



informing the food industry

ILSI Madrid

VITAL[®] 2.0 – VITAL[®] 2.0 as a Risk Assessment and Allergen Management Tool

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Director – Sherlock Food Allergen Risk Management

Overview

- VITAL® 2.0 – a brief genesis
 - Voluntary Incidental Trace Allergen Labelling.
- How do we see VITAL applied in the industry
- Strengths and challenges of the VITAL program
- VITAL in the future



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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

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

Organisation

Our Members

<http://allergenbureau.net/about-us/our-members>

Board of Directors

Kirsten Grinter • Caroline Gray • Debbie Hawkes
David Henning • Karen Robinson

Secretariat

Dr Tom Lewis
Ray Murphy

Management Committee

Kirsten • Caroline • Debbie
Tom

Website & VITAL Online

External service providers

Operations

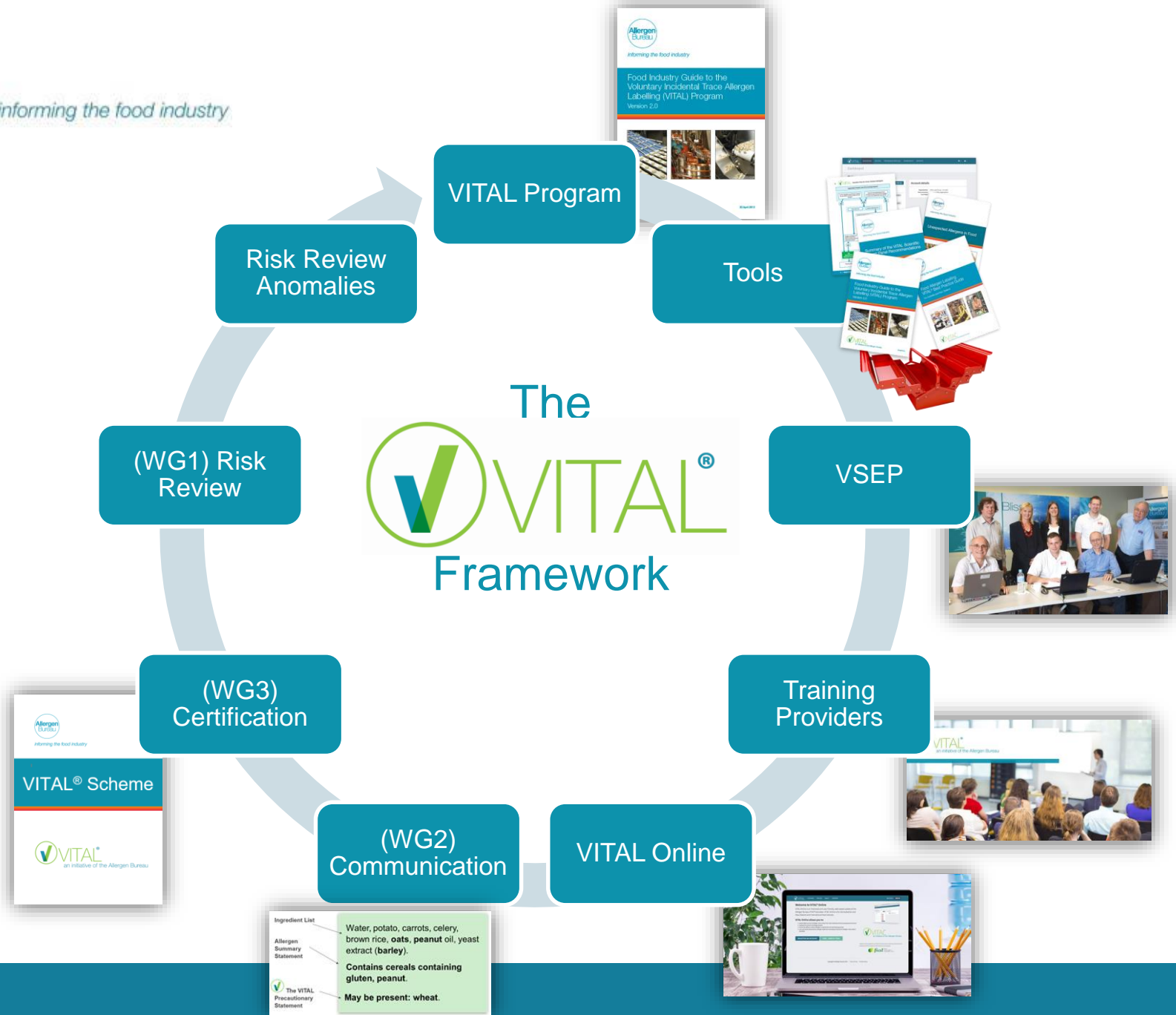
Ray

Scientific & Technical

Georgina Christensen • Lisa Warren
Dr Simon Brooke-Taylor • Robin Sherlock



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The VSEP

VITAL® Scientific Expert Panel



- **Dr Steve Taylor** (Chair of Panel) – Food Allergy Research & Resource Program (FARRP) (USA)
- **Dr Joseph Baumert**– Food Allergy Research & Resource Program (FARRP). Supported by **Mr Benjamin Remington**
- **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 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)

The VSEP overarching scientific approach

- ~ analysed existing published clinical data and some unpublished data (>1800 data points)
- ~ 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

Next VSEP meeting planned for Oct 2018,
at EAACI-FAAM, Copenhagen



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Summary of the VITAL Scientific
Expert Panel Recommendations

