

Allergen Bureau

The VITAL Program

Food Fakty eFORUM

PRESENTED BY:

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Allergen Bureau President &
BVAQ Food Safety Manager

Informing the
food industry



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

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 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, New Zealand & the world

- Adopted by food business operators on a **voluntary** basis – widely used in Australia & New Zealand
- 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 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 also

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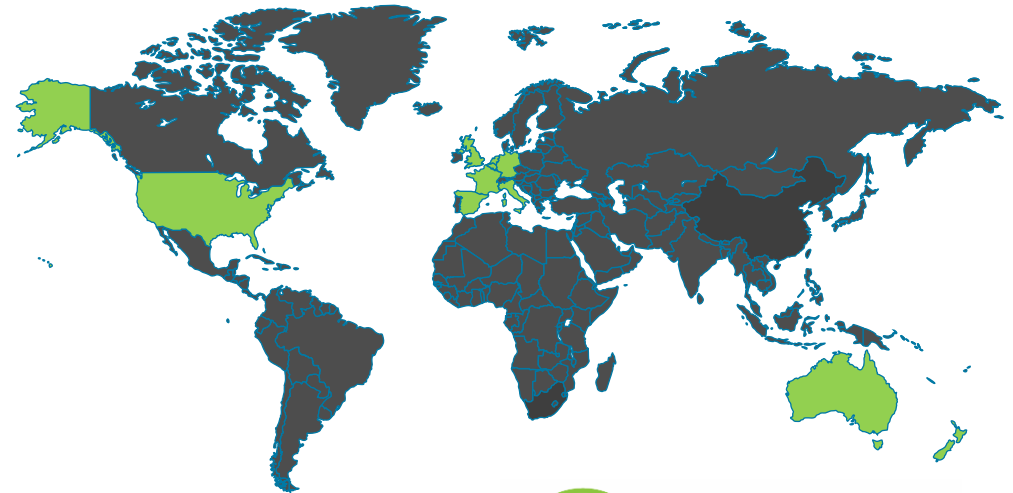


Growing International Interest

Over 2500 registered organisations use the VITAL Program

TOP 5 VITAL Online countries (as at February 2023)

