

Allergen Bureau

Informing the
food industry

The VITAL Program

Finnish Society of Food Sciences

PRESENTED BY:
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Agenda

- About Us
- Vision and Mission
- The VITAL Program
- Ongoing Development
- 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

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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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Australia & New Zealand Have High Rates of Food Allergy

Rapid increase in food allergic disease in last 30 years in mainly Western countries

Food allergy affects*

- 10 % infants (up to 12 months old)
- 4 - 8% children (up to 5 years)
- 2 % adults (approx.)

*ASCIA www.allergy.org.au

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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

Why was the VITAL 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
- global harmonized thresholds for cross contact allergens & best practice approach for cross contact allergen risk assessment



The VITAL 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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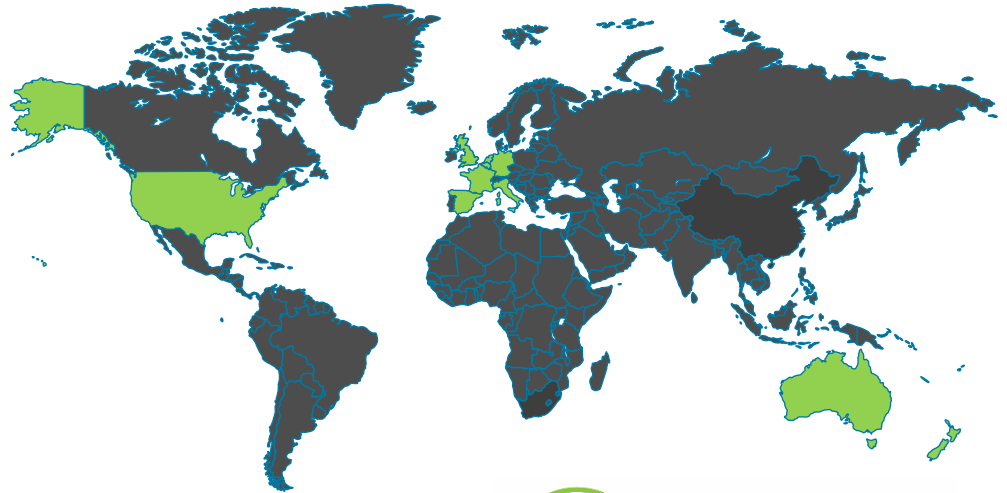


Growing International Interest

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





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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VITAL 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 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 Program?