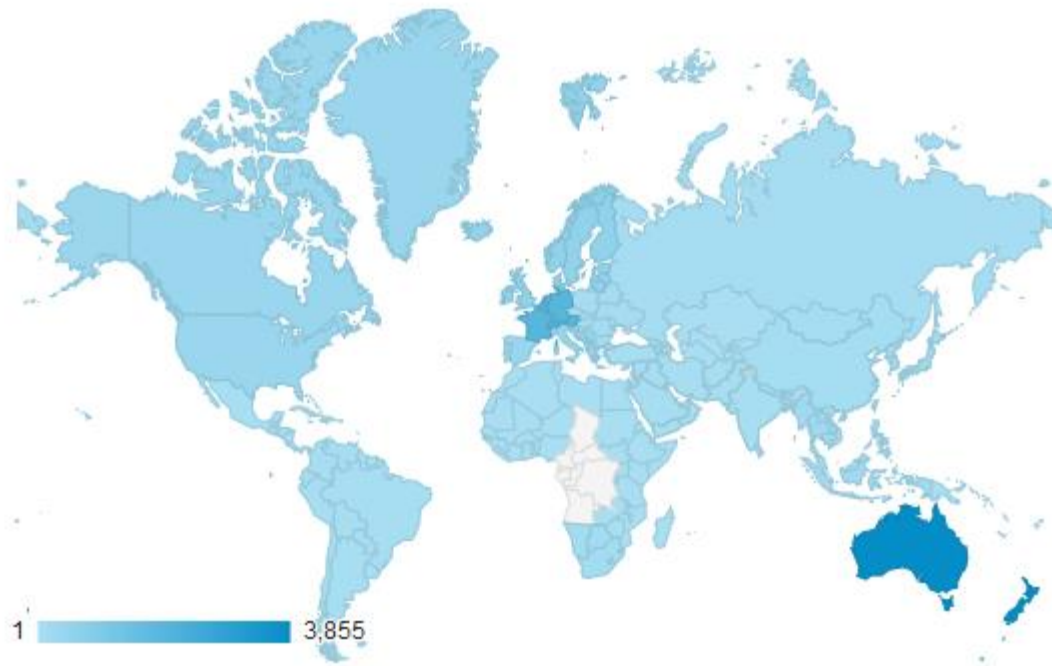


Our current successes

- Allergen Bureau membership continues to grow, comprising over 100 food industry organisations and individuals
 - ✓ 32 Full Members, 33 Associate Members and 37 Individual Members
 - ✓ International memberships increasing
- Technical support helpline for Allergen Management and VITAL® enquiries
- Excellent free resources available via website, including eNews distribution
- VITAL Best Practise Labelling Guide for ANZ
- VITAL Online continuing to increase in usage:
 - ✓ 2,090 registered organisations, equating to over 3,400 individual users, with 'active users' of VITAL Online between 340 – 540 in any month
 - ✓ Since it's launch in August 2015, users have generated over 13,000 VITAL reports, with over 8,500 ingredients, and 7,000 recipes.

Growing International Interest

Interactive VITAL Online
website sessions



The VITAL[®] Program tools

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



Reference Doses

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

* Original VITAL value applied

