

# Allergen Bureau

## FACTS & Allergen Bureau Joint Webinar **What is the VITAL Program?**

### **PRESENTED BY:**

Jasmine Lacis-Lee – Allergen Bureau President

2<sup>nd</sup> August 2022



Informing the  
food industry

# Agenda

- About Us
- The VITAL Program
  - The science
  - The benefits
  - Where it fits in AMP
- Best Practice Quantitative Risk Assessment
- Codex and VITAL
- Allergen Bureau Resources

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# Food Allergen Management Guidance

*For industry, by industry*

The Allergen Bureau is the peak industry body representing best practice food industry allergen management globally.

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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

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# Allergen Bureau

## 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.







# Accurate & Consistent Allergen Declaration

- Allergen labelling is the key method to inform a consumer of the allergen status of a product
- Appropriate allergen declaration can:
  - help allergenic consumers choose foods which do not present a personal health risk
  - positively affect a consumer's relationship with a brand
  - avoid additional compliance costs
  - avoid allergen-related product recalls & other costs

## POLL QUESTION 1

- a) Have you heard of the Allergen Bureau VITAL program?
- b) Have you implemented the VITAL Program
- c) Do you use the VITAL online tool?

# Why was the VITAL<sup>®</sup> Program Developed?

- to provide a consistent method to **assess** and **declare** allergens which are not intentionally formulated into a product
- to address the needs of and protect allergic consumers
- to respond to a regulatory background where there are no regulations for assessing or declaring cross contact allergens
- to support regulatory environments where PAL is legislated, provides guidance on risk assessment and labelling outcomes
- global harmonized thresholds for cross contact allergens & best practice approach for cross contact allergen risk assessment





# The VITAL<sup>®</sup> Program in Australia and New Zealand

- Adopted by food business operators on a **voluntary** basis – widely used in Australia & New Zealand
- The VITAL Program is well-known in Australia and New Zealand & acknowledged by regulatory and enforcement agencies for role as a voluntary industry guide
- Supported by the Product Information Form (PIF) – an industry-agreed questionnaire. The PIF is almost exclusively used in Australia as the source of information for legal and regulatory compliance for food products.

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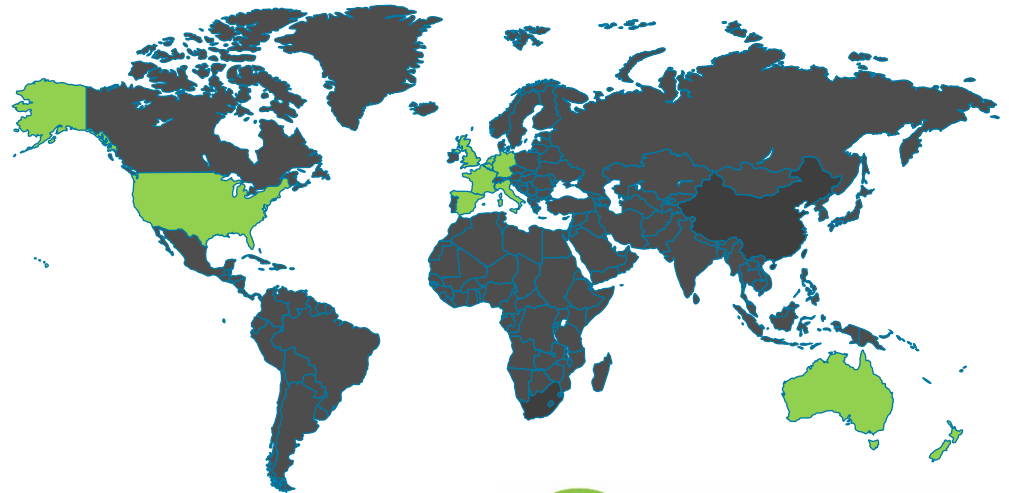


# Growing International Interest

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



# Three Core Concepts the Food Industry Must Know

1. Allergen Risk Review
2. Allergen Management
3. Allergen Risk Assessment

The food industry uses this knowledge to identify and manage allergens within their facilities and to determine if cross contact allergens are to be declared.



# Allergen Risk Review

*The process of thoroughly investigating the allergen status of food.*

This begins with raw materials and continues throughout the manufacturing process until the food is packed and labelled.

The information collected in an allergen risk review can be used to inform both:

- an allergen management program
- a risk assessment



# Allergen Risk Review Website

- The Allergen Risk Review Website (ARRW) is a freely available interactive factory map designed to assist the food industry with understanding the allergen status of its products.
- Includes 15 different areas which can impact on the status of a food.
- Here you can find detailed information about assessing allergen risk at every stage of the process to make food.
- Can help inform your own allergen control plan.

