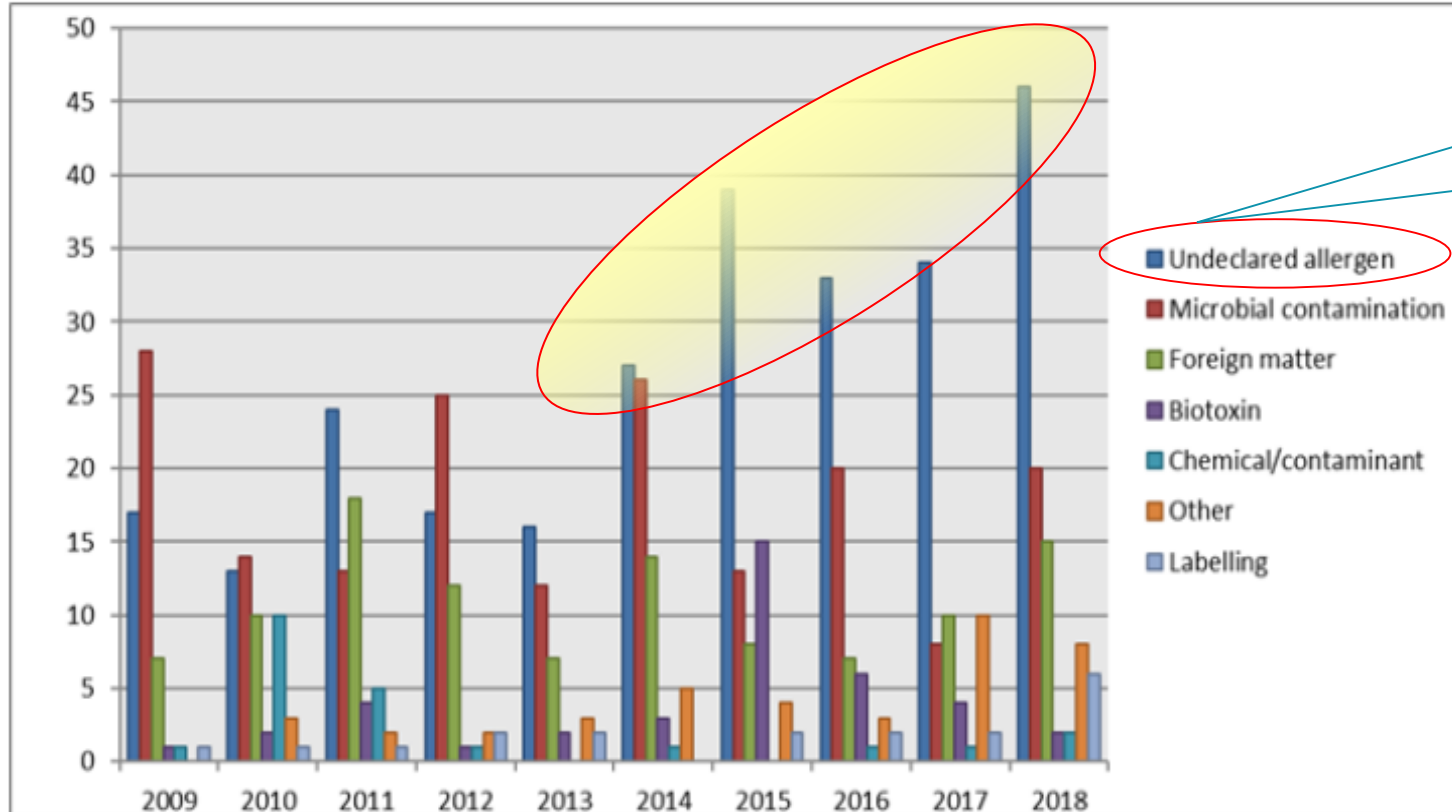


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Overview

- FSANZ Allergen related recall stats...
- Who is the Allergen Bureau? Mission & Vision
- FAMS2019, VSEP & new Reference Doses
- Transition VITAL[®] 2.0 to VITAL[®] 3.0
- Allergen Risk Review Website
- Risk Review Anomalies
- Agricultural Cross Contact Working Group
- VITAL Standard - Certification

FSANZ Allergen related Recall Stats



Undeclared Allergens
are still the major cause of
FSANZ recalls
(46% in 2018)

FSANZ identified key causes for allergen related recalls:

- ✓ Packaging errors
- ✓ Supplier allergen verification
- ✓ Lack of skills/knowledge of labelling requirements
- ✓ Accidental cross contamination

Source: <http://www.foodstandards.govt.nz/industry/foodrecalls/recallstats/Pages/default.aspx>



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Who is 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





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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 Organisation