1. Australia
2. Netherlands
3. Belgium
4. United Kingdom
5. Germany





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

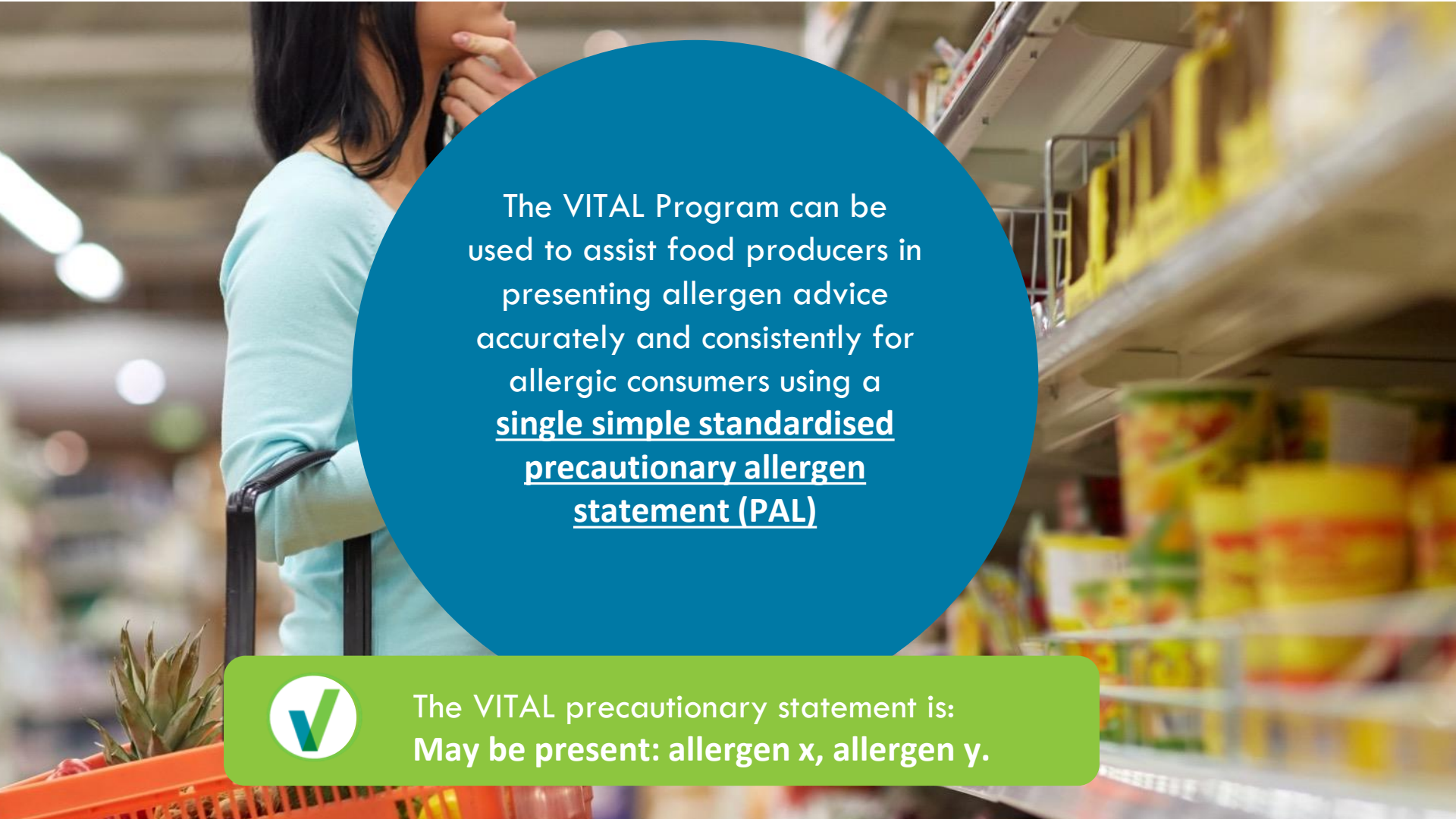
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VITAL Program Objective

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 (PAL)