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Easy  
Step-by-step  
Industry  
Guidance

*[info.allergenbureau.net](http://info.allergenbureau.net)*



# A Physical Risk Review is Key

- Assemble a cross-functional team
- Consider all areas of the production line / facility
- Perform a physical audit by inspecting the processing equipment
- Identify hang up points and other cross contact points
- Consider the form of the cross contact (readily dispersible or particulate)
- Quantify any cross contact that is present





# Allergen Management

- The procedures, policies and practices put in place to manage allergens
- Allergen management is a fundamental element of a food safety plan and Good Manufacturing Practice (GMP)
- Use a HACCP plan with allergens included as an independent category of food hazard
- Include the “life-cycle” of the product from raw materials, every step of production, and labelling & packing
- Establish systems to prevent unintentional cross contact for allergens to other products



## POLL QUESTION 2

**a) Have you identified any allergen CCPs?**

# HACCP Based Food Safety Program Adapted for Allergen Control

- applying classical tools of HACCP does not fit for allergens and requires adaption
- document allergens in HACCP plans
- **identify allergen CCPs**, develop and implement allergen control plans
- all allergens requiring mandatory declaration are classified as high risk
- Allergen controls are required in the prerequisite programs
- audit and update periodically



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# Transferring the Risk Assessment to Label - The VITAL Program

- Your due diligence - understanding the risk of cross contact allergens from ingredients and the manufacturing process
- Your commitment to consumers
- Your commitment to consistent risk review and allergen labelling across industry

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# Risk Assessment

*The scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards (Codex).*

A risk assessment for allergen cross contact should determine whether the cross contact is present in a food at levels that may trigger an allergic response.

Conducting a VITAL<sup>®</sup> risk assessment using the VITAL Program principles is an example of a science-based risk assessment for allergen cross contact.

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# Allergen Management & Labelling



## 1. ALLERGEN MANAGEMENT

The procedures, policies and practices put in place to manage allergens



## 2. ALLERGEN RISK REVIEW

Thorough investigation of the allergen status of a food including cross contact.



## 3. ALLERGEN COMMUNICATION

Forming an ingredient list.





# The VITAL<sup>®</sup> Program

# What is the VITAL<sup>®</sup> Program?

The VITAL<sup>®</sup> 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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# VITAL<sup>®</sup> 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.







The VITAL<sup>®</sup> 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.**

# What do you Need to Implement the VITAL<sup>®</sup> Program?

An Allergen Management Plan includes the procedures, policies and practices contributing to the control of allergens within a food business.



A robust allergen management plan is a pre-requisite before considering implementing the VITAL Program

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*Allergen  
Management  
Plan*



# The 10 Steps of VITAL<sup>®</sup>

## *'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 and 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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Consider VITAL as a  
systematic allergen  
risk assessment tool.  
It is not just about  
cross contact!





# Key Components of the VITAL<sup>®</sup> Program

- Cross Contact Allergens
- Reference Dose
- Reference Amount
- Action Levels
- Precautionary Allergen Labelling (PAL)

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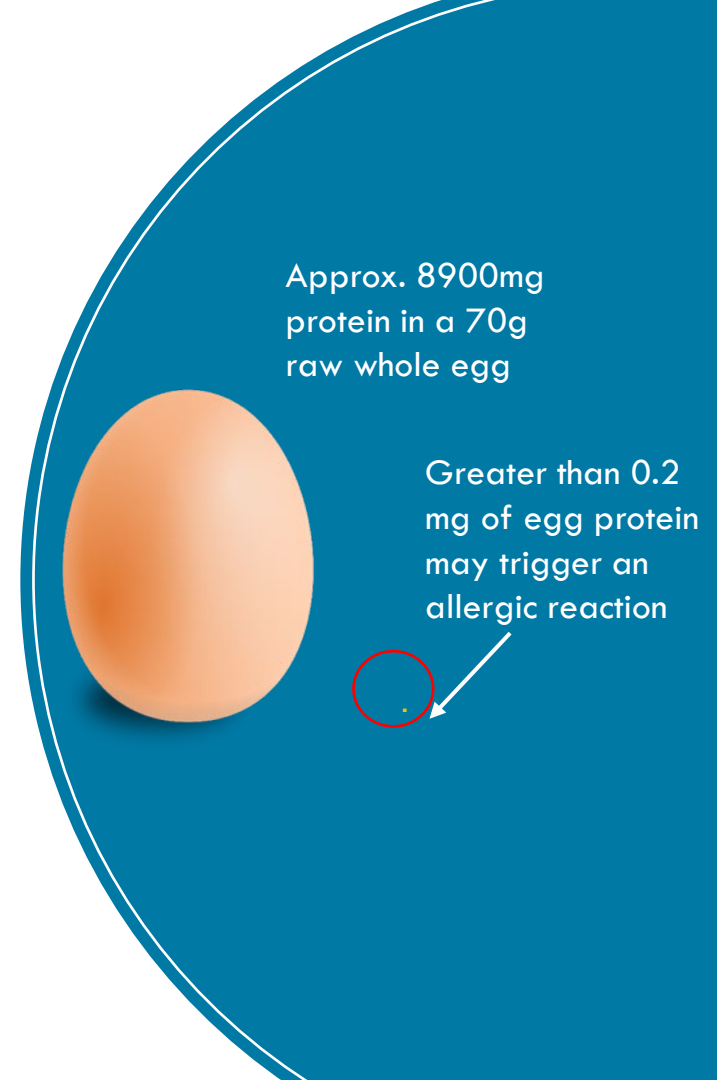


