

Allergen Bureau

Applying Allergen Risk Assessments at your facility

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Informing the
food industry



Agenda

- About Us
- 3 Core Concepts
- The VITAL Program
- Application of VITAL Online – reducing and understanding risk

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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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Accurate & Consistent Allergen Declaration

- Allergen labelling is the key mechanism to inform a consumer of the allergen status of a product
- Appropriate allergen declaration can:
 - help food allergic 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

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 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

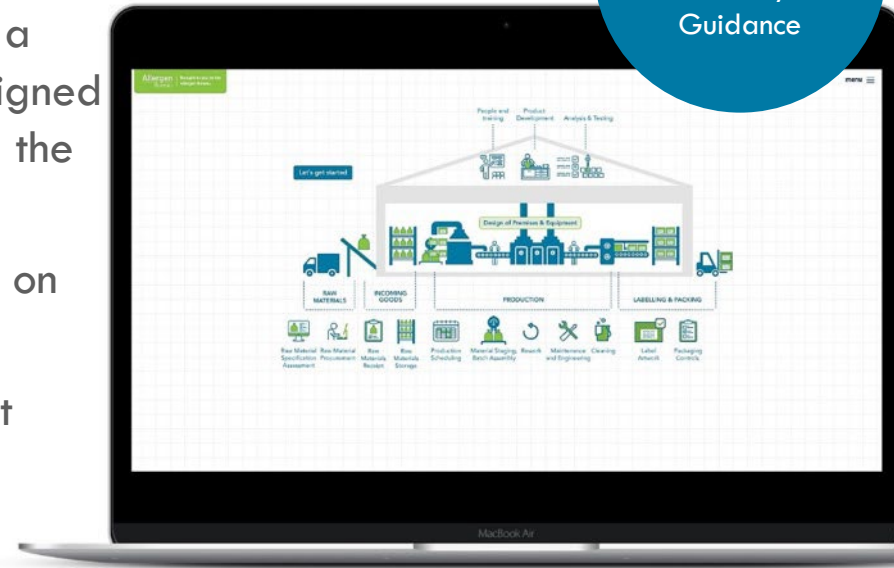
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Allergen Risk Review Website

- 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.

Easy
Step-by-step
Industry
Guidance



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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

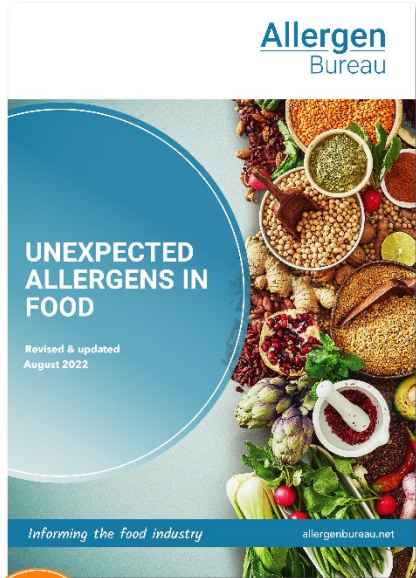
Further information

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

See Step – [Analysis & Testing](#)

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Resources Available to Assist Supply Chain Assessment



Free Resources for Industry

Unexpected Allergens in Food provides the food industry with a list of foods, ingredients and raw materials that may unexpectedly contain allergens.

Download at allergenbureau.net



Free Resources for Industry

The guide assists industry to identify and manage agricultural cross contact risk.

Download at allergenbureau.net



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 hazards
- 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
- Allergen Management is not allergen harmonisation

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

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All 3 Create a Feedback Loop



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 environment where there are no regulations for assessing or declaring cross contact allergens
- With a vision of global harmonized thresholds for cross contact allergens & a best practice approach for cross contact allergen risk assessment





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.

The VITAL Program in Australia, New Zealand & the World

- Adopted by food business operators on a **voluntary** basis
- VITAL 1.0 was released in 2007
- The VITAL Program is well-known in Australia and New Zealand & acknowledged by regulatory and enforcement agencies for its role as a voluntary industry guide
- The VITAL Reference Doses and the concept of Action Levels are used by regulatory and enforcement agencies in other parts of the world

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Global Reach and Use

- Approximately 7300 organisations have registered to use the VITAL online tool
- More the 73000 reports generated since online version available
- This does not capture the application of the VITAL Program is other ways (i.e. manual, consultants, other platforms)

TOP 5 VITAL Online regions (as at Jan 2024)

1. ANZ (68.1%)
2. Europe (27.6%)
3. South America
4. North America
5. Asia



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.