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

Considered in conjunction with a reference amount to provide a ppm outcome and labelling recommendation

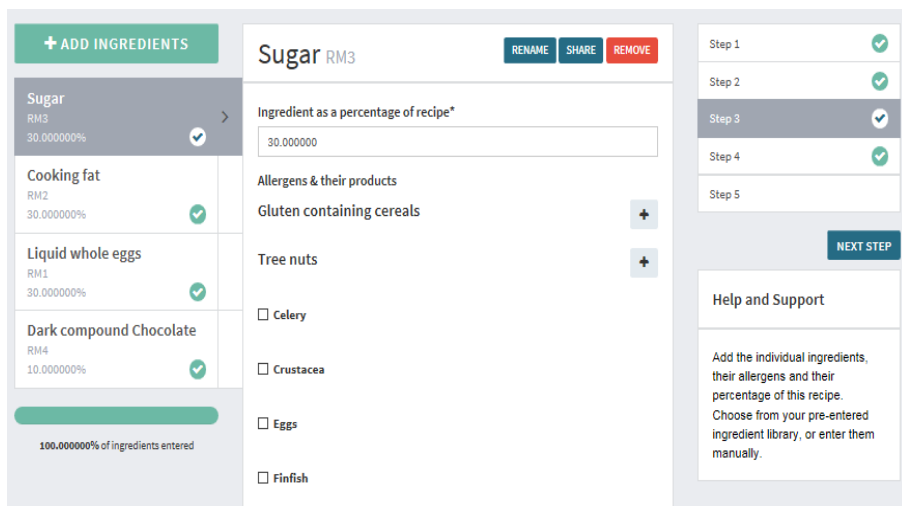
Particulate : non homogeneous and could deliver the reference dose

The 10 Steps of VITAL[®]

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>

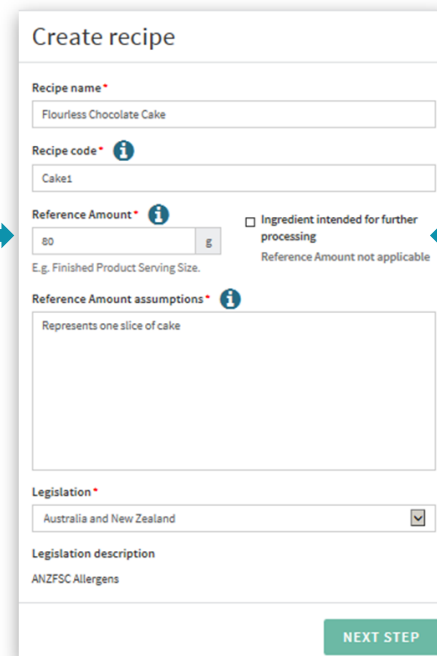
VITAL[®] Online (vital.allergenbureau.net)



The screenshot shows the VITAL Online interface. On the left, there's 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 at the bottom indicates 100.000000% of ingredients entered. In the center, the 'Sugar' ingredient is selected, showing its name, code (RM3), and buttons for RENAME, SHARE, and REMOVE. Below this, there's a field for 'Ingredient as a percentage of recipe*' with the value 30.000000. To the right, there's a section for 'Allergens & their products' with a list of allergens: Gluten containing cereals, Tree nuts, Celery, Crustacea, Eggs, and Finfish. A 'NEXT STEP' button is visible at the bottom right of the allergen section.