# Cross Contact Allergens

- Residues or other trace amount of an allergenic food **unintentionally** incorporated into another food that is not intended to contain that allergen
- May be present despite Good Manufacturing Practice
- Can enter a product at any point of the supply chain (harvesting, handling, storage, production, etc.)
- In the VITAL Program, it is necessary to control and manage **all** cross-contact allergens to the lowest practicable level

# 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.



# The VSEP Today

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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# 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 and decision-making process that incorporates relevant VSEP findings
- Scientifically robust resources
- VITAL and Codex – more on this soon



## POLL QUESTION 3

- a) Choose the allergen that you think someone would need to eat the least of to have a reaction



# VITAL 3.0 Reference Doses

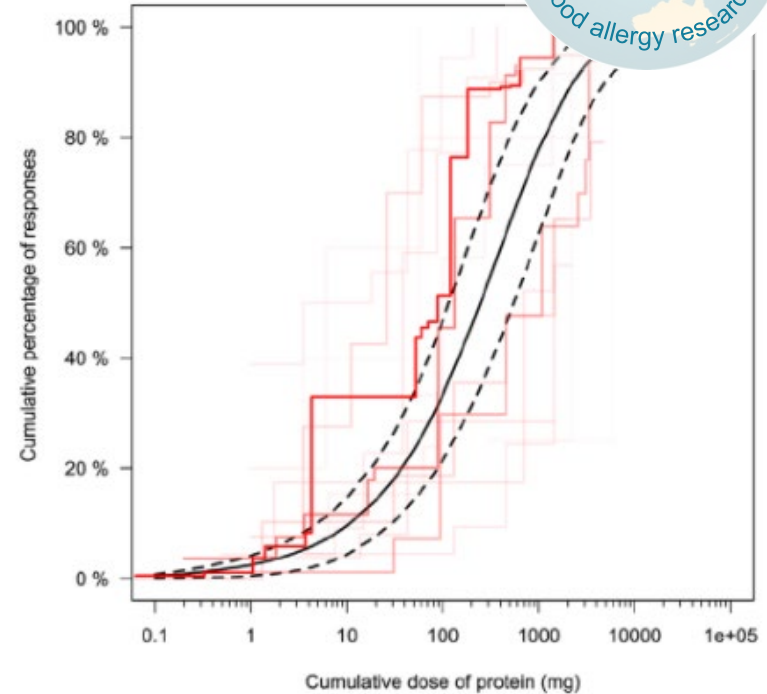
Food	Reference Dose (mg)
Cereal containing gluten* (barley, oats, rye, wheat)	0.7
Crustacea	25
Egg	0.2
Fish	1.3
Milk	0.2
Peanut	0.2
Molluscs	None set
Sesame	0.1
Soy	0.5
Tree nuts (cashew, pistachio)	0.05
Tree nuts (walnut, pecan)	0.03
Tree nuts (almond, Brazil nut, hazelnut, macadamia nut, pine nut)	0.1

\*Action Level transition maximum point is 20ppm

# The VSEP Expertise

- 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

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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.

# Validating the Reference Doses

- participants ate 1.5mg peanut protein = 6mg whole peanut = 1/100<sup>th</sup> of a peanut kernel = ED05
- Reference Dose for peanut in the VITAL<sup>®</sup> Program is 0.2 mg

So, in this study, the peanut-allergic participants were fed an amount of peanut protein that is more than 7 times greater than the Reference Dose

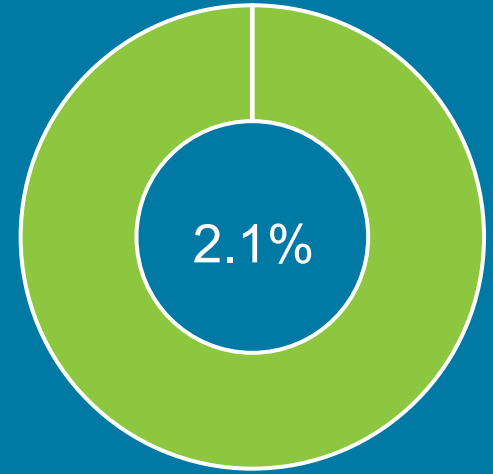


378 people aged  
1-18yrs participated

# Validating the Reference Doses

- 8 (2.1%) people met the criteria of an objective and likely allergic reaction. (The reactions were mild.) This is less than the predicted 5%
- These results suggest that the use of 0.2mg peanut protein in the VITAL<sup>®</sup> Program is conservative
- Studies repeating this experiment & validation studies for other allergens are planned & are helpful to support the VITAL<sup>®</sup> Program

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8

people met the criteria of  
an objective and likely  
allergic reaction.