The Board of Directors

Kirsten Grinter (Nestlé Australia Ltd)

Caroline Gray (DuPont)

Debbie Hawkes (Hawkins Watts)

Jasmine Lacis-Lee (DTS Food Assurance)

David Henning (Invited Director)

Our support network

VITAL® Coordinator / Support

Technical expertise

VITAL Scientific Expert Panel (VSEP)

Georgina Christensen & Lisa Warren

Simon Brooke-Taylor & Robin Sherlock

Funded Secretariat

Tom Lewis, Ray Murphy, Alice Doyle

Top ten countries visiting Allergen Bureau website

Australia (41%)

United States (7%)

New Zealand (7%)

United Kingdom (6%)

Germany (4%)

France (4%)

Netherlands (3%)

India (2%)

Spain (2%)

Italy (2%)

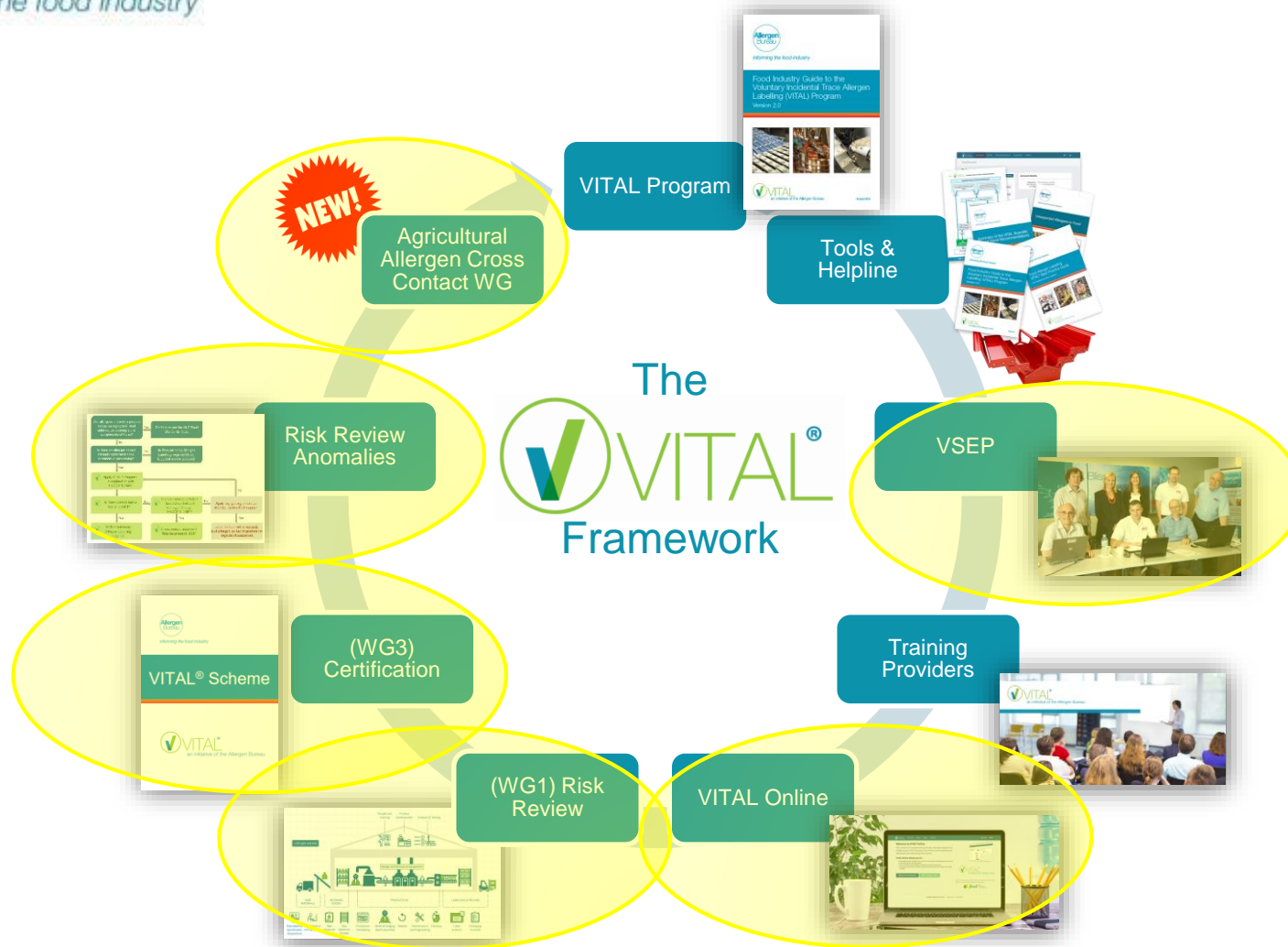
Non-bounce sessions July – December 2018



