

Allergen Bureau

**The VITAL Program? How the
program helps companies
manage allergen risk**

PRESENTED BY:

Jasmine Lacin-Lee – Allergen Bureau President



Informing the
food industry

Agenda

- About Us
- Identifying & controlling allergen hazards
- The VITAL Program
- Best Practice Quantitative Risk Assessment
- 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

- Established in 2005, pre-competitive, 'not-for-profit', Allergen Bureau directors provide voluntary, unpaid services
- Membership based organisation established to provide food industry with rapid responses to questions about allergen risk management in food ingredients and manufactured foods

Become a member



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 consumers with food allergy 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.



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 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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Easy
Step-by-step
Industry
Guidance



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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



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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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





The VITAL Program

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 individuals with food allergy
- 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 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 7400 organisations have registered to use the VITAL online tool
- More the 74500 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 March 2024)

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




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.

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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.



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[®]

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 Program

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





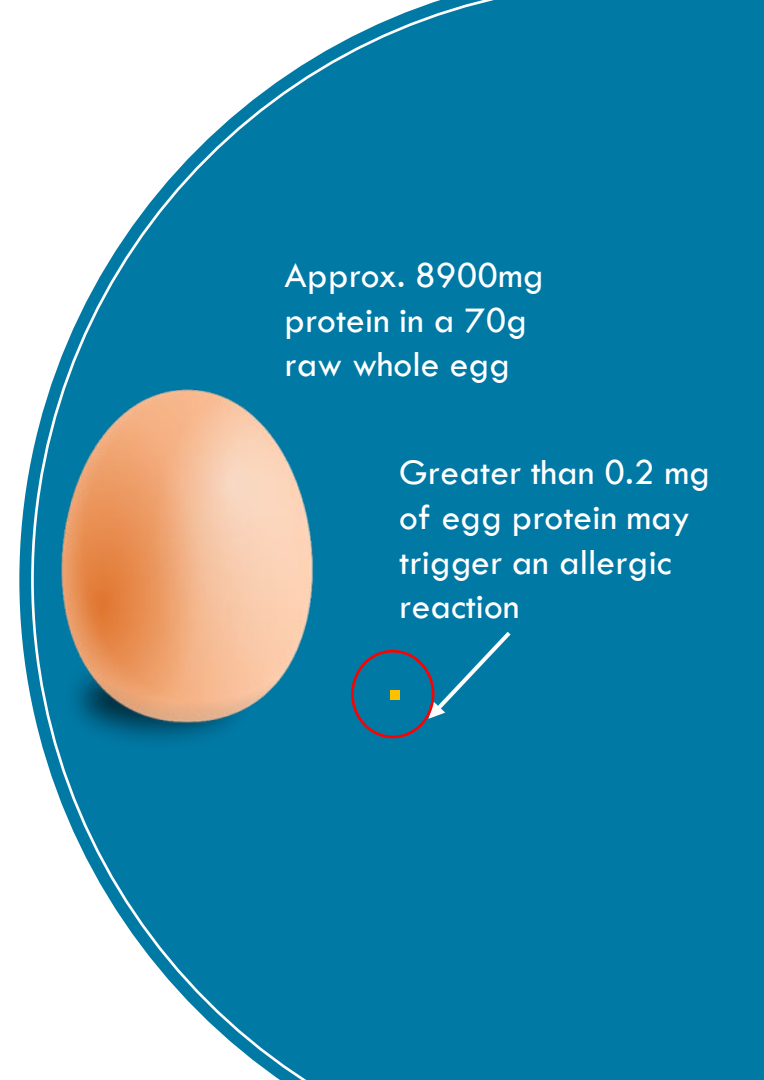
Cross Contact Allergens

- 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

- The milligram protein level (total protein from an allergenic source) below which only the most sensitive (1%) of individuals in the allergic population are likely to experience an objective reaction.
- If reactions to (unlabelled) allergens do occur from exposure at or below the Reference Dose, they will be mild and transient
- The Allergen Bureau is moving to adopt the FAO/WHO recommendations (ED_{05})