# 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



# Thresholds in the VITAL Program

## Action Level 1

low concentration of the relevant allergen under evaluation, low chance of adverse reaction

**no PAL statement is required**

## Action Level 2

significant concentration of the relevant allergen under evaluation, significant chance of adverse reaction

**PAL statement is required**

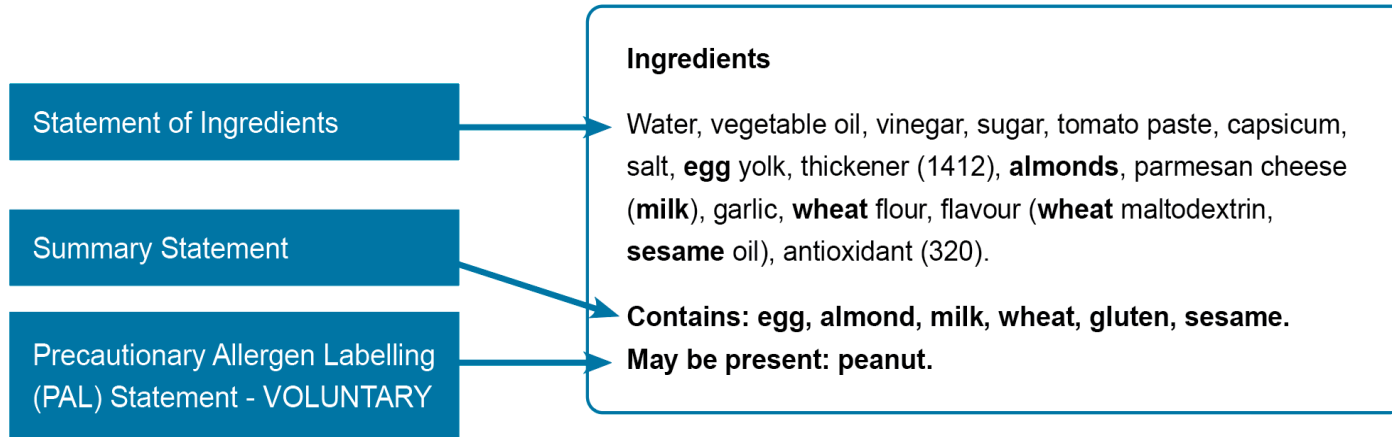
# VITAL<sup>®</sup> Assessment Report (excerpt)



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

# Recommended Labelling Format



“May be present: allergen x, allergen y.” is recommend in conjunction with the VITAL Program

- Incorporates mandatory requirements
- Additional guidance for consistency for how to set out an allergen declaration



## Key Take Home Message When Competing the VITAL<sup>®</sup> Risk Assessment

1. When done well, it decreases your business risk
2. Philosophy: IDENTIFY, ELIMINATE, REDUCE, MANAGE, COMMUNICATE
3. Decreased and well managed risk = less PAL statements
4. Key: Businesses must managed allergen cross contact at the VITAL outcome, scope creep is not acceptable when PAL statements have been identified as required

# The VITAL<sup>®</sup> Program

- The VITAL Program has been industry best practice for the assessment of cross contact allergens since 2007
- 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](http://vital.allergenbureau.net)



# The VITAL<sup>®</sup> 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

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# CODEX - GSLPF

- Many countries adopt fully or partially CODEX – General Standard for the Labelling of Pre-packaged Foods (GSLPF) – [CODEX STAN 1-1985 rev 2018]
- Since 1999, GSLPF has included the list of 8 major Foods known to cause IgE-mediated food allergy.
- Questions were raised by Codex Committees on Food Labelling (CCFL) and on Food Hygiene (CCFH)
- **Ad Hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens** started work in Dec 2020
- All 6 Vital Scientific Expert Panel (VSEP) members were invited to join this Expert consultation, and also included other regular FAMS speakers.



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization



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# Ad Hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens Aims

1. Validating and updating the list of foods and ingredients in the GSLPF based on risk assessment;
2. Establishing threshold levels in foods of the priority allergens;
3. Evaluating the evidence in support of precautionary labelling.