International Interest still growing

- Over 2500 registered organisations use the VITAL[®] Online
- VITAL Online website Top 10 Countries
 - ✓ Australia
 - ✓ Netherlands
 - ✓ New Zealand
 - ✓ Germany
 - ✓ United Kingdom
 - ✓ France
 - ✓ Belgium
 - ✓ Spain
 - ✓ United States
 - ✓ Italy







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FAMS2019 3rd Food Allergen Management Symposium

Navigate the science, manage the risk

Key Speakers

- ✓ Professor Steve Taylor, Food Allergy Research & Resource Program, University of Nebraska, USA
- ✓ Joseph Baumert, Food Allergy Research & Resource Program, University of Nebraska, USA
- ✓ René Crevel, René Crevel Consulting Ltd
- ✓ Samuel Godefroy, Université Laval, Québec, Canada
- ✓ Jonathon Hourihane, University College Cork, Ireland
- ✓ Derek Castles, Food Standards Australia New Zealand
- ✓ Professor Clare Mills, The University of Manchester, UK
- ✓ Ben Remington, Netherlands Organisation for Applied Scientific Research
- ✓ Maria Said, Allergy & Anaphylaxis Australia, Australia
- ✓ Penny Jorgensen, Allergy New Zealand, NZ
- ✓ Sandra Vale, National Allergy Strategy, Australia



<http://allergenbureau.net/resources/conference-presentations/2019-conference-presentations/>

VSEP: More clinical data, better modelling => new Reference doses

Refer : [Ben Remington - The Modelling Behind the Translation from Individual Thresholds to Population Threshold Dose Distribution](#) at FAMS2019.

“Bayesian Stacked Parametric Survival with Frailty Components & Interval Censored Failure times”....
Collaboration with Dr. Matthew Wheeler, National Institute Occupational Safety & Health, USA.

This project determines how individual thresholds from food allergic subjects can be grouped and analyzed statistically to determine the population threshold for a number of regulated Food allergens.

Based on objective Double blind, placebo-controlled food challenges, with description of NOEAL (No observed adverse effect level) and/or LOAEL (Lowest observed adverse effect level)

New stacked model averaging incorporates 5 different models
(Weibull, Log Logistic, Log Double Exponential, General Pareto)

Better modelling accounts for study-to-study heterogeneity (different locations, clinicians etc)

VSEP Recommended Reference Doses (mg protein)

Allergen	No. of individuals	VITAL 2.0 Ref Dose (mg protein)	2019 VSEP Recommended Ref Dose (mg protein) = ED01	ED05 (mg protein)	Distribution
Egg	431	0.03	0.2	2.5	Discrete (0.23) and Cumulative (0.22)
Hazelnut	410	0.1	0.1	3.5	Discrete
Lupin	25	4.0	2.6	16.9	Cumulative
Milk	440	0.1	0.2	2.4	Discrete
Mustard	33	0.05	0.05	0.5	Cumulative
Peanut	1294	0.2	0.1	2.0	Discrete
Sesame	40	0.2	0.1	2.7	Discrete
Shrimp	75	10.0	25	280.3	Discrete
Soy (milk + flour)	87	1.0 (soy flour)	0.5	10.0	Discrete
Wheat	99	1.0	0.7	6.1	Discrete
Cashew	245		0.05	0.8	Discrete
Celery	82		0.05	1.3	Cumulative
Fish	82		1.3	15.7	Cumulative
Walnut	74		0.03	0.8	Discrete

ED = Eliciting Dose

ED01 = 1% of allergic consumers may have mild transitory reaction

ED05 = 5% of allergic consumers may have mild transitory reaction



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The VSEP Recommendation Impacts for VITAL[®]

Considerations for Allergen Bureau

- ✓ Need to strike a balance between blanket labelling and not labelling effectively
- ✓ Increasing global interest in VITAL so we need to ensure acceptance, integrity and trust until consensus emerges

Methodology

Moved to Stacked Model Averaging which gives more robust science

Reference Dose based on ED01

1% of allergic consumers could have a mild reaction

This allows the majority of allergic consumers to eat a normal diet

More consistent approach across all reference doses

Some reference doses will change and new reference doses added



Proposed VITAL[®] V3.0 Reference Doses, ED01 (mg protein)

Allergen	VITAL 2.0	VITAL 3.0
Reference Dose - Increased		
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



