THE VITAL® PROGRAM

AN EXAMPLE OF ALLERGEN THRESHOLDS IN ALLERGEN MANAGEMENT

VITAL

Allergen Bureau

INFORMING THE FOOD INDUSTRY

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The Allergen Bureau Ltd ACN 162 786 389

THE VITAL® PROGRAM

AN EXAMPLE OF ALLERGEN THRESHOLDS IN ALLERGEN MANAGEMENT

Overview

- The Allergen Bureau
- Intentionally & Unintentionally added Allergens
- Introduction to Australian consumers
- Why was the VITAL Program developed?
- The VITAL Program
- Resources

THE ALLERGEN BUREAU

THE ALLERGEN BUREAU

- The Allergen Bureau is the **peak industry body** representing food industry allergen management in Australia and New Zealand
- The Allergen Bureau is a **membership based** organisation established to provide food industry with rapid responses to questions about allergen risk management in food ingredients and manufactured foods
- Established 2005, **pre-competitive**, '**not-for-profit**', industry volunteer Board

Global Members

THE COCA-COLA COMPANY

Full Members

- Cargill Protein Europe

OUR VISION

The Allergen Bureau is a globally recognised and supported industry organisation promoting best practice **food industry allergen management**, **risk review** and **consistent labelling** to facilitate **informed consumer choice**

OUR MISSION

To facilitate a globally accepted, consistent, science-based approach to food allergen risk assessment, management and communication that:

- guides **industry** best practice
- assists allergen sensitive **consumers** to make informed choices based on label information

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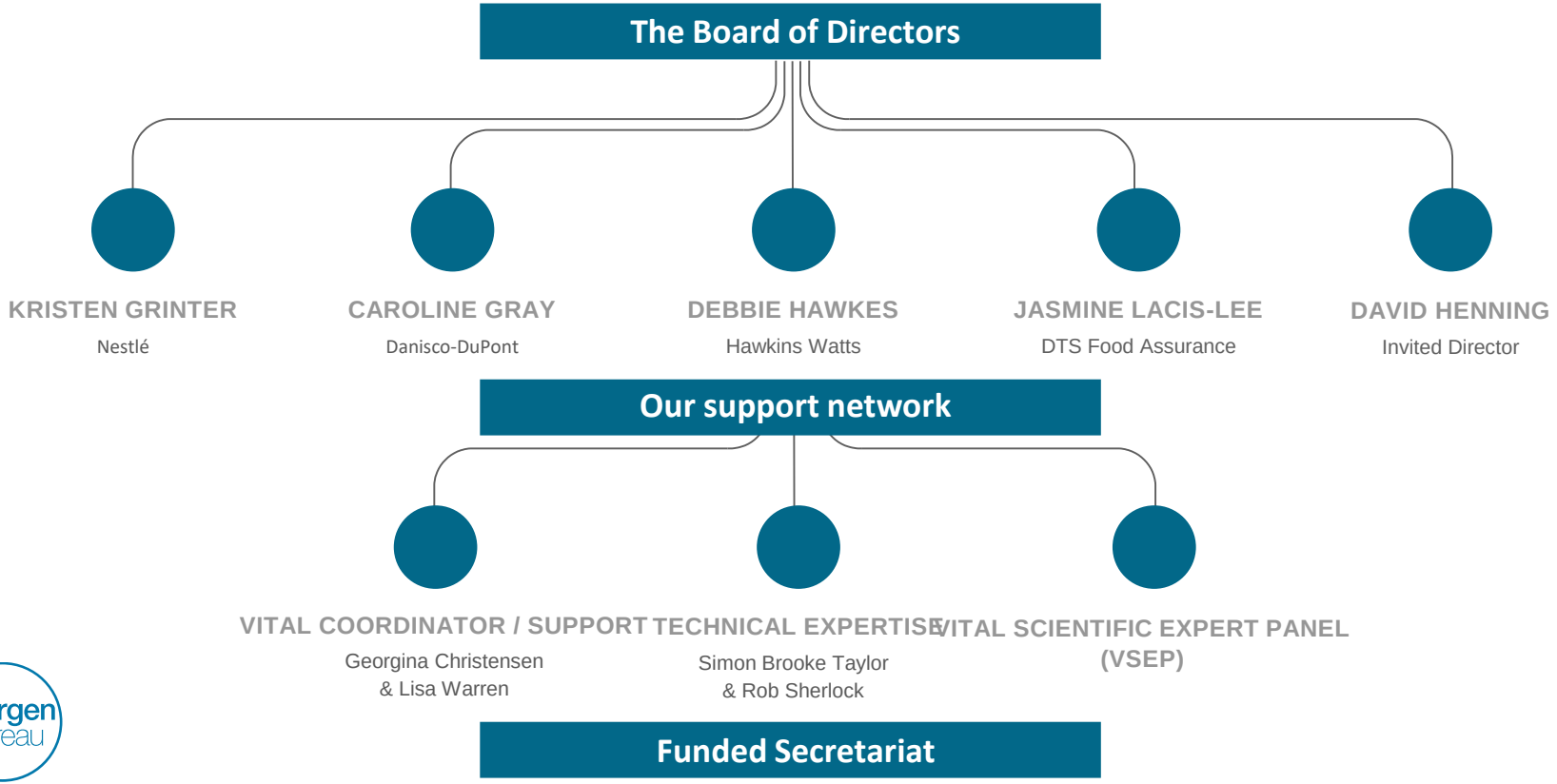
ALLERGEN BUREAU MANAGEMENT