## ***Part 1:***

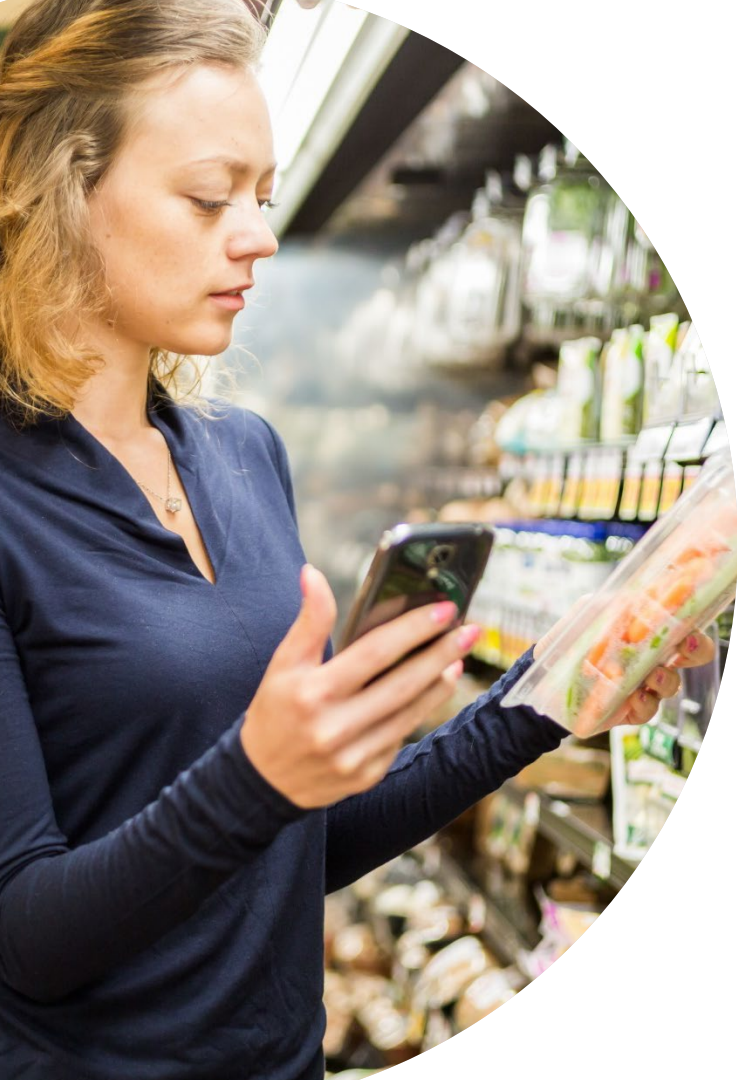
# **Review and validation of Codex priority Allergen list through risk assessment**

Are the criteria for assessing additions and exclusions still current and appropriate?

And therefore:

- Are there foods that should be added or deleted from the list?
- Clarification of allergen groupings?
- Can certain foods, such as highly refined foods, be exempted from mandatory declaration?






## ***Part 1:*** **Review and validation of Codex priority Allergen list through risk assessment**

Evaluated “The Big 8” and other food allergens based on 3 criteria:

- ✓ community prevalence
- ✓ severity (objective reactions to a food/ingredient such as anaphylaxis)
- ✓ potency of food/ingredient  
(amount of the food/ingredient required to cause objective symptoms).

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# Part 1: Recommendations

- Recommended global priority allergens should be limited to:
  - ✓ Cereals containing gluten (i.e., wheat & other Triticum species, rye & other Secale species, barley & other Hordeum species & their hybridized strains),
  - ✓ Crustacea
  - ✓ Eggs
  - ✓ Fish
  - ✓ Milk
  - ✓ Peanuts
  - ✓ Sesame
  - ✓ Specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).
- Recommended that some allergens such as: buckwheat, oats, celery, lupin, mustard, soybeans and Brazil nuts, macadamia and pine nuts **should not** be included in the CODEX listing, but instead included as required in individual countries
-  Watch list for CODEX: pulses, insects, kiwi fruit...







## ***Part 2:*** **Review & Establish Threshold Levels in Foods of Priority Allergens for Use in PAL**

1. What are the threshold levels for the priority allergens below which the majority of allergic consumers would not suffer an adverse reaction?
2. For the priority allergens, what are appropriate analytical methods for testing food and surfaces?
3. What should be the minimum performance criteria for these different analytical methods?





## **Part 2:** **Review & Establish Threshold Levels in Foods of Priority Allergens for Use in PAL**

Four approaches were considered:

1. Analytical-based –  
*similar to approach currently in Switzerland & Japan*
2. No Observed Adverse Effect Level [NOAEL] +  
Uncertainty Factor [UF] – *VITAL 1*
3. Benchmark Dose combined or not with the application of a  
Margin of Exposure - *VITAL 2.0 & 3.0*
4. Probabilistic Hazard Assessment –  
*option 3 with a probabilistic modelling overlay*



## Part 2: Recommendations

- ✓ Based around a Reference Dose (RfD) approach similar to VITAL 2.0
- ✓ Use Eliciting Dose ED05.  
(Up to 5% of reactions at both ED01 & ED05 could be classed as anaphylaxis, but none were severe.)
- ✓ Simplify RfD by rounding ED05 down to 1 significant figure.
- ✓ Analytical results to be standardised as mg total protein of allergenic food per kg of food.