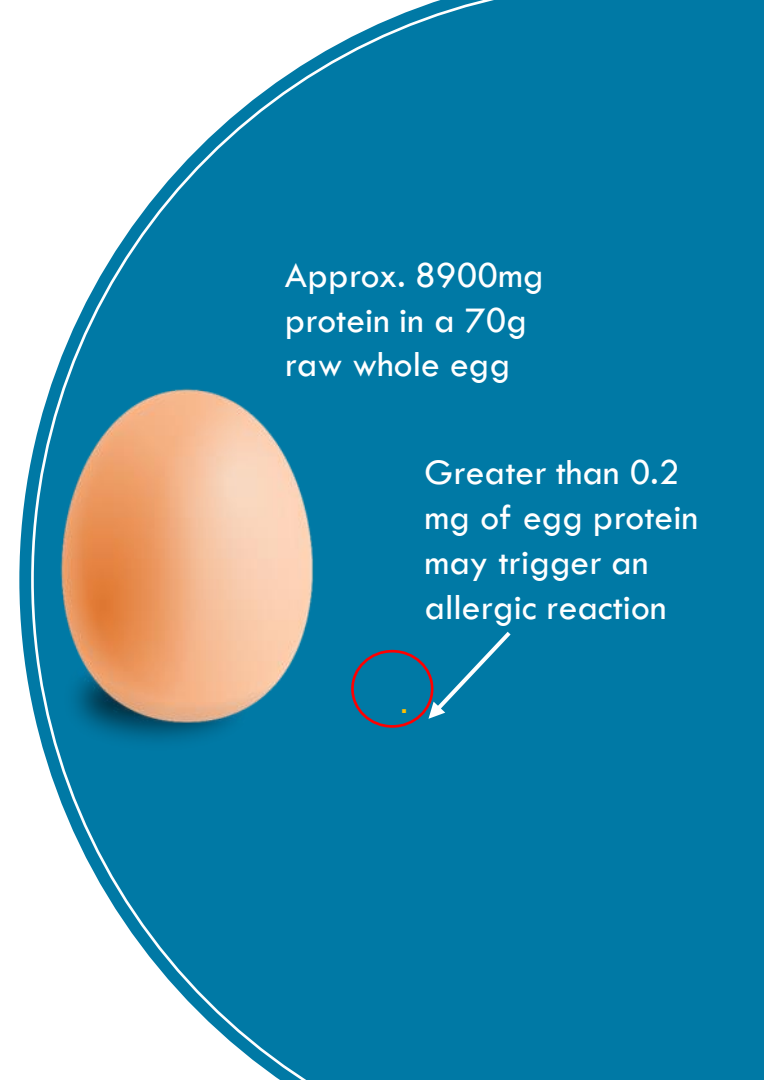
Cross Contact Allergens

- Residues or other trace amount of an allergenic food **unintentionally** incorporated into another food that is not intended to contain that allergen
- 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

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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 VITAL Scientific Expert Panel

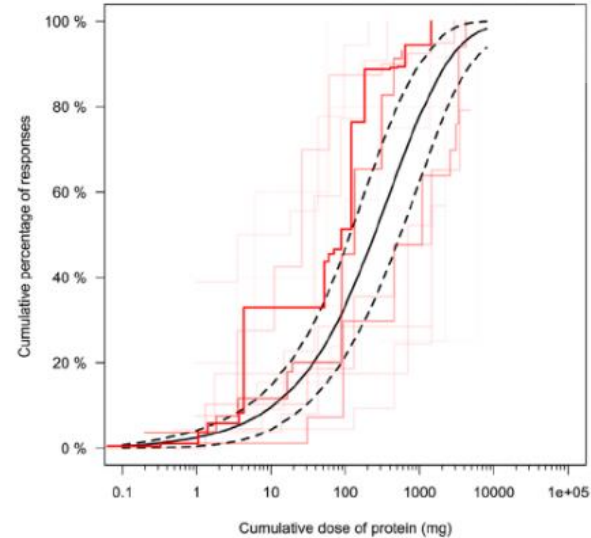
- **Dr Steve Taylor** (Chair of Panel) – Food Allergy Research & Resource Program (FARRP) (USA)
- **Dr Joseph Baumert** – Food Allergy Research & Resource Program (FARRP)
- **Dr Geert Houben** – Program Manager Food Safety, Netherlands Organisation for Applied Scientific Research (TNO) (NL)
- **Dr Rene Crevel** (RENE CREVEL Consulting Ltd) (UK) (formerly of Allergy & Immunology, Unilever)
- **Dr Simon Brooke Taylor** (Food Safety & Risk Analysis Consultant, Allergen Bureau) (AUS)
- **Dr Paul Turner** – Paediatric Allergy & Immunology, National Heart & Lung Institute, Imperial College (UK)

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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.

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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 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