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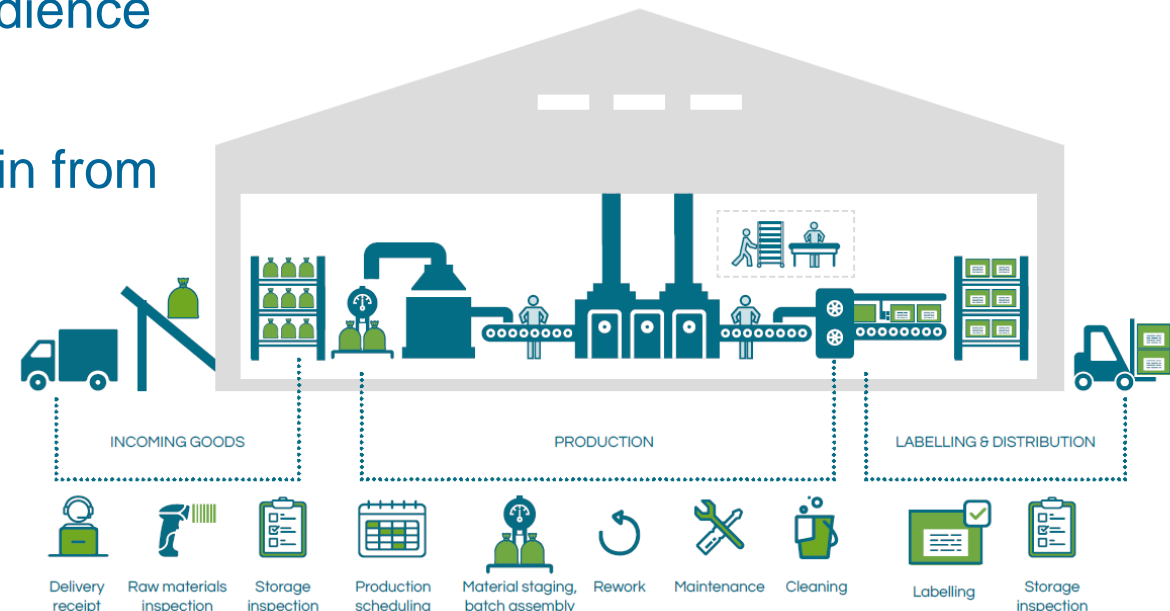


Transition VITAL[®] 2.0 to VITAL[®] 3.0

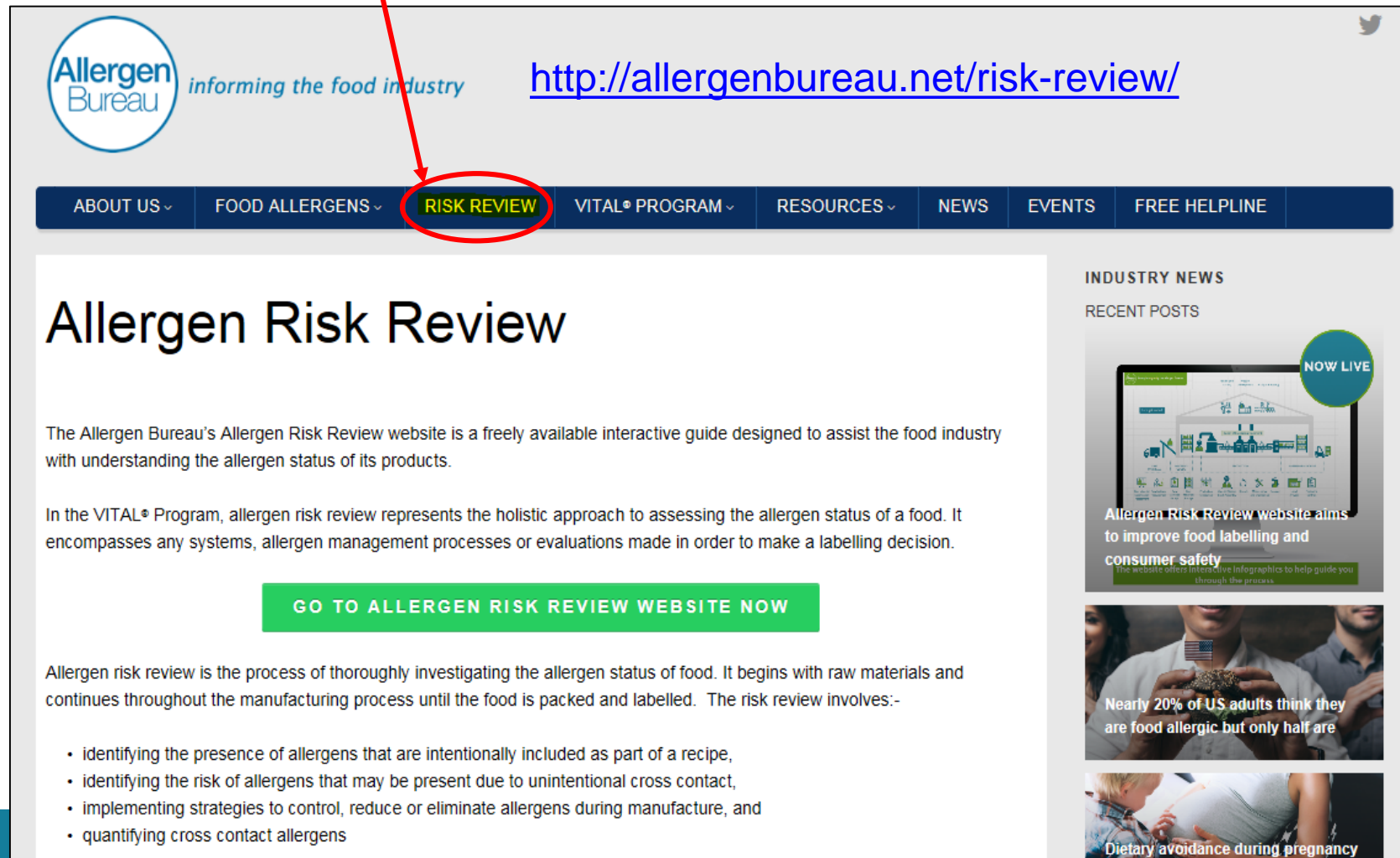
- VITAL Version 2.0 is the current version of the VITAL Online
- Assessments continue to be done in VITAL Online
- Work in progress to enhance Online program update functionality to assist with VITAL 3.0 transition
- Work in progress to update VITAL Training to include Risk Review website and VITAL 3.0.
- Reference Doses used in VITAL 2.0 will be changing to VITAL 3.0 in the coming months
- So VITAL Online users should review the new Reference Doses
Ref: Kirsten Grinter's FAMS2019 presentation [VITAL 2.0 to 3.0 – An industry approach to thresholds & ref. doses](#)
- Be aware of Reference Dose changes - increases, decreases, or new in the change to VITAL 3.0
- **Tree Nuts:** Reference Doses have been provided for some individual tree nuts and further information will be provided as it becomes available
- **It is important to emphasise that the process of doing an overall risk review and a VITAL risk assessment will not change. The basis of the VITAL Program continues to be good risk review and good manufacturing processes (GMP).**