## Part 2: Recommendations – VITAL 3.0 vs ED05

	RfD Recommendation (mg total protein from the allergenic Source)	VITAL 3.0 ED01	2019 VSEP ED05 (mg protein)
Walnut (and Pecan*)	1.0	0.03	0.8
Cashew (and Pistachio*)	1.0	0.05	0.8
Almond (**)	1.0	0.1	
Peanut	2.0	0.2	2.1
Egg	2.0	0.2	2.3
Milk	2.0	0.2	2.4
Sesame	2.0	0.1	2.7
Hazelnut	3.0	0.1	3.5
Wheat	5.0	0.7	6.1
Fish	5.0	1.3	12.1
Shrimp	2.0	25	280

## ***Part 3:***

# **Review and Establish Precautionary Labelling in Foods of the Priority Allergens**

1. What methods to determine whether allergen cross-contact is reasonably likely to occur after cleaning, & the level of cross-contact?
2. Guidance for using PAL, based on the use of scientifically based threshold levels
3. How can thresholds be used by FBOs to determine:
  - the extent cleaning removes an allergen to minimise risk to allergic consumers;
  - whether an ingredient that contains a low-level allergen (e.g. an ingredient with a PAL) warrants control of its use to prevent cross-contact





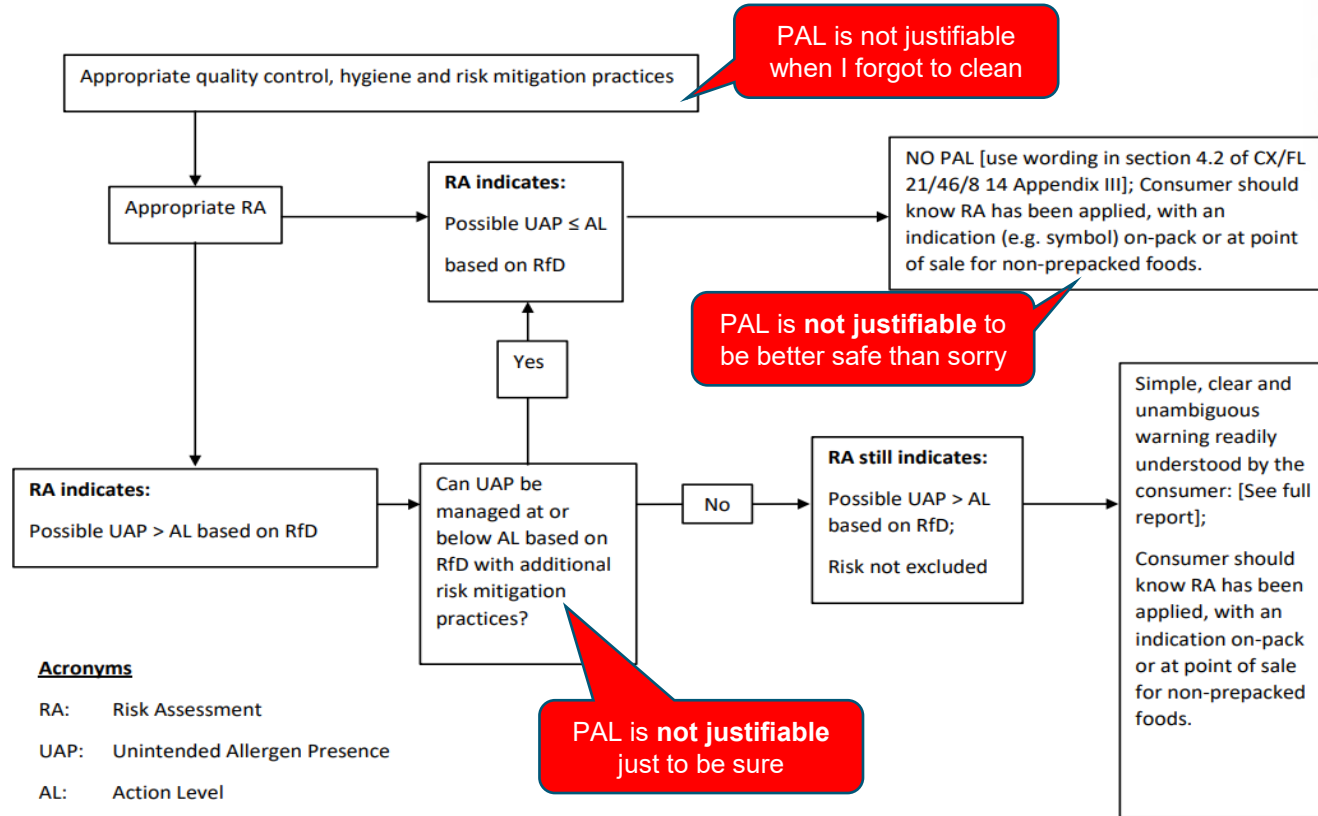
## Part 3: Recommendations



- PAL only when Unintended Allergen Presence (UAP), cannot be prevented and exceeds RfD
- Provide label indication (e.g. using a symbol) that a qualified RA has been done, irrespective of RA outcome
- If RfD not established for a particular priority allergenic food, an estimated RfD can be used
- Compliance with existing Codex codes of practice, good allergen management are a prerequisite, to ensure that the level and frequency of UAP is minimized
- PAL to the consumer should be simple, clear, unambiguous and not false or misleading, with use of a single unified and harmonized wording, and thus “**is not suitable**” for them.
- Education of allergic consumers and other relevant stakeholders is critical, to ensure understanding of the applied principles and the implications of the chosen phraseology



# Part 3: Recommendations



## Acronyms

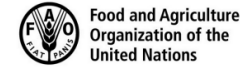
RA:	Risk Assessment
UAP:	Unintended Allergen Presence
AL:	Action Level
RfD:	Reference Dose



