

Allergen Bureau

The VITAL Program

Food Allergy Forum 2021

PRESENTED BY:
Kirsten Grinter

Informing the
food industry



Agenda

- About Us
- Vision and Mission
- The VITAL Program
- VITAL learnings and next steps
- Allergen Management Resources



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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Our 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





The VITAL Program

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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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.

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 that incorporates relevant VSEP findings
- Scientifically robust resources



VITAL Scientific Expert Panel (VSEP)

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

Members of the VSEP

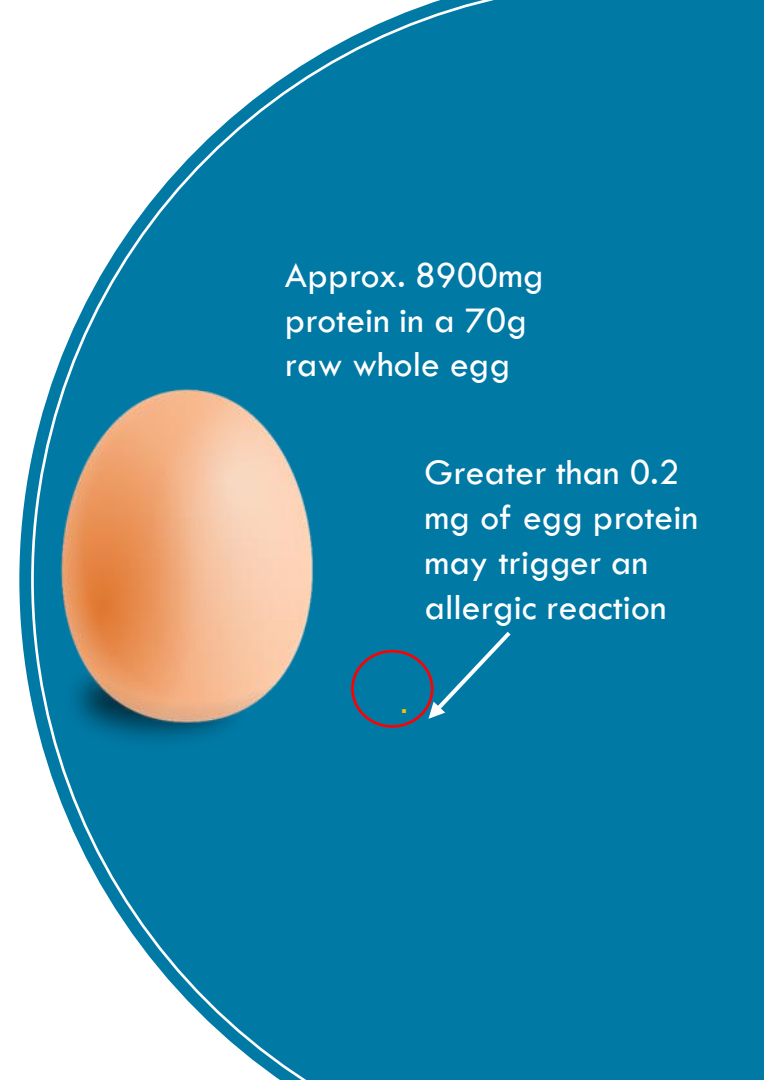
- **Dr Steve Taylor** (Chair of Panel) – Food Allergy Research & Resource Program (FARRP) (USA)
- **Dr Joseph Baumert** – Food Allergy Research & Resource Program (FARRP)
- **Dr Geert Houben** – Program Manager Food Safety, Netherlands Organisation for Applied Scientific Research (TNO) (NL)
- **Dr Rene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

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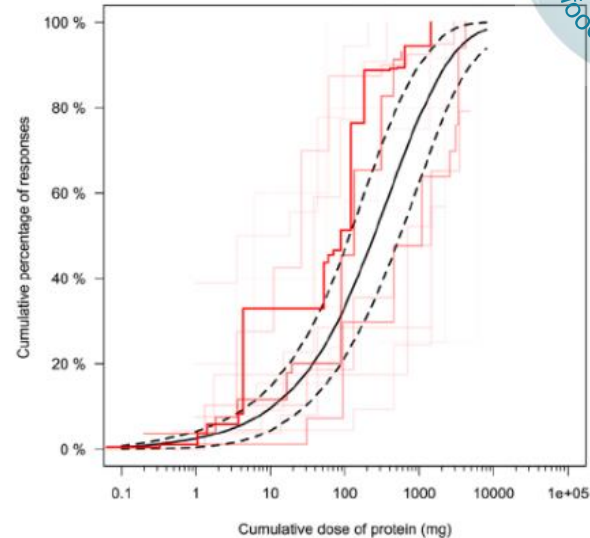
Reference Dose

- Is the milligram protein level (total protein from an allergenic food) below which only the most sensitive (1%) of individuals in the allergic population are likely to experience an adverse reaction.
- If reactions to (unlabelled) allergens do occur from exposure below the Reference Dose they will be mild and transient, requiring no emergency medical intervention.



