

Allergen Bureau

**Food Allergen Management,
Food Allergen Risk Review &
Food Allergen Risk Assessment**

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NSW TAFE Allergen Spotlight Session 2 – 7th April 2022

Informing the
food industry



Agenda

- Allergen Risk Review
- Allergen Management
- Allergen Risk Assessment & VITAL



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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.



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Allergen management

BOTH

- are documented systematic approaches
- identify allergen risks & allergen challenges in manufacturing
- cover all aspects of the supply chain / supply matrix

BUT

although similar, they are not the same

Allergen risk review



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 and 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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Example: Cleaning



Production Step 9 of 15 Cleaning

Cleaning equipment, preparation areas and the production lines of a food manufacturing site is necessary to eliminate allergen residue and the potential for cross contact. As facilities can vary in complexity, food materials, the allergen type, number, and nature, equipment type, and food contact surfaces, cleaning parameters may be unique to each process or site.

Hang Up



Cleaning controls and trouble spots



Cleaning validation and verification



Risk review considerations



Allergen Management Program (AMP)



prev step

next step



Performing physical risk review

1. Assemble a cross-functional team
2. Consider all areas of the production line
3. Perform a physical audit by inspecting the processing equipment
4. Identify Hang Up points and other cross contact points
5. Consider the form of the cross contact (readily dispersible or particulate)
6. Quantify any cross contact that is present

Further information

See Step – [Design of Premises & Equipment](#)
See Step – [Analysis & Testing](#)

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

Unexpected Allergens in Foods

- Original edition - 2011
- Version 2 – issued January 2021
- Updates include:
 - Additions to unexpected allergens associated with foods and ingredients
 - Inclusion of Agricultural Co-Mingling section
 - Inclusion of a Food Fraud section
 - Inclusion of Case Studies – examples of agricultural co-mingling

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UNEXPECTED ALLERGENS IN FOOD

Revised & updated
January 2021

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Table 1: Unexpected allergens associated with foods and ingredients

Food	Details
Soy Sauce	Does it contain wheat (in addition to soy)?
Spice extract(s)	Do they contain any bases, carriers, anti-caking agents (e.g. maltodextrin, flour, oleoresins, emulsifiers)? If yes, what are they derived from (e.g. wheat , maize, soy , egg etc.)?
Spice(s)	Do they contain any bases, carriers, anti-caking agents (e.g. maltodextrin, flour, oleoresins, emulsifiers)? If yes, what are they derived from (e.g. wheat , maize, soy , egg)? Refer to Table 2 (Allergens associated with agricultural co-mingling).
Stabilisers	What are they derived from (e.g. soy , egg , cereals containing gluten)?

Examples provided by industry, for industry

Table 2: Allergens associated with agricultural co-mingling

Food	Details
Dehydrated garlic	What is the geographical origin of the garlic? Refer to Case study - Crop rotation practices can impact upon ingredient allergen status.
	What other crops are used for crop rotation by the grower? Does the farming source crop rotate with peanut ?
	What other crops are being (or can be) grown nearby?
	What crop measures are in place to effectively remove physical remains of other crops?
	How is the garlic (fresh or dehydrated) traded/sourced (e.g. through general markets with lesser known controls; contracted farms; controlled Backward Integration programs)?

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



HACCP based food safety program adapted for allergen control

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

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AMP are **unique** to each site / company

- Approach to risk is unique to every company/site/product & this will be reflected in the AMP
- Consider
 - who is the target market?
 - complexity / simplicity of the manufacturing site
 - the number of allergens on the site
 - spectrum (which allergens)
 - form of the allergen
 - load of the allergen protein



Where are the largest risk?

- Ingredient not to specification
- Wrong ingredient used
- Cleaning not performed
- Cleaning not effective
- Wrong product in the wrong pack
- Wrong meal to the wrong consumer



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



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[®] risk assessment using the VITAL Program principles is an example of a science-based risk assessment for allergen cross contact.

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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.