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# Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens



Part 1: Review and validation of Codex priority allergen list through risk assessment

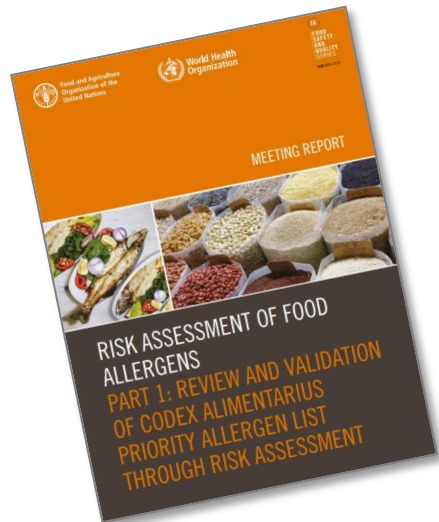
(Nov 20 – Feb 21)

Part 2: Review and establish threshold levels in foods of the priority allergens

(Mar 21 – Apr 21)

Part 3: Review and establish precautionary labelling in foods of the priority allergens

(Oct 21 – Nov 21)



- Achieved consensus on recommended revision to global priority allergens
- Established threshold levels (ED05) for these priority allergens and reviewed available analytical capabilities for the monitoring of food allergens.
- To be effective, PAL should only be used when the level of Unintended Allergen Presence (UAP), demonstrated through risk assessment, exceeds established risk-based threshold values for a particular food allergen

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# What's on the Horizon for the Allergen Bureau Resources?

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# Reference Doses

- ED01 or ED05?
- Stakeholder discussions needed
- Reference doses and the consumer impact

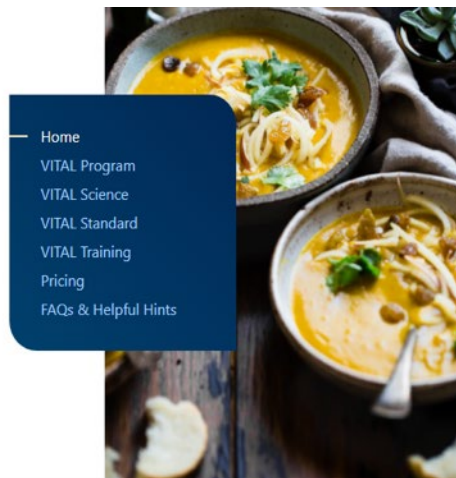
# Industry and Consumer Education

- VITAL program = best practice
- Implementation = future ready
- Label communication
- Applicable to food service, not just manufacturing

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# Consumption Data May Inform Reference Amounts

- Food Category Consumption data rather than nominated Reference Amounts?
- Another level of consistency and robustness
- Collaboration on this work has commenced

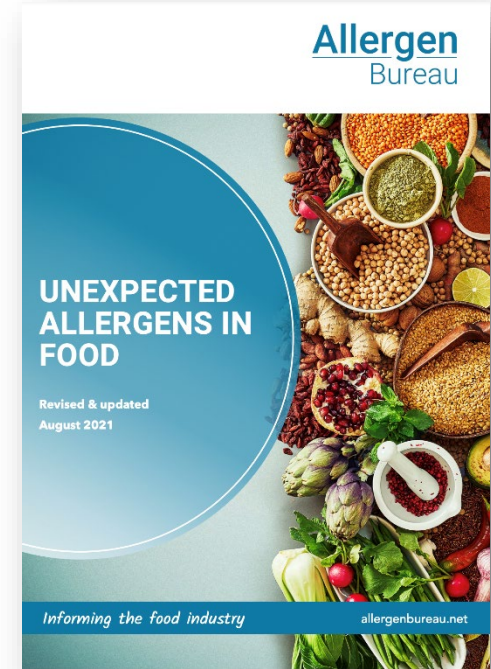


## Voluntary Incidental Trace Allergen Labelling

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

# Unexpected Allergens in Food & Agricultural Co Mingling

- This document is published and freely available on our website
- New version launching August 2022
- Includes risk assessment, sampling and testing guidance
- Ongoing collaboration and working in partnership is pivotal – Become an Allergen Bureau member