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 screenshot shows the 'Create recipe' form. It includes fields for 'Recipe name*' (Flourless Chocolate Cake), 'Recipe code*' (Cake1), and 'Reference Amount*' (80). There's a checkbox for 'Ingredient intended for further processing' and a note 'Reference Amount not applicable'. Below this, there's a section for 'Reference Amount assumptions*' with a text area for 'Represents one slice of cake'. At the bottom, there's a 'Legislation*' dropdown menu set to 'Australia and New Zealand' and a 'Legislation description' field with the value '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[®] Online Labelling Outcome Summary

VITAL labelling outcomes will appear like this

These Action Levels will change depending on the product's Reference Amount

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			
Finfish	0.1	< 1.25 ppm	≥ 1.25 ppm		24	
Lupin						
Milk	0.1	< 1.25 ppm	≥ 1.25 ppm		0.9	
Mustard						
Other						
Peanut	0.2	< 2.5 ppm	≥ 2.5 ppm	yes		
Sesame	0.2	< 2.5 ppm	≥ 2.5 ppm			
Shellfish/Molluscs						
Soy	1	< 12.5 ppm	≥ 12.5 ppm			
Sulphites						
Tree nuts (Total)	0.1	< 1.25 ppm	≥ 1.25 ppm			

Intentionally added

Action level 2

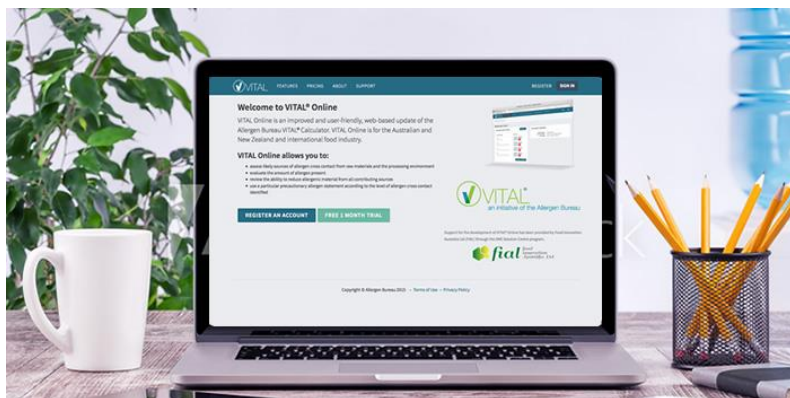
Action Level 1

Action Level 2

Intentionally added

VITAL[®] Online - Features

- ~ Libraries
 - ~ Ingredients and Processing Profiles
- ~ Documented and traceable assumptions and findings
- ~ Scenario Testing
- ~ Secure User permissions



VITAL Training - 19 endorsed Training Providers

Australia and New Zealand

North and S.E Asia

Pacific region

Africa

Europe

USA & Canada

Mexico & S. America

Virtual and Online training

Over 2,500 people trained in VITAL Version 2.0

- Australia and New Zealand – 2,150 participants
- Other countries – 350 participants