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

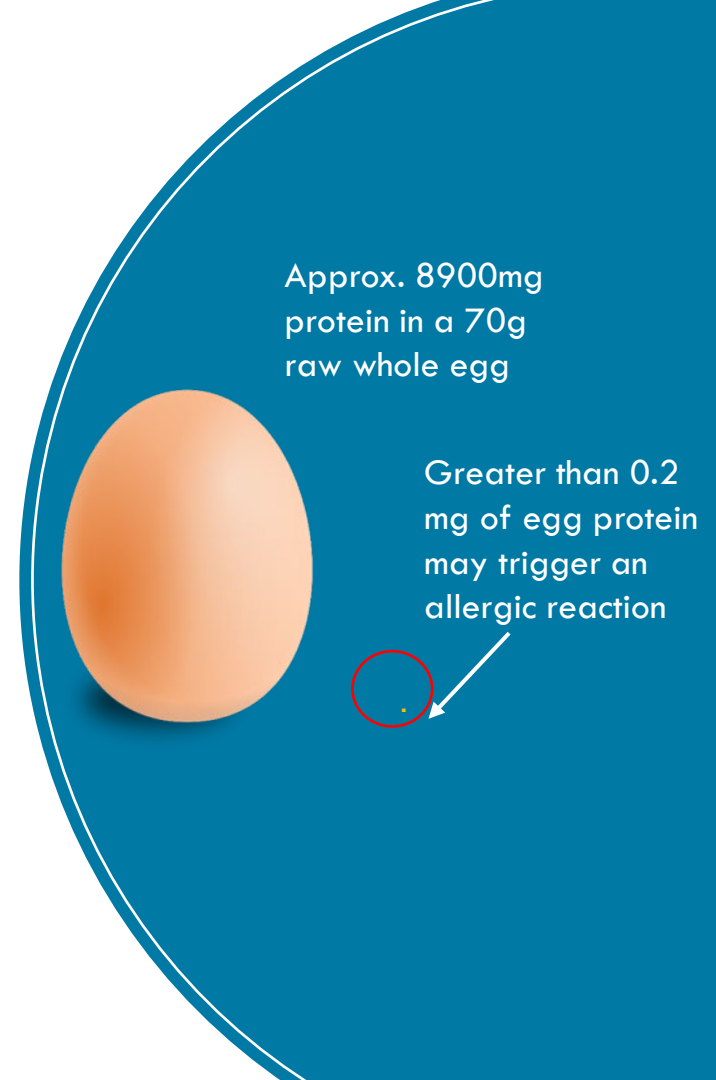


Cross Contact Allergens

- Residues or a small amount of an allergenic food **unintentionally** incorporated into another food that is not intended to contain that allergen
- May be present despite GMP
- 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.



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

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

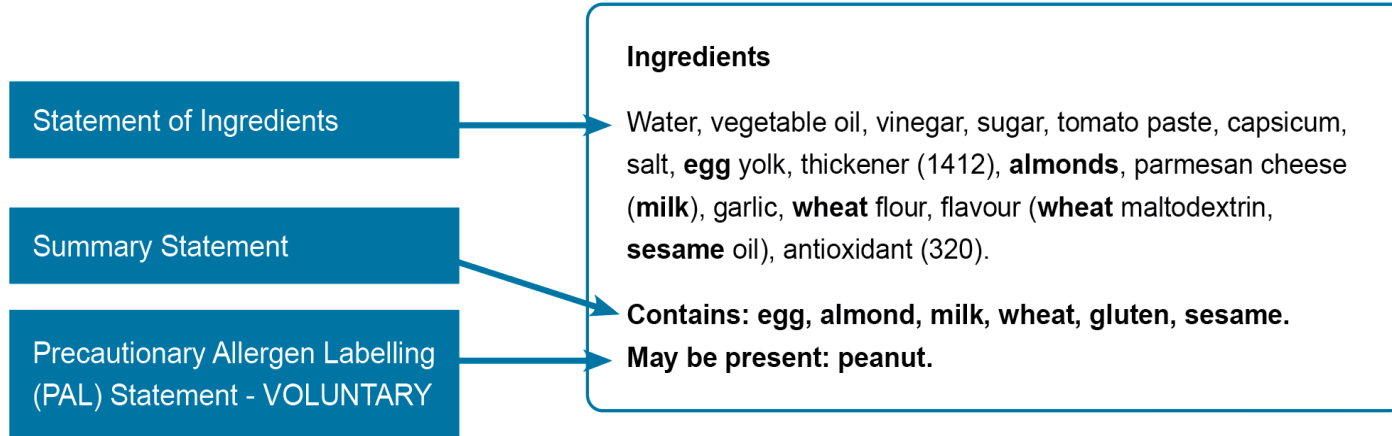
no PAL statement is required

Action Level 2

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

PAL statement is required

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

Food Allergen Analysis



Food Allergen Analysis

Food allergen analysis is the testing of a material or a surface to identify and/or quantify the presence of a food allergen. Analytical test results are a useful tool for allergen management in food processing and may be used to enhance an allergen management plan and can be a valuable tool for a risk-based approach to allergen management. Test results can provide assurance and verification of critical controls within a comprehensive allergen management plan and assist the implementation of quantitative risk assessment. Analysis has a critical place in allergen management but is not a substitute for a robust allergen management plan and requires a clear understanding of the limitations of analysis.