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

ALLERGEN MANAGEMENT PLAN



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

Key Components of the Vital Program

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



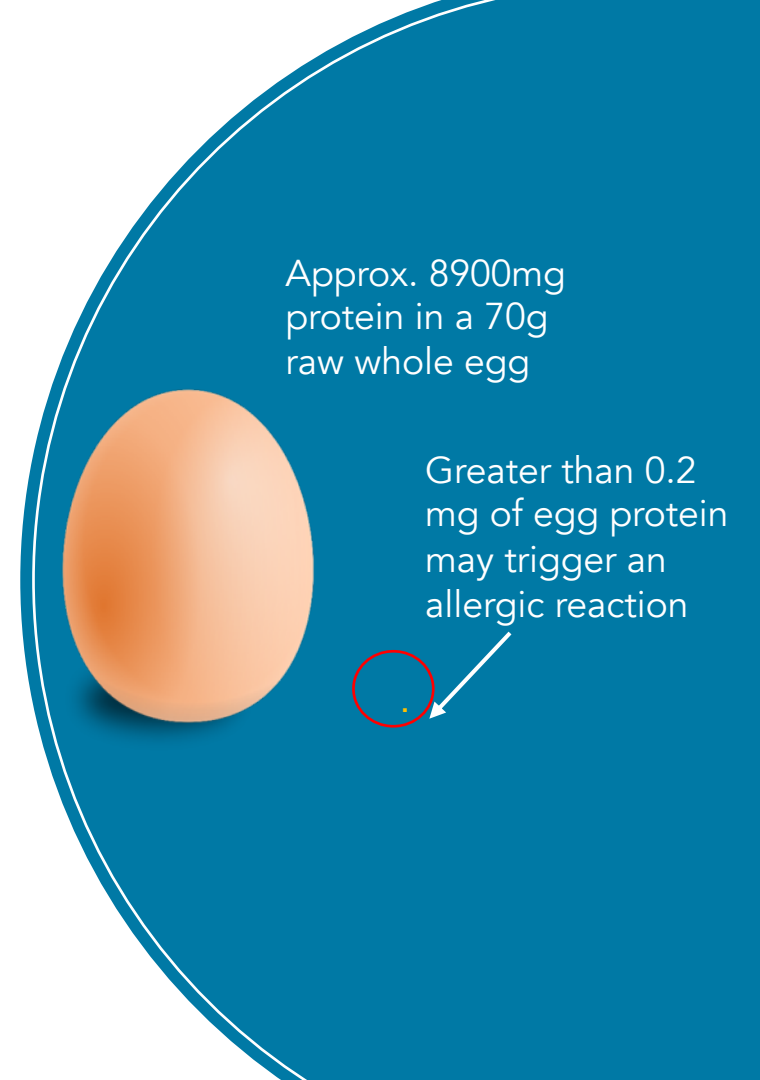


Cross Contact Allergens

- 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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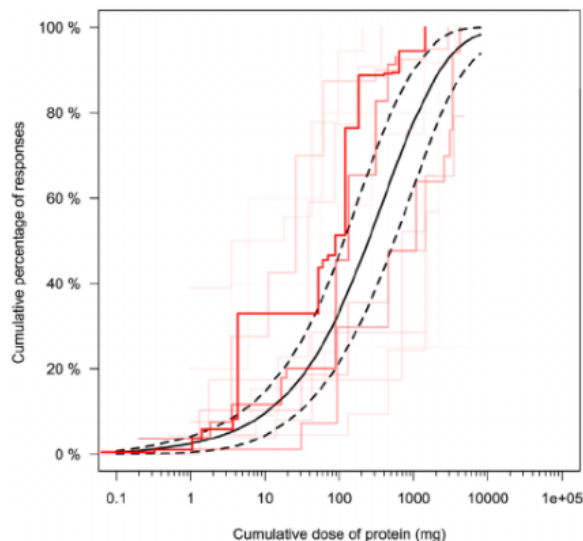
Evidence based science

- 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



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



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
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)	0.2

*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



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

Calculating Action Level: for a product with peanut cross contact

Peanut Reference Dose = 0.2 mg protein

5g Reference Amount or
Serving Size:

(Transition = $0.2 \times 1000/5$
= 40ppm)

Action Level 1: <40ppm

Action Level 2: ≥ 40 ppm

50g Reference Amount or
Serving Size:

(Transition = $0.2 \times 1000/50$
= 4ppm)

Action Level 1 : <4ppm

Action Level 2 : ≥ 4 ppm



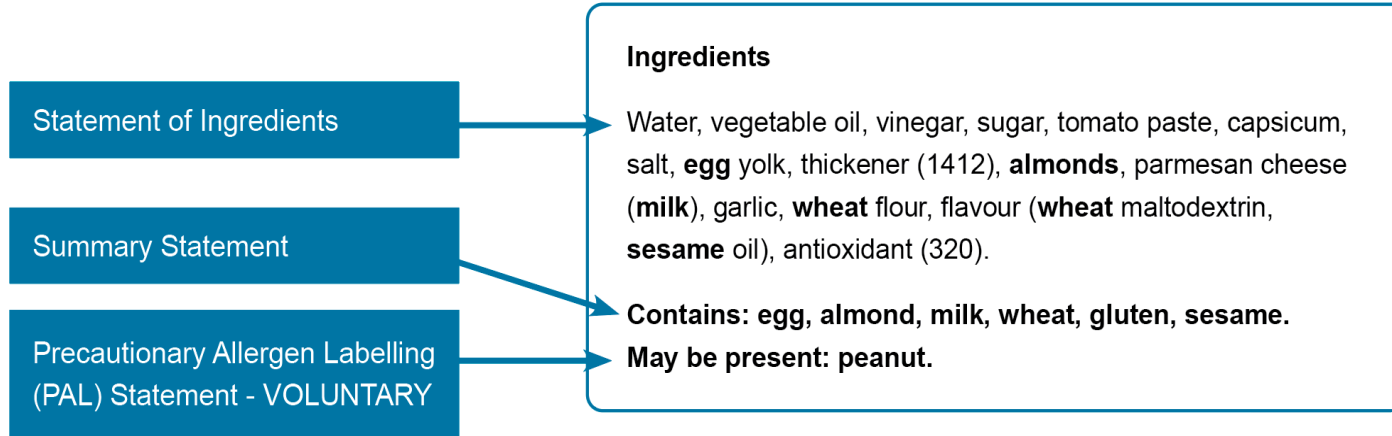
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Precautionary Allergen Labelling (PAL)

- To declare the possible presence of cross contact (a residue or an amount of a food allergen that is unintentionally incorporated into another food)
- Voluntary
- Important to help consumers know what food is safe for them to eat
- Most helpful when applied consistently across industry
- May be present: allergen x, allergen y.

May contain ...	May contain traces of ...	Packed in an environment where ... may be present	Made in a facility that also processes ...
Produced in a factory which handles ...	Produced on shared equipment that also processes	Made on the same production line as...	Made in a production area that also uses...
No nuts in ingredients, but cannot guarantee to be nut-free	Not suitable for ... allergy sufferers	Due to methods used in the manufacture of this product, it may occasionally contain ...	May be present: ...