Setting the Reference Dose

- 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
Crustaceans	25
Eggs	0.2
Fish	1.3
Milk	0.2
Peanuts	0.2
Molluscs	None set
Sesame seeds	0.1
Soybeans	0.5
Nuts (cashew, pistachio)	0.05
Nuts (walnut, pecan)	0.03
Nuts (almond, Brazil nut, hazelnut, macadamia nut, pine nut)	0.1
Celery/Celeriac	0.05
Mustard	0.05
Lupin	2.6

*Action Level transition maximum point is 20ppm

Reference Amount

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



Action Levels

Action Levels are the concentrations (of protein) which define the allergen cross contact labelling outcomes


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

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

VITAL Assessment Report (excerpt)



Table 2: Summary of VITAL Assessment for Chocolate Cake (AL4)

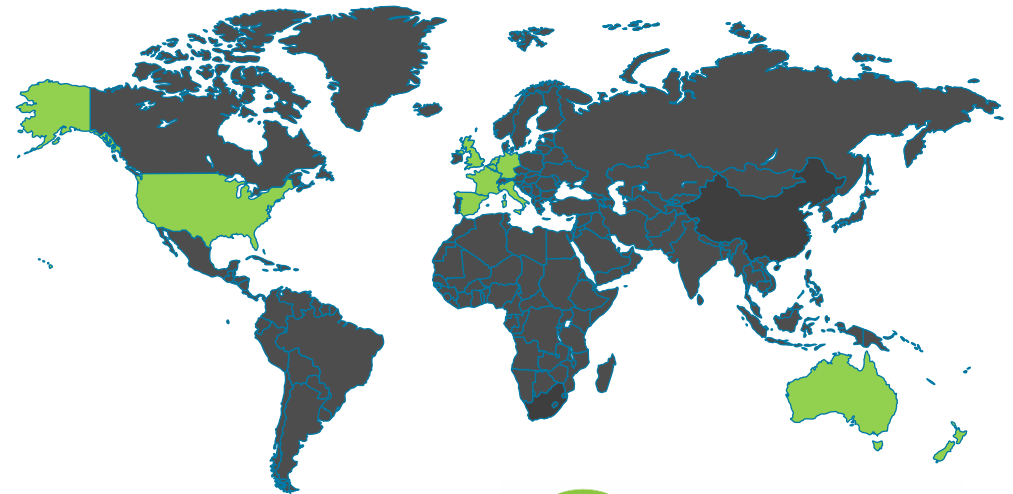
Substance	Action Level 1	Action Level 2	Intentionally Added	Particulate	Readily Dispersible	Labelling Outcome
Cereals containing gluten (Totals)	< 5.8 ppm	≥ 5.8 ppm	yes	–	–	Intentionally Added
Wheat	< 5.8 ppm	≥ 5.8 ppm	yes	–	–	Intentionally Added
Rye	< 5.8 ppm	≥ 5.8 ppm	–	–	–	–
Barley	< 5.8 ppm	≥ 5.8 ppm	–	–	–	–
Oats	< 5.8 ppm	≥ 5.8 ppm	–	–	–	–
Crustaceans	< 208 ppm	≥ 208 ppm	–	–	–	–
Eggs	< 1.7 ppm	≥ 1.7 ppm	yes	–	–	Intentionally Added
Fish	< 11 ppm	≥ 11 ppm	–	–	–	–
Peanuts	< 1.7 ppm	≥ 1.7 ppm	–	yes	–	Action Level 2
Soybeans	< 4.2 ppm	≥ 4.2 ppm	–	–	1.000000 ppm	Action Level 1
Milk	< 1.7 ppm	≥ 1.7 ppm	yes	–	–	Intentionally Added

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



VITAL Learnings



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Learning #1 – Implementation Challenges, why?