Food allergen analysis is useful to:

- establish allergen status of ingredients
- identify equipment that is difficult to clean
- inform the risk assessment
- confirm VITAL® (Voluntary Incidental Trace Allergen Labelling Program) assumptions
- verify final product status in high risk environments
- monitor effect of critical changes

Allergen analysis has a place in finished product testing and verifying free from claims, but a single test result should not be considered in isolation and choosing the correct type of analysis and test can be complex. The analysis should be appropriate for the matrix and allergen and the method chosen should be robust, reliable, repeatable, sensitive and specific. As with all food testing methods, results are only representative of the samples tested and it is of critical importance to use an appropriate risk-based sampling plan.

Find out more about Food Allergen Analysis via the tabs below.

See also

[Food Allergens](#)

[Clinical Information about Food Allergies](#)

[Food Allergen Analysis](#)

Allergen Bureau Web Resource

- Sampling plans
- Methods & Test Kits
- Choosing a method of analysis
- Relevant Links
- <https://allergenbureau.net/food-allergens/food-allergen-analysis/>

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VITAL Online Update

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

Major platform upgrade in 2021!

Update includes:

- New PEAL requirements
- Sesame in the US legislation



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The Food Industry Guide to the
**VOLUNTARY
INCIDENTAL
TRACE ALLERGEN
LABELLING
(VITAL®) PROGRAM**

Version 3.0



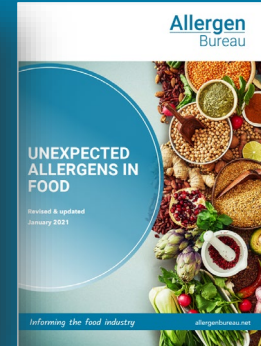
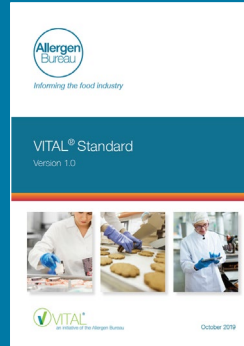
April 2021

PEAL
updated

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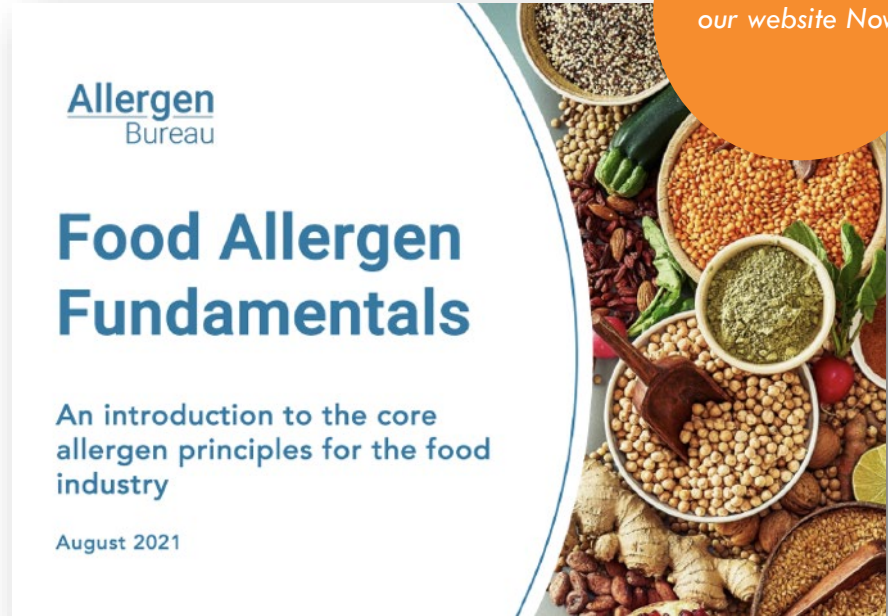
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VITAL Program Version 3.0 and supporting documents



Food Allergen Fundamentals

- Overview of food allergens to assist the food industry with the complex task of managing allergens.
- A free resource for people
 - New to the subject of food allergens in manufacturing
 - In the food industry who might benefit from a 'going back to the basics' refresher.



<https://allergenbureau.net/food-allergen-fundamentals-faf-updated-to-include-peal/>

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Other Resources

- Food Standards Australia New Zealand – Allergen Portal
 - Manufacturing
 - Food service / retail
 - Catering
 - Hospital and Childcare
- National Allergy Strategy – All about allergens online training
 - Food service / retail
 - Hospital and Childcare
 - Chefs
- Allergy Anaphylaxis Australia
- ASCIA (Australian Society Clinical Immunology and Allergy)

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.

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THANK YOU

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