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

Ongoing Development

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Reference Doses

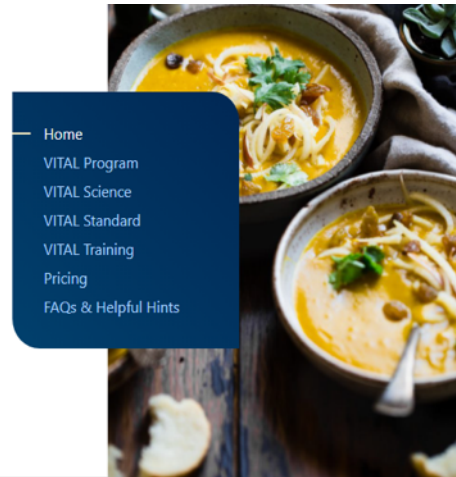
- ED01 or ED05?
- considerations

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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
- Working group activity



Voluntary Incidental Trace Allergen Labelling

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

A collage of healthy food items including avocados, apples, nuts, seeds, and various grains, arranged in a circular pattern. The items are presented in a top-down view, showcasing a variety of textures and colors. The circular arrangement suggests a holistic or balanced approach to nutrition.

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- # UNEXPECTED ALLERGENS IN FOOD
- Revised & updated
January 2021

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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

and a new platform for VITAL® Online

Vital. allergenbureau.net

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3 Step Industry Guidance



Industry Guidance

1. Food Industry Guide to Allergen Management and Labelling for Australia and New Zealand – PEAL updated edition
2. Allergen Bureau's Allergen Risk Review website
3. Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program.



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



Trial VITAL
Online
today



Developed by industry for industry and is
adopted on a voluntary basis

A New VITAL Online

We have responded to advances in web-based technology and embarked on a rebuild of the VITAL Online application to improve performance, manageability, and reliability of the VITAL Online platform.

You can now access the brand new VITAL Online website for the VITAL Online Calculator, as well as VITAL Science, VITAL Training, the VITAL Standard, and more, via the new VITAL Online portal.



Industry Guidance

vital.allergenbureau.net

The Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program

Access our suite of Food Industry Guides via
the Allergen Bureau website.

Easy
Step-by-step
Industry
Guidance



2. THE VITAL PROCEDURE

2.1 Scope

The VITAL Procedure is applicable to allergens which are:

- homogeneously distributed or particulate cross contact allergens in food which is being prepared or manufactured; and
- listed in the VITAL Action Level Grid.

The VITAL Procedure is not applicable to:

- food specifically formulated for infants who often have heightened sensitivity to the presence of allergens, and may require an alternative risk management approach; or
- food for special medical purposes.

2.2 Pre-requisites

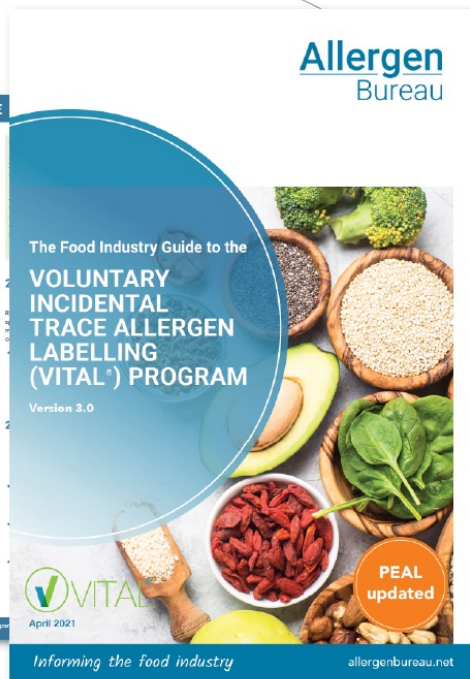
- It is not appropriate to apply the VITAL Program in the absence of a HACCP/Hazard Analysis Critical Control Point based food safety program which includes allergens.
- The manufacturer must have documented and implemented an allergen management program.

Allergen Identification

2.3 Determination of relevant allergens

Determine the allergens to be included in the VITAL risk assessment. All allergens regulated for mandatory or precautionary allergen labelling should be considered, including both intentionally added and potential cross contact allergens.

Consider the relevant legislation for your product. For example, products sold in Australia and New Zealand markets should use, as a minimum, the allergens listed in allergens listed in Australia New Zealand Food Standards Code table to section 3.3 in Schedule 9. It is the responsibility of the user to ensure that all relevant allergens are included in the assessment.



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The VITAL Standard

- Voluntary
- Consumer visibility
- Cost effective
- Internationally recognised
- Robust
- Product specific
- Auditable



Allergen Risk Review Website

- Claims substantiation of any type needs robust risk review and focus.
- 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.
- Here you can find detailed information about assessing allergen risk at every stage of the process to make food.

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info.allergenbureau.net



THANK YOU

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

CONTACT US:



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