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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 (Unintended Allergen Presence (UAP))
- Reference Dose
- Reference Amount
- Action Levels
- Precautionary Allergen Labelling (PAL)





Cross Contact Allergens

- Residues of an allergenic food **unintentionally** incorporated into another food that is not intended to contain that allergen
- Also know as Unintentional Allergen Presence (UAP)
- 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

Thresholds in the VITAL Program

Action Level 1

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

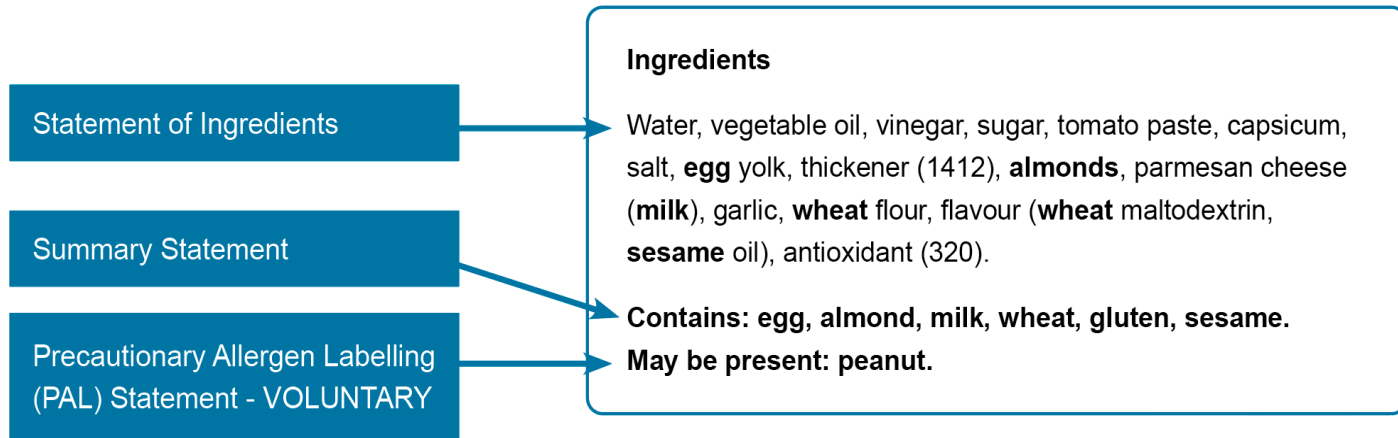
no PAL statement is required

Action Level 2

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

PAL statement is required

Recommended Labelling Format (Australian Example)



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

VITAL and Your facility

Helps answer questions like:

- Can we make our runs longer?
- How frequently should we run this allergen recipe?
- What is the impact of changing my production schedule?
- What if we run a smaller batch?
- How do I explain the risk to our senior leadership team?
- What would it take to reduce my hang-up or eliminate this allergen?
- Is there a tangible operational benefit (reduced downtime, increased site flexibility)?



Example 1 – Coconut Ice Cream: Hang Up

(currently 500g of previous milk product remains after cleaning)


Intentionally Added	Soy
Action Level 2	Wheat, Gluten Milk Peanut
Action Level 1	Fish

Action Level Transition Point	1.3ppm
Action Level Before Source	0.000000ppm Action Level 1
Action Level After Source	2.571429ppm Action Level 2
	Action Level Transition Point
Hang Up	> 259.259259g
Batch Size	

Example 2 – Coconut Ice Cream: Batch Size

(currently produce minimum batch runs of 5000kg)

Intentionally Added	Soy
Action Level 2	Wheat, Gluten Milk Peanut
Action Level 1	Fish

Action Level Transition Point	1.3ppm
Action Level Before Source	0.000000ppm Action Level 1
Action Level After Source	2.571429ppm Action Level 2
Action Level Transition Point	
Hang Up	
Batch Size	9642.857143kg

Example 3 – Coconut Ice Cream: Substitute Ingredient

(currently coconut sugar contains 135ppm wheat cross contact)

Intentionally Added	Soy
Action Level 2	Wheat, Gluten Milk Peanut
Action Level 1	Fish

Substitute ingredient contains 15ppm wheat cross contact – what is the impact to my labelling outcome

Substance	Action Level 1	Action Level 2	Intentionally Added	Particulate	Readily Dispersible	Labelling Outcome
R Cereals (Totals)	< 4.7 ppm	≥ 4.7 ppm	—	—	0.685714 ppm	Action Level 1
B Cereals (Totals)	< 4.7 ppm	≥ 4.7 ppm	—	—	6.171429 ppm	Action Level 2



Let's Talk
Legal Defense

How VITAL is Supporting Enforcement Decisions & Protecting Businesses

- Australian & NZ acknowledge a statutory due diligence in respect to breaches in the food standard code
- The application of VITAL demonstrated due diligence to an enforcement agency

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Due Diligence – The Legal Terms

Defence of due diligence

- (1) the person **took all reasonable precautions and exercised all due diligence**
- (2) Without limiting a person satisfies those requirements if ..—
 - (a) ... the commission of the offence was due to—
 - (i) an act or default of another person, or
 - (ii) reliance on information supplied by another person, and
 - (b) that—
 - (i) .. carried out all such checks ... reasonable in all the circumstances, or
 - (ii) it was reasonable to rely on checks ..