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The VITAL Scientific Expert Panel (VSEP) Today

- **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)
- **Prof Dianne Campbell** – Academic Paediatric Immunologist (Sydney University, Children’s Hospital Westmead, DBV-Technologies)



CODEX - GSLPF

- Many countries adopt fully or partially CODEX – General Standard for the Labelling of Pre-packaged Foods (GSLPF) – [CODEX STAN 1-1985 rev 2020]
- 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
- VITAL Scientific Expert Panel (VSEP) members were invited to join this Expert consultation



Food and Agriculture
Organization of the
United Nations



World Health
Organization




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Food and Agriculture Organization of the United Nations World Health Organization
14 FOOD SAFETY AND QUALITY SERIES

MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS
PART 1: REVIEW AND VALIDATION OF CODEX ALIMENTARIUS PRIORITY ALLERGEN LIST THROUGH RISK ASSESSMENT

Food and Agriculture Organization of the United Nations World Health Organization
16 FOOD SAFETY AND QUALITY SERIES

MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS
PART 3: REVIEW AND ESTABLISH PRECAUTIONARY LABELLING IN FOODS OF THE PRIORITY ALLERGENS

Food and Agriculture Organization of the United Nations World Health Organization
23 FOOD SAFETY AND QUALITY SERIES


MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS
PART 5: REVIEW AND ESTABLISH THRESHOLD LEVELS FOR SPECIFIC TREE NUTS (BRAZIL NUT, MACADAMIA NUT, QUEENSLAND NUT, PINE NUT), SOY, CELERY, LUPIN, RYE, BUCKWHEAT AND OATS

Food and Agriculture Organization of the United Nations World Health Organization
15 FOOD SAFETY AND QUALITY SERIES

MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS
PART 2: REVIEW AND ESTABLISH THRESHOLD LEVELS IN FOODS FOR THE PRIORITY ALLERGENS

Food and Agriculture Organization of the United Nations World Health Organization
17 FOOD SAFETY AND QUALITY SERIES

MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS
PART 4: ESTABLISHING EXEMPTIONS FROM MANDATORY DECLARATION FOR PRIORITY FOOD ALLERGENS



Part 2: Recommendations

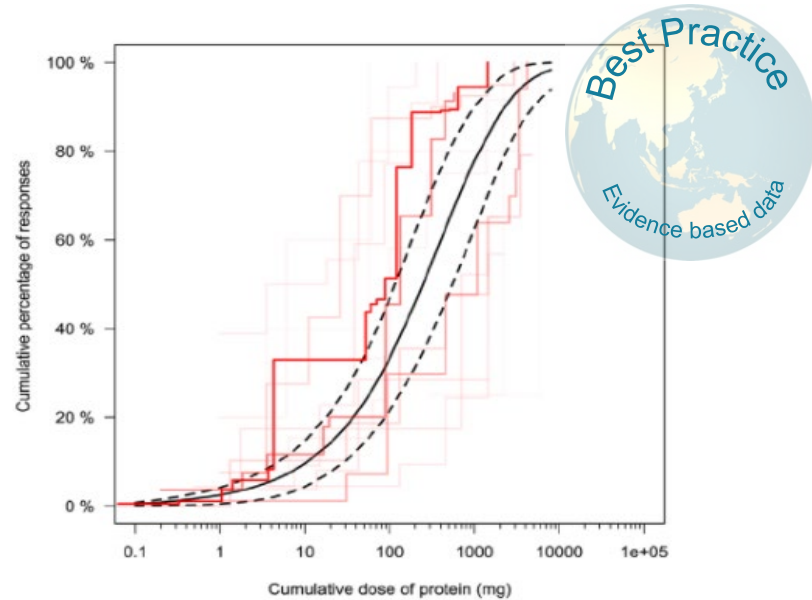
- Reference doses (RfD) for allergens determined by dose-distribution modelling of results from DBPC challenge studies.
- Data set was updated, additional studies added & non-publicly available studies removed.
- Data included additional studies for milk and sesame.
- Safety objective is met by setting an RfD at $ED_{0.5}$.
- Simplify RfD by grouping and rounding down to 1 significant figure.
- Analytical results to be standardized as *mg total protein of allergenic food per kg*.