# The VITAL<sup>®</sup> Standard

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



# Our Resources



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For the Food  
Industry

## Free Resources Available on our Website

We have recently launched a new and improved corporate  
website

**[allergenbureau.net](http://allergenbureau.net)**

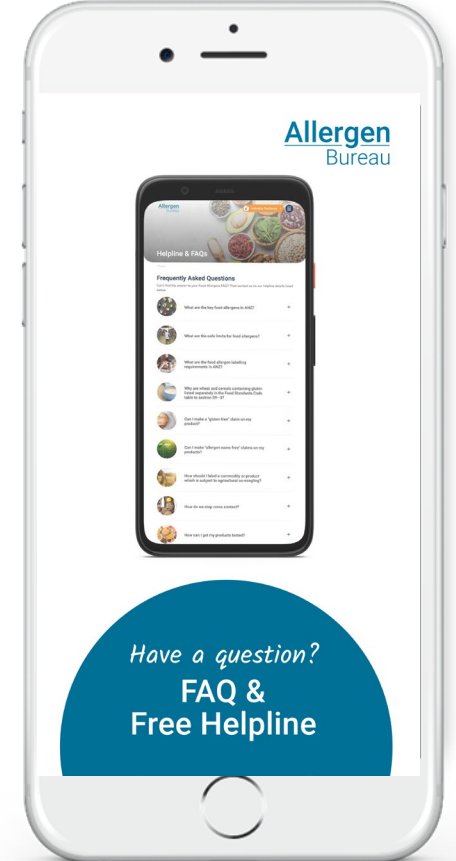
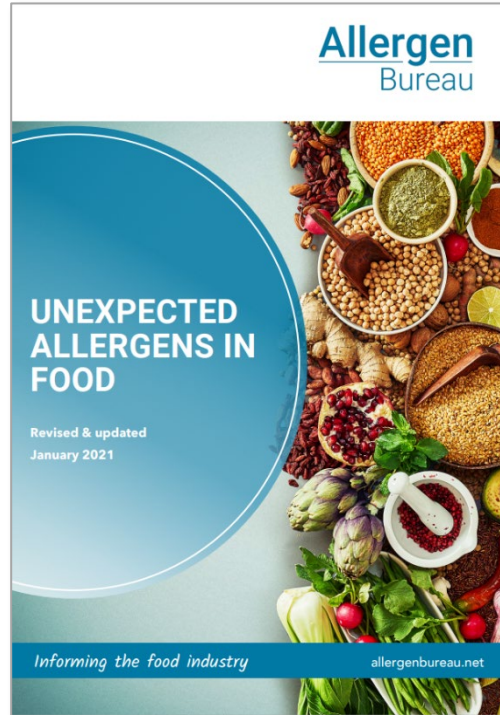
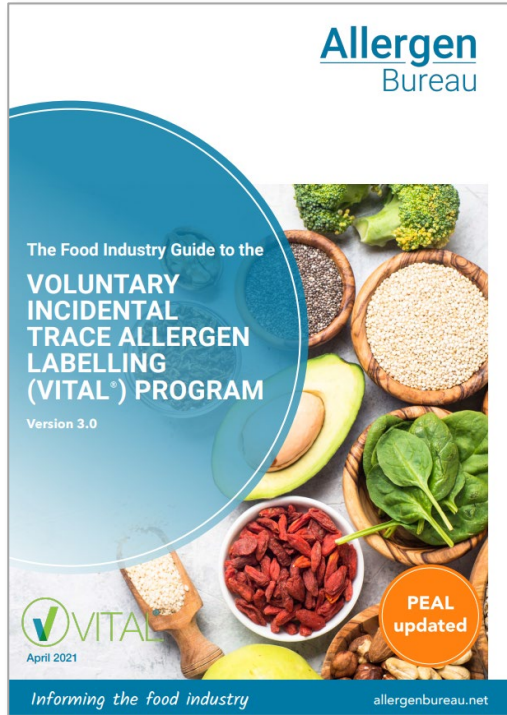
and a new platform for VITAL® Online

**[Vital. allergenbureau.net](http://Vital.allergenbureau.net)**

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# Industry Guidance

Access via the Allergen Bureau website > [Resources](#)



## In Summary...

- The VITAL<sup>®</sup> Program & other tools continue to be the best practice available for the assessment of cross contact allergens
- VITAL<sup>®</sup> is based on scientific threshold data
- The VITAL<sup>®</sup> 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



# THANK YOU

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

CONTACT US:



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