Australia – all jurisdictions

Food Safety Program

- ... a person may satisfy those requirements by proving that—
- (a) the person complied with a food safety program for the food business; or
 - (b) in any other case, the person complied with a scheme (for example, a quality assurance program or an industry code of practice) that was—
 - (i) **designed to manage food safety hazards** and was based on Australian national or international standards, codes or guidelines designed for that purpose; and
 - (ii) documented in some manner.

VITAL & Due Diligence Defence

Food Authority



VITAL® – PAL due diligence

- VITAL® is a recognised system for assessing incidental allergen contamination risk.
- industry code of practice) that is **designed to manage food safety hazards** – allergens, and is a guideline designed for that purpose

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Source: Presentation by A.Edwards Food Law Conference: Navigating Regulation and Risk. Title: Rethinking HACCP, Why Label Approval and Application Should be a Critical Control Point in Food and Beverage Production (01.12.2023)

Case Study – No PAL

- A single consumer reports a reaction to a product.
- Allergy to cows milk
- The product does not contain milk, nor carries a PAL
- Dairy detected in the product at 0.19ppm
- Enforcement agency reviews the companies' procedures
- VITAL risk assessment had been conducted, outcome = no PAL required
- Levels detected were below which would have required a PAL and supported the VITAL outcome
- No action was taken against the company
- “took all reasonable precautions and exercised all due diligence to prevent the commission of the offence” (s26(1) *Food Act 2003 (NSW)*)

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



Case Study - PAL

- Product does not contain milk, but carries a PAL statement
- Multiple consumer complaints across Australia, with varied levels of reactions
- Product investigated and found to be compliant
- Product was not recalled, but the distributor voluntarily withdrew the effected product
- Most concerning:
 - HCP advice that it is safe to eat products with PAL
 - Consumers ignore PAL
 - “safe” consumption = false PAL perception

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The Pathway to Harmonized PAL

- Education & Collaboration must be the focus
 - Healthcare professions (dietitians, allergy nurses, clinicians)
 - SME food manufacturers
 - Legislators and enforcement agencies
 - Consumers and carers
- Joint consensus statement on PAL currently being drafted
- Aligned key stakeholder messaging
- Allergen Bureau led Industry research study on PAL impact

The graphic is a white document with a blue header and footer. The header contains the title 'Food Allergen Management Consensus Statement'. The main body is divided into three sections: 'IT IS THE RESPONSIBILITY OF CONSUMERS TO:', 'IT IS THE RESPONSIBILITY OF PACKAGED FOOD MANUFACTURERS TO:', and 'IT IS THE RESPONSIBILITY OF FOOD SERVICE ESTABLISHMENTS/PROVIDERS TO:'. Each section contains a numbered list of responsibilities. Below these sections is a paragraph stating that food safety is a shared responsibility and that the statement is part of a strategy to improve safety and quality. At the bottom, there are logos for the Centre for Food & Allergy Research, national allergy strategy, Allergen Bureau Australia, ascia, allergy New Zealand, and FAMS.

Food Allergen Management Consensus Statement

IT IS THE RESPONSIBILITY OF CONSUMERS TO:

1. declare their allergies and read food labels (including ingredient lists and allergen declaration statements), and
2. ultimately make their own judgement about the foods they choose to consume.

WE CONSIDER THAT IN ORDER TO ENABLE CONSUMERS TO MAKE INFORMED DECISIONS ABOUT THEIR SAFETY:

IT IS THE RESPONSIBILITY OF PACKAGED FOOD MANUFACTURERS TO:

1. follow robust allergen management practices including quantitative risk assessment, and
2. use clear, consistent labelling to inform consumers about that food's allergen content, including the possible presence of unintended allergens.

IT IS THE RESPONSIBILITY OF FOOD SERVICE ESTABLISHMENTS/PROVIDERS TO:


1. follow robust allergen management practices, and
2. ensure that staff understand and can inform consumers about the allergen content of the food they provide, including the possible presence of unintended allergens.

We recognise that the safety of consumers with food allergy is a shared responsibility of consumers, packaged food manufacturers, food service establishments/providers, health professionals, retailers, and regulatory and enforcement agencies.

This consensus statement is specific to consumers, packaged food manufacturers and food service establishments/providers, and is part of a strategy to improve the safety and quality of life of consumers with food allergy.



VITAL Program - Key Take Home Messages

- 
1. When done well, it decreases your business risk
 2. Philosophy: IDENTIFY, ELIMINATE, REDUCE, MANAGE, COMMUNICATE
 3. Decisions are underpinned by scientifically based Reference Doses
 4. Decreased and well managed risk = less PAL statements
 5. Key: Businesses must manage allergen cross contact at the VITAL outcome, scope creep is not acceptable when PAL statements have been identified as required
 6. QRA / VITAL is not just about PAL. QRA and Allergen management rely on each other for the best outcome, for your business and for the consumer!



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THANK YOU

CONTACT US:



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