Allergen Risk Review Website

- ✓ Detailed guidance to investigate allergen status of a food.
- ✓ Interactive webpage accessible from the Allergen Bureau website to guide the user to do best practice Allergen Risk Review.
- ✓ Appropriate for a broad food industry audience (local, international, SME, corporations)
- ✓ Expandable to include entire supply chain from primary production to finished product
- ✓ Lots of detail, but easy to use and focus on specific areas of concern.
- ✓ We welcome your feedback!!



Allergen Risk Review website



The screenshot shows the Allergen Bureau website with the 'RISK REVIEW' link highlighted in the navigation bar. A red arrow points from the title 'Allergen Risk Review website' to this link. The main content area features the title 'Allergen Risk Review', a description of the website's purpose, a 'GO TO ALLERGEN RISK REVIEW WEBSITE NOW' button, and a list of steps involved in the risk review process. The right sidebar contains 'INDUSTRY NEWS' and 'RECENT POSTS' with images and headlines related to food labelling and dietary avoidance.

Allergen Bureau informing the food industry

<http://allergenbureau.net/risk-review/>

ABOUT US ▾ FOOD ALLERGENS ▾ **RISK REVIEW** VITAL[®] PROGRAM ▾ RESOURCES ▾ NEWS EVENTS FREE HELPLINE

Allergen Risk Review

The Allergen Bureau's Allergen Risk Review website is a freely available interactive guide designed to assist the food industry with understanding the allergen status of its products.

In the VITAL[®] Program, allergen risk review represents the holistic approach to assessing the allergen status of a food. It encompasses any systems, allergen management processes or evaluations made in order to make a labelling decision.

GO TO ALLERGEN RISK REVIEW WEBSITE NOW

Allergen risk review is the process of thoroughly investigating the allergen status of food. It begins with raw materials and continues throughout the manufacturing process until the food is packed and labelled. The risk review involves:-

- identifying the presence of allergens that are intentionally included as part of a recipe,
- identifying the risk of allergens that may be present due to unintentional cross contact,
- implementing strategies to control, reduce or eliminate allergens during manufacture, and
- quantifying cross contact allergens