Recommended Threshold approach for Priority Allergens (Part 2)

Approaches considered:

1. Analytical-based
2. No Observed Adverse Effect Level [NOAEL] + Uncertainty Factor [UF]
3. ***Benchmark Dose with or without the application of a Margin of Exposure***
4. Probabilistic Hazard Assessment

Same methodology used in the VITAL Program.



Based on “Stacked Model Averaging” – 5 different statistical models produce a single “averaged distribution.”

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 4.0 (FAO/WHO Recommended Values) Priority Allergens

Allergen	RfD Recommendation (mg total protein from the allergenic Source)
Walnut (and Pecan*)	1.0
Cashew (and Pistachio*)	1.0
Almond (**)	1.0
Peanut	2.0
Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Shrimp	200

VITAL 4.0 (FAO/WHO Recommended Values): Non - Priority Allergens

Allergen	RfD Recommendation (mg total protein from the allergenic Source)
Celery	1.0
Mustard *	1.0
Brazil Nuts, Macadamia Nuts, Pine Nuts *	1.0
Lupin *	10
Buck Wheat *+	10
Soy	10
Mollusc *+	20

*Risk Management Values
(data set did not meet RfD criteria)

+ New values not previously defined

Mollusc value set by VSEP, based on
the similar proteins in crustacea with a
x 10 safety margin

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?



Thresholds to 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

Action Levels 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

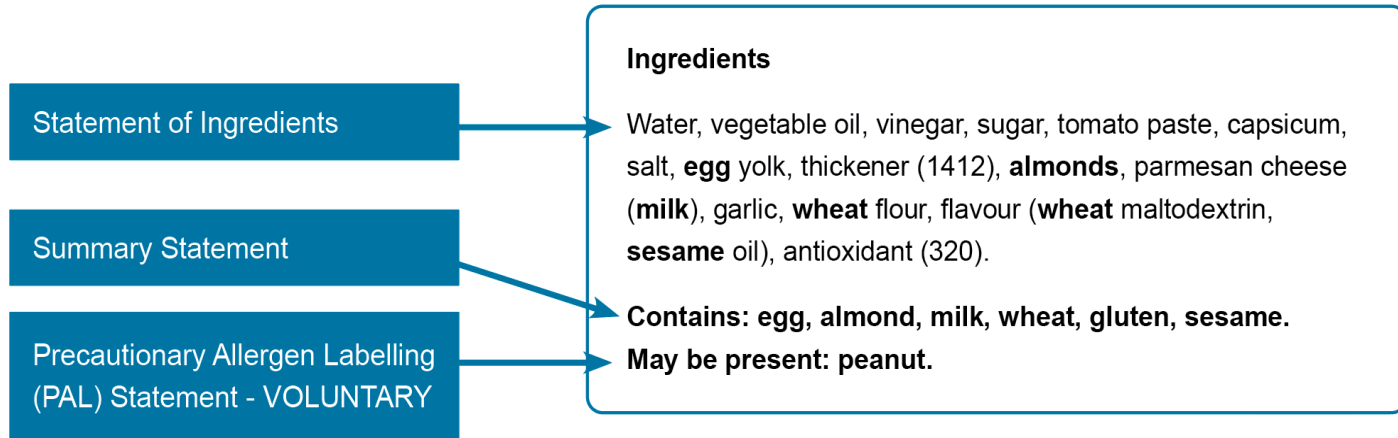
VITAL Assessment Report (example)