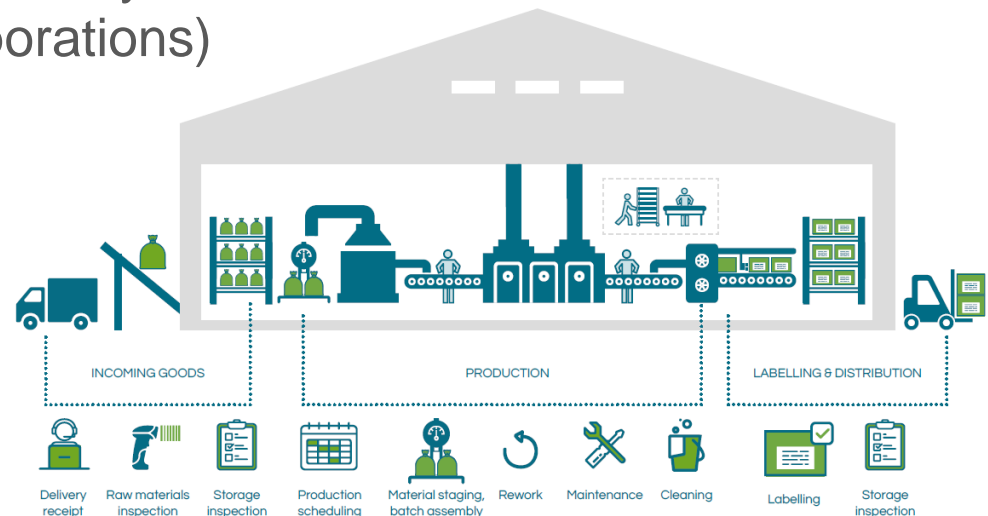
Plans and Activities – Working Groups

- **Phase 3 – Certification**
Pursuing VITAL certification
- **Phase 2 – Risk Communication**
Labelling & pursuing exemptions
- **Phase 1 – Allergen Risk Review**
Expanding & enhancing



Phase 1 - Risk Review Working Group

- ✓ Detailed guidance to investigate allergen status of a food.
- ✓ Interactive webpage accessible from the Allergen Bureau website to guide the user to do Allergen Risk Review, planned launched by Sep 2018
- ✓ Appropriate for a broad food industry audience (local, international, SME, corporations)
- ✓ Entire supply chain from farm to finished product



Risk Review Anomalies

AB & Ai Group - working together on Risk Review Anomalies

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

These anomalies occur where the process or environment cannot be altered or impacted through good manufacturing practices.

e.g. Dairy in Chocolate due to single conch

Consultation in progress with consumer groups to discuss impact of including these allergens in ingredient lists.



Phase 3 - Certification Working Group

- ✓ Completed drafting the 'VITAL Scheme' under ISO 17065
 - auditable 'VITAL Standard'; plus
 - rules and processes to be followed by accredited certification bodies (to meet ISO 17065)
- ✓ Draft VITAL Standard being trialled by industry to ensure it can be interpreted & applied consistently
- ✓ Draft Scheme to be reviewed by Certification Bodies to ensure it is practical & achievable for industry
- ✓ Seeking JAS-ANZ accreditation of VITAL Scheme in mid-late 2018



VITAL[®] 2.0 : Benefits to the allergic consumer

- ~ consistent approach to assessing cross contact
- ~ cross contact allergens are declared based upon a standardised risk assessment process
- ~ founded upon scientific principles
- ~ clear, accurate and consistent information about the allergen status of the product

Allows the consumer to trust the information

VITAL® 2.0 : Benefits to the food industry

- ~ Standardised, systematic risk assessment process
- ~ Suitable for raw materials and finished product
- ~ Labelling outcomes are based upon science
- ~ VITAL® Online - user-friendly, web-based VITAL Calculator
- ~ Supported by regulators

**Provides reassurance by virtue of
informed decision making**

Challenges

- ~ VITAL[®] Program has regulator support but is voluntary
 - ~ Allows a flexibility around response which is valuable to the industry and the consumer
- ~ Perceived cost of compliance
 - ~ Tiered approach to VITAL Online subscription; free helpline support via VITAL Coordinator, continued investment in further industry tools
- ~ International acceptance of Reference Dose (Threshold) concept
 - ~ Growing acceptance of the concept and continued science to support the approach
- ~ Global acceptance of VITAL Program

Conclusion

- ~ 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

Acknowledgements and Contact Details

Allergen Bureau

- Secretariat (Dr Tom Lewis & Ray Murphy)
- VITAL[®] Coordinator (Georgina Christensen) & Support (Lisa Warren)
- Website: www.allergenbureau.net
- FREE Helpline
 - email: info@allergenbureau.net
 - International phone: + 61 437 918 959

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