Action Level Thresholds in the VITAL Program

Action Level 1

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

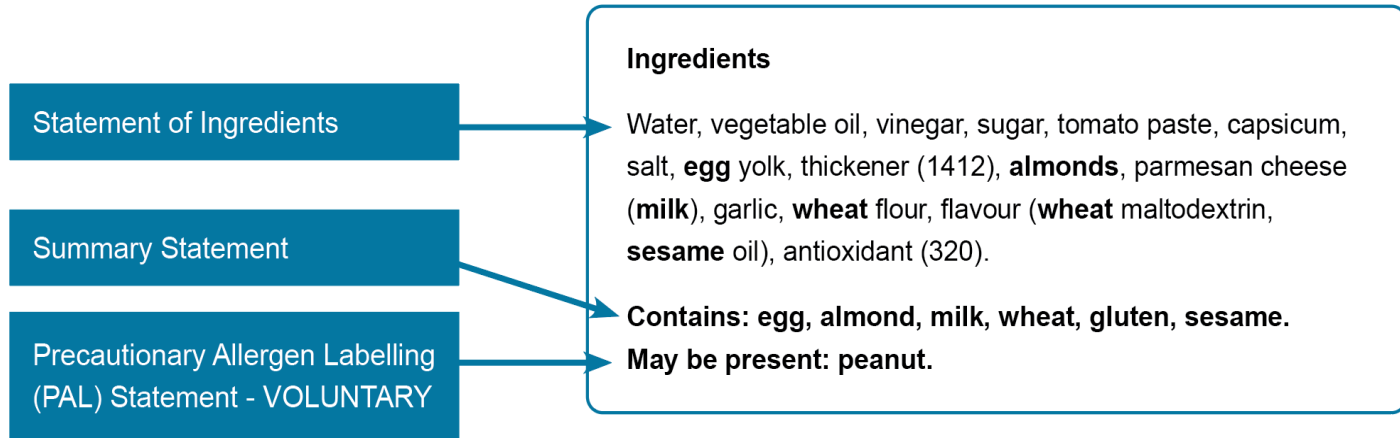
no PAL statement is required

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

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

Ongoing Development



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Reference Doses to reflect Expert panel outcomes

- ED01 or ED05?
- Stakeholder discussions have commenced on considerations for ED05 to the VITAL Program
- ED05 thresholds recommended by Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 2: Review and establish threshold levels in foods of the priority allergens

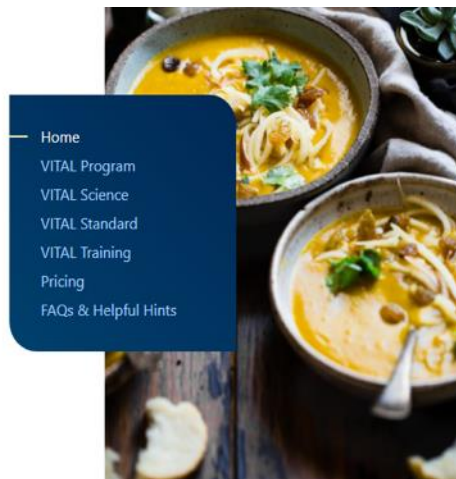


WHO Expert Consultation vs VITAL ED01

	Expert Panel (FAO/WHO) ED05 based (mg total protein from the allergenic source)	VITAL 3.0 Reference Dose (ED01) (mg total protein)
Walnut (& Pecan) Cashew (& Pistachio) Almond	1.0	0.03 0.05 0.1
Egg Milk Peanut Sesame	2.0	0.2 0.1 0.1 0.1
Hazelnut	3.0	0.1
Wheat Fish	5.0	0.7 1.3
Shrimp	200	25

Consumption Data May Inform Reference Amounts

- Food Category Consumption data rather than nominated Reference Amounts?
- Another level of consistency and robustness
- Collaboration with TNO



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.

Our Resources



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Your VITAL[®] Resources

- Allergen Risk Review Website
- The Food Industry Guide to the VITAL Program
- VITAL Best Practice Labelling Guide
- The VITAL Standard
- VITAL Online

Resources for the Food Industry



NEW Corporate Website



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.




Easy
Step-by-step
Industry
Guidance

info.allergenbureau.net

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Resources Available

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UNEXPECTED ALLERGENS IN FOOD

Revised & updated
August 2022

Informing the food industry allergenbureau.net

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



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ASSESSING AGRICULTURAL CROSS CONTACT