- What are the hurdles to significant industry uptake?
- Do companies see implementation of the VITAL Program as optional because of no official endorsement?
 - Endorsement or regulation would challenge rapid response to science processes
- The VITAL Program is considered Best Practice
 - Required by some retail organizations
 - Provides a scientific basis for labelling decisions
 - Makes complex process accessible for SMEs



Learning #2 - Consumption Data Standardisation

- Currently manufacturers make their own decisions nominating a Reference Amount for the purposes of determining an Action Level
- This is not consistent across each food business
- Standardised consumption data will enable another level of robustness for the VITAL program
- This is strong focus for the future



Learning #3 - Which Eliciting Dose (ED01 or ED05)?

- The underpinning science of the VITAL Program uses Reference Doses (ED01)
- Support amongst FAO/WHO Expert Consultation for thresholds to be based on ED05
- We need to understand the Stakeholder views – Industry, Government, Consumer, Clinicians
- How will industry react to a change from ED01 to ED05? We need to unpack this carefully



Learning #4 – PAL, the Consumers' 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



Learning #4 – PAL, 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 adequately
- Key to PAL being effective is robust allergen management risk assessment processes and inputs



Learning #5 PAL – 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?



The VITAL Program

- The VITAL Program has been industry best practice for the assessment of cross contact allergens for more than a decade
- The VITAL is underpinned by science
- The VITAL Program is voluntary – so the results of an assessment can be aligned with company policy
- The VITAL Program provides an approach that is accessible for companies

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Have you used VITAL?

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



vital.allergenbureau.net



The VITAL Program

- Has grown and responded to changing science around allergy and food science
- The Allergen Bureau IS the food industry – it exists to serve the needs of the food industry with the allergic consumer at its heart
- Poised for further growth and remains flexible to respond to allergen management gaps or challenges



VITAL Resources



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VITAL Online

The VITAL Online is a web-based calculator to help with the implementation of the VITAL Program

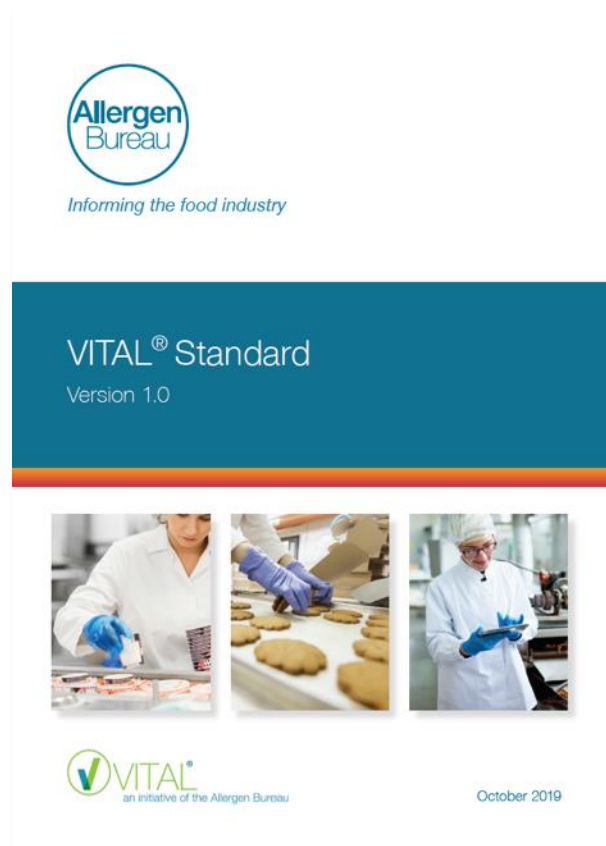
Free trial available!



vital.allergenbureau.net

The VITAL Standard

- Voluntary
- Consumer visibility
- Cost effective
- Internationally recognised
- Robust
- Product specific
- Auditable
- Current status – awaiting industry uptake!



In summary...

- The VITAL Program & other tools continue to be the best practice available for the assessment of cross contact allergens
- VITAL is based on scientific threshold data
- The VITAL Program continues to be flexible and adapt to the needs of the food industry globally
- Collaboration with key stakeholders has been instrumental part of our AB strategy and will continue to ensure our relevance into the future





For the Food
Industry

Free resources on our new website

We have recently launched a new and improved
corporate website

allergembureau.net

and a new platform for VITAL[®] Online

Vital. allergembureau.net

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THANK YOU

Don't forget to tell your ideas about this presentation and share it with us!

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