INDUSTRY NEWS

RECENT POSTS

NOW LIVE

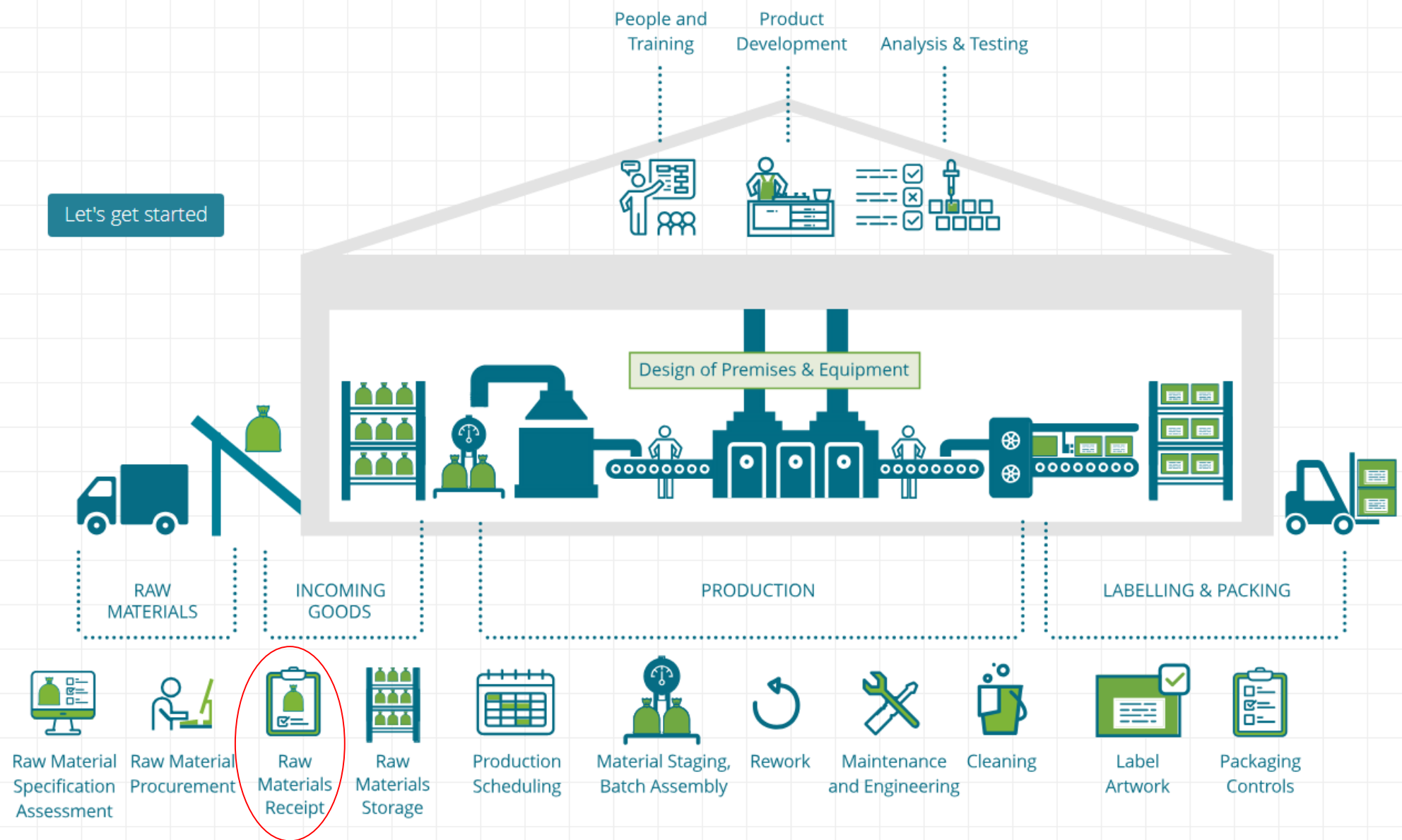
Allergen Risk Review website aims to improve food labelling and consumer safety

Nearly 20% of US adults think they are food allergic but only half are

Dietary avoidance during pregnancy



Let's get started





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Case Study

A food manufacturer received a supply of powdered ingredient packed into 25kg multiwalled paper valve bags. However, upon receipt, it was discovered that the bags had been overfilled, causing the paper valve to be jammed open with powder. This resulted in some of the ingredient escaping from the bags during transport and settling on other surfaces inside the shipping container. The ingredient could potentially be an allergen cross contact hazard and therefore the manufacturer took the appropriate actions to isolate and reject the stock.



step

next step



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Risk Review Anomalies

AB, Ai Group & AFGC - working together on Risk Review Anomalies

Anomaly = Allergens known to be present at significant levels but not formulated as an ingredient & inappropriate to label as “**May be present XXX**”.