AUGUST 2022

Informing the food industry allergenbureau.net

Free Resources for Industry

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

Download at allergenbureau.net




RAW MATERIAL RISK MATRIX QUESTIONNAIRE

Risk Assessment Questions	Low Risk	Response Options		High Risk	Year Introduced	Total Score (0-25)	Quantity Observed	Number of Occurrences			
		Yes	No					0	10	20	%
Q1. Is the material produced from an equivalent regulatory jurisdiction?	Yes	1	No	3							
Q2. Does the supply chain include growers or processors from international sources?	No	2	Yes	7							
Q3. Is the supplier GFSI certified?	Yes	2	No	7							
Q4. Does the supplier have a documented and robust allergen management plan?	Yes	2	No	7							
Q5. Does your contract have a robust understanding and resolution of the applicable supply chain's CoA history, provided unless noted due to shared responsibility among growers, processors and trading partners?	Yes	2	No	7							
Q6. Are other allergenic crops used in crop rotation or grown in close proximity?	No	2	Yes	8							
Q7. How is the commodity stored / contained?	Compartments	2	Open bins	2							
Q8. Are effective measures in place to prevent or minimize potential allergen cross contact from shared equipment and facilities throughout the supply chain?	Yes	2	Partial	2							
Q9. Are there unique and quantified processes involved in the processing and/or distribution of the material?	No	2	Partial	2							
Q10. Are effective measures in place to identify, prevent or minimize the presence of other allergenic materials (e.g. risk and control in the commodity being purchased) that is effective in cleaning, control separation?	Yes	2	Partial	2							
Q11. Has allergen analysis been conducted on the allergen of concern for this commodity?	Yes	2	No	2							
Q12. If not, has testing been performed by an ISO 17025 accredited laboratory?	Yes	2	No	2							
Q13. Has the commodity undergone a robust validation for stability, for the commodity used? (See Allergen Bureau Data Allergen Control Response)	Yes	2	No	2							
Q14. Is the commodity otherwise in the industry of concerned allergen due to unique market needs or considerations?	No	2	Yes	2							
Q15. How have you managed any previous instances of allergen cross contact and/or allergen detection?	Not Reported	2	Yes	2							
Q16. If not, has the supplier successfully addressed the previous instances of cross contact?	Not Reported	2	Yes	2							
Q17. Does your supplier have measures and controls in place to manage any changes in the supply chain?	Yes	2	No	2							
Q18. Are there any allergen "hot spots" claims associated with the purchase of this raw material?	Yes	2	No	2							
Q19. What is the form of the material received?	Quantity dependent	2	Particulates	2							
Q20. What is the expected form of the cross contact allergen in the material?	Quantity dependent	2	Particulates	2							
Total						Score	0	10	20		

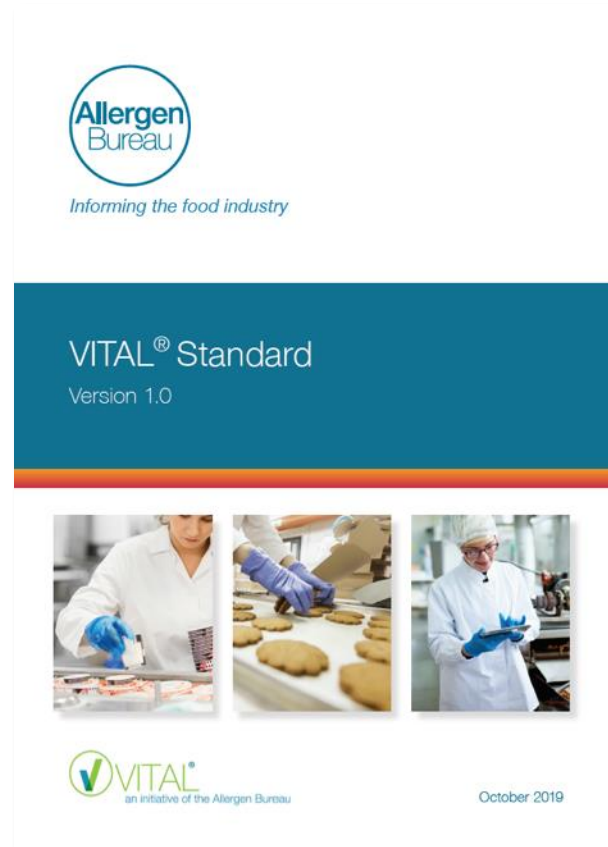
VITAL Online

- Online VITAL Calculator
- Operates on a subscription model
- Easy-to-use
- Stores, manages and updates VITAL risk assessments



The VITAL Standard

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



THANK YOU

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

CONTACT US:



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