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

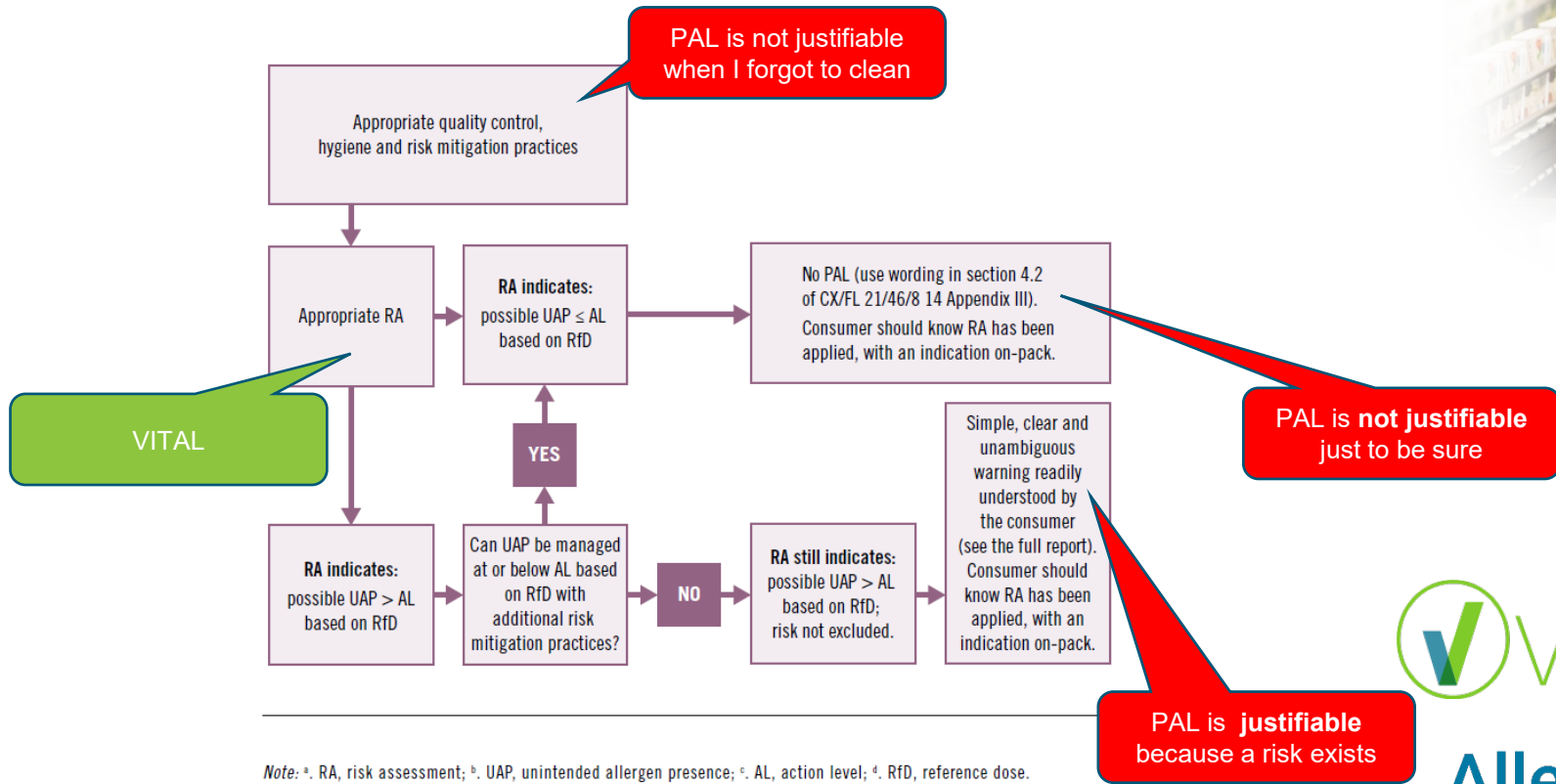
Recommended Labelling Format



“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

PAL Should not be Used Indiscriminately



Note: ^a. RA, risk assessment; ^b. UAP, unintended allergen presence; ^c. AL, action level; ^d. RfD, reference dose.
Source: Authors' own elaboration.