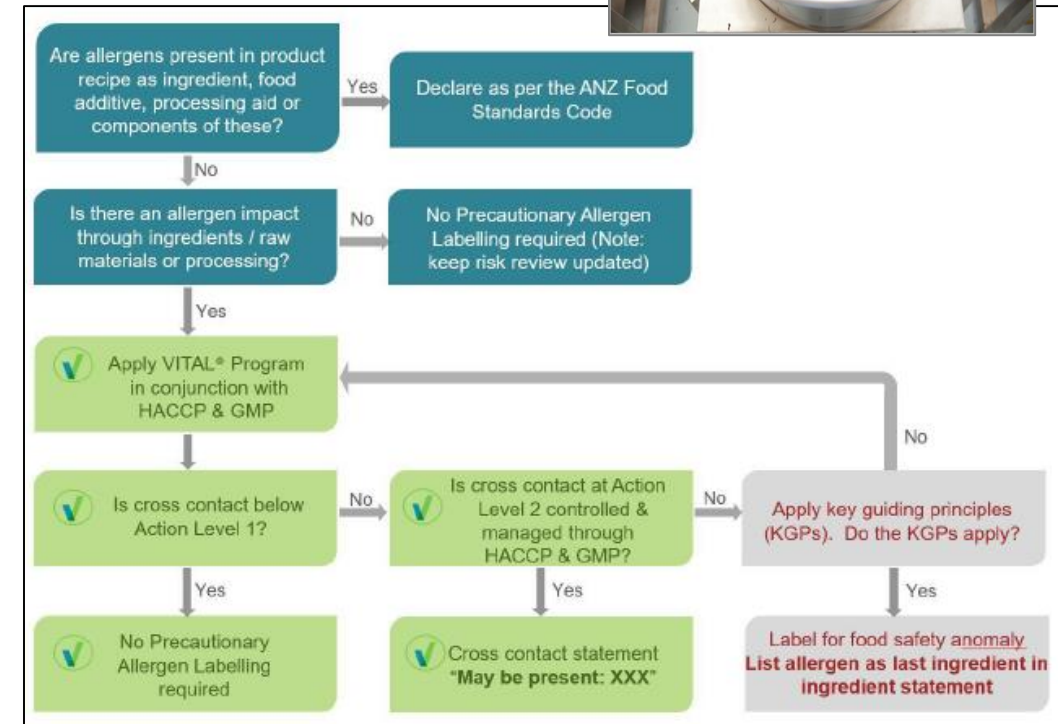
Occur where the process or environment cannot be altered or impacted through GMP.

e.g. Milk/Dairy in Dark Chocolate due to single conch

Collaborated with ANZ jurisdictions, Allergy NZ, and Allergy & Anaphylaxis Australia (A&AA).

Guiding principles & decision tree published to ensure appropriate labelling for the Food allergic consumer.

<https://tinyurl.com/Risk-Review-Anomaly>



N.B. Declaring the allergen substance, ie milk, as the last ingredient in the ingredient list is not a substitute for appropriate risk review. Every attempt should be made to eliminate the allergen effectively.



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Agricultural Cross Contact Working Group

- Food industry driven working group
 - Intent is to identify and communicate the challenges in this area
 - Provide guidance on assessing the risk
 - Provide guidance to determine labelling outcomes
 - Inform international suppliers
- Phase 1 and Phase 2
- Board approved April 2019



Agricultural Cross Contact Working Group

Phase 1 - Quick Wins for Industry

1. Update “Unexpected Allergens in Food” resource
2. Develop agricultural cross contact issue flow chart
3. Publish an informative paper
4. Guidance resource on ingredient allergen declarations from suppliers/growers
5. Sampling and testing guidance
6. Establish cross sectoral working relationship

Phase 2 - Overarching Guidance document

7. Agricultural allergen cross contact
Food Industry Management Guide



VITAL[®] Standard - Certification

- VITAL Standard has been written in compliance with ISO 17065.
- 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.
- Exploring 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 Standard accreditation to be determined based on industry need