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)?



The VITAL Program – the Future

- 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
- If there is demand, we can add in Latin American Legislation.

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VITAL Program - Key Take Home Messages



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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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Allergen Bureau Resources:
designed to support businesses



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For the Food
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Free Resources Available on our Website

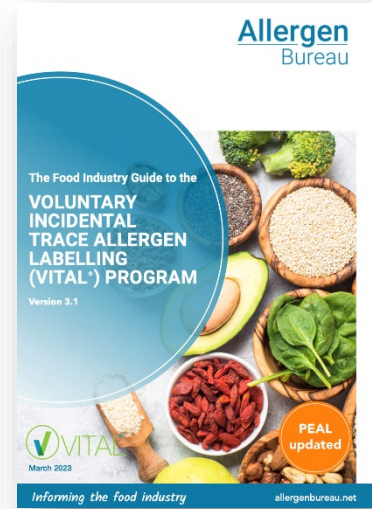
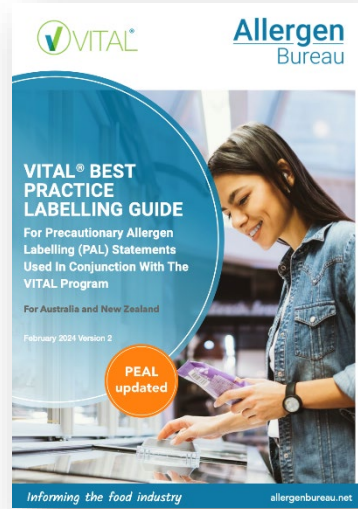
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and a new platform for VITAL[®] Online

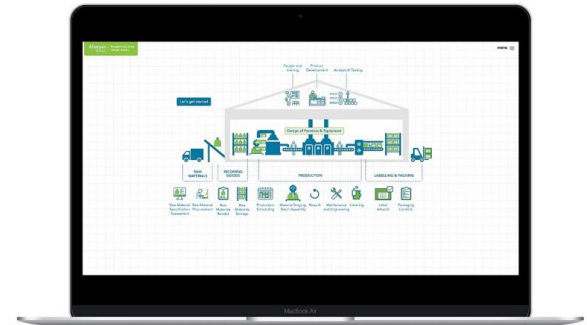
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Resources
for the
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The VITAL Standard

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



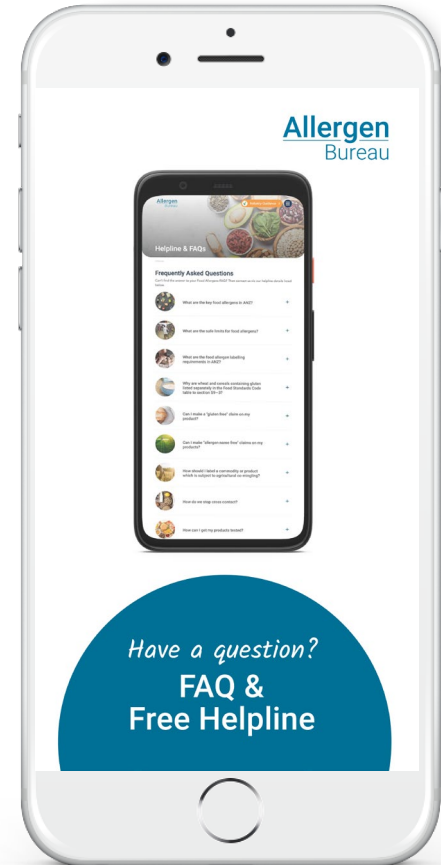
Free Helpline

- Allergen labelling
- Allergen management
- The VITAL Program
- VITAL Online
- “Curly” questions!

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THANK YOU

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