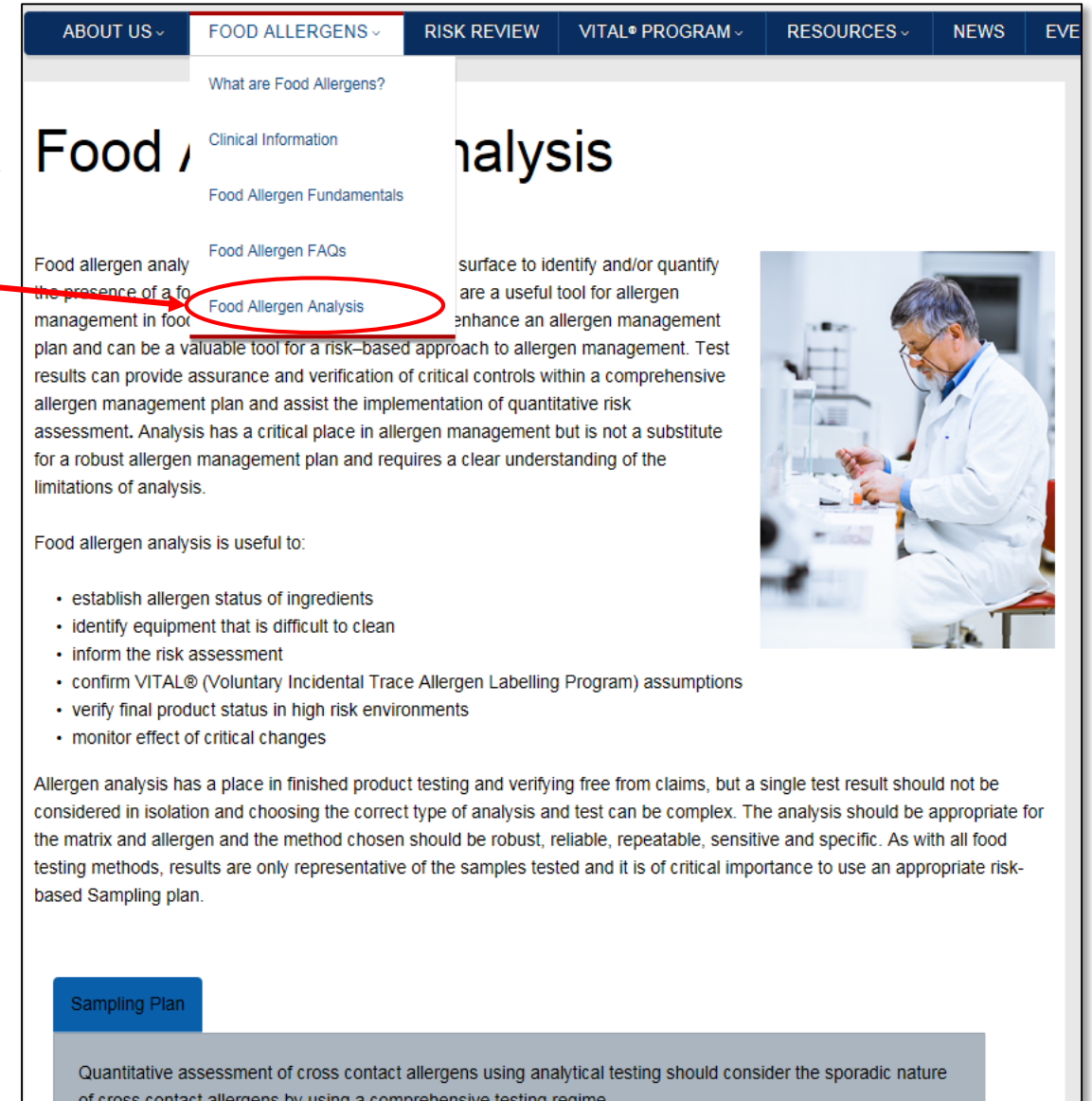


Food Allergen Analysis – Website Addition



Includes valuable guidance on:

- Sampling Plans
- Test Kits and their uses
- Types of Laboratory Analysis
- How to choose the most appropriate method
- What you should be asking your laboratory providers



Conclusion

- ✓ Allergen Bureau continues to respond to stakeholder needs
 - Working groups
 - Investment in development of resources to support allergen management & VITAL
 - Awards for best practice allergen management - **Congratulations** to Woolworths NZ
- ✓ Collaborate with key stakeholders
 - [National Allergy Strategy](#)
 - [Allergen Collaboration \(FSANZ\)](#)
 - [Allergy NZ](#), [Allergy & Anaphylaxis Australia \(A&AA\)](#)
 - [Australian Food & Grocery Council](#) – FIGAML (Food Industry Guide to Allergen Mgmt & Labelling)
 - [Food Technology Association of Australia](#) (SME Project)
 - FSANZ & Codex consultation pieces
- ✓ International Collaborations



national allergy strategy





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For further engagement & information

- Visit the Allergen Bureau website www.allergenbureau.net
- Join us & enjoy the benefits of the Allergen Bureau membership www.allergenbureau.net/about-us/join-us/
- Subscribe to our free monthly Allergen Bureau eNews www.allergenbureau.net/news/
- Access the free Allergen Bureau Helpline
 - ✓ email: info@allergenbureau.net
 - ✓ Phone: +61 437 918 959 (International)
- Secretariat (Dr Tom Lewis & Ray Murphy)
- VITAL® Coordinator (Georgina Christensen) & Support (Lisa Warren)