Allergen Bureau ('Not for Profit')

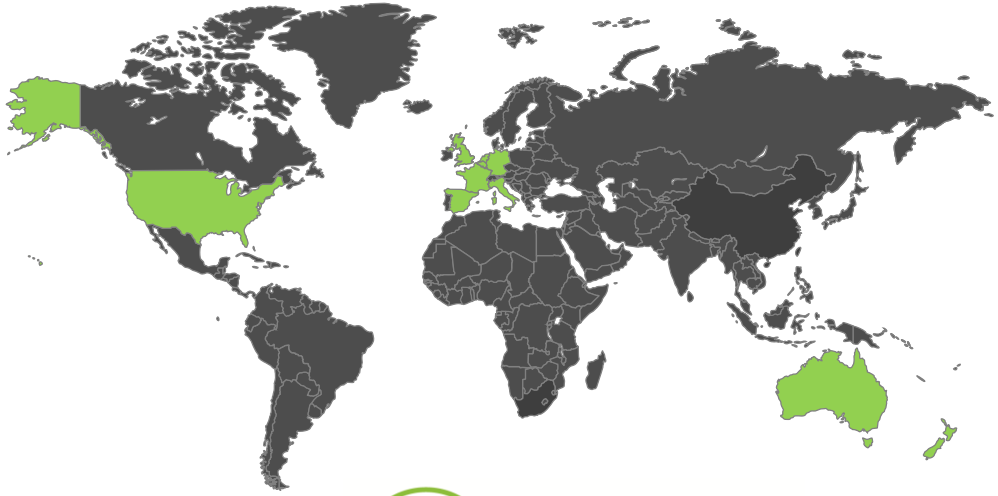


GROWING INTERNATIONAL INTEREST

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



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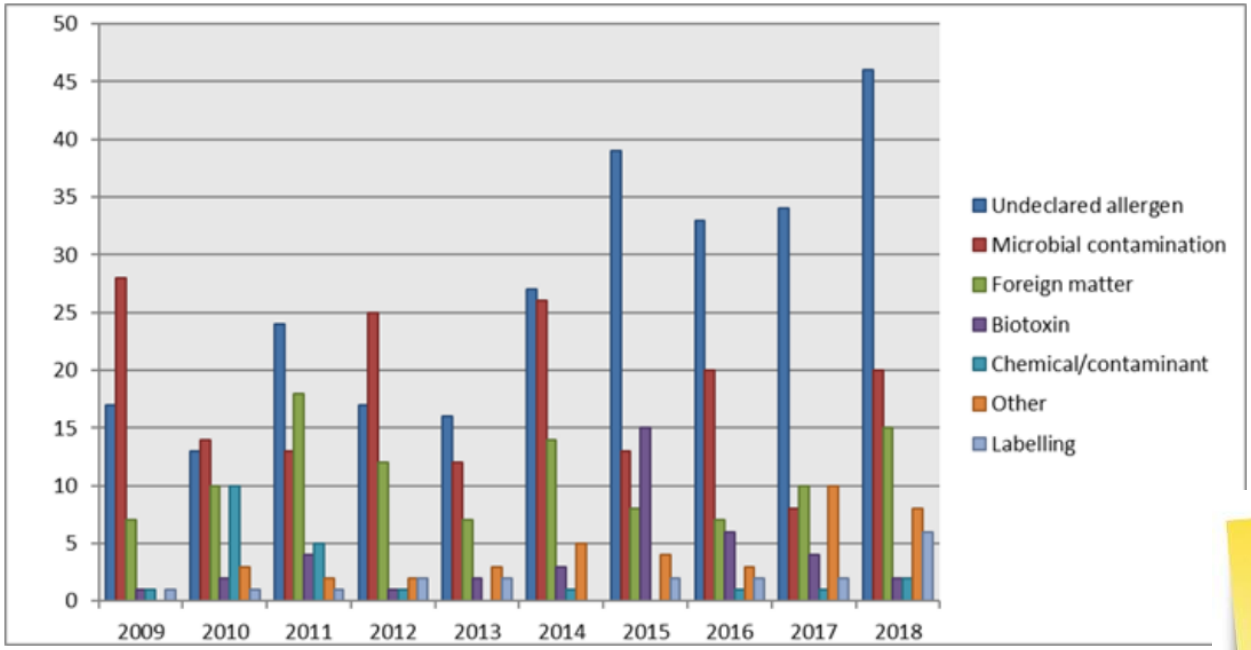
VITAL

WHY SHOULD THE FOOD INDUSTRY MANAGE ALLERGENS?

WHY SHOULD THE FOOD INDUSTRY MANAGE FOOD ALLERGENS?

- protect allergic consumers
- food safety necessity
- consumers depend on food that is labelled correctly
- legal requirement for declaring food allergens
- costly to have non-compliance, allergen issues with consumers, recalls, withdrawals, re-labelling

FOOD RECALLS IN AUSTRALIA (2009 – 2018)



39% of recalls in this period are due to undeclared allergens

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Case Study

RETAIL

Coconut drink importer fined over labelling after child's death

SYDNEY 2015

A Sydney food importer whose coconut drink has been linked to the death by anaphylactic reaction of a 10-year old boy from Melbourne has been fined $18,000.

The company Narkena Pty Ltd from western Sydney had previously pleaded guilty to three charges relating to packaging and labelling of the drink called Greentime Natural Coconut imported from Taiwan.

INTENTIONALLY & UNINTENTIONALLY ADDED ALLERGENS

INTENTIONALLY ADDED ALLERGENS

- intrinsic part of the ingredient materials for a product
- added to foods via ingredients, compound ingredients, additives & processing aids

Example:
A cake has ingredients Eggs and Milk.
Eggs & Milk are intentionally added allergens in the cake.

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UNINTENTIONALLY ADDED ALLERGENS

- a residue or other trace amount of an allergenic food that is unintentionally incorporated into another food
- present despite conditions of Good Manufacturing Practice (GMP)
- can occur at any point along the food chain from primary production, ingredients and through the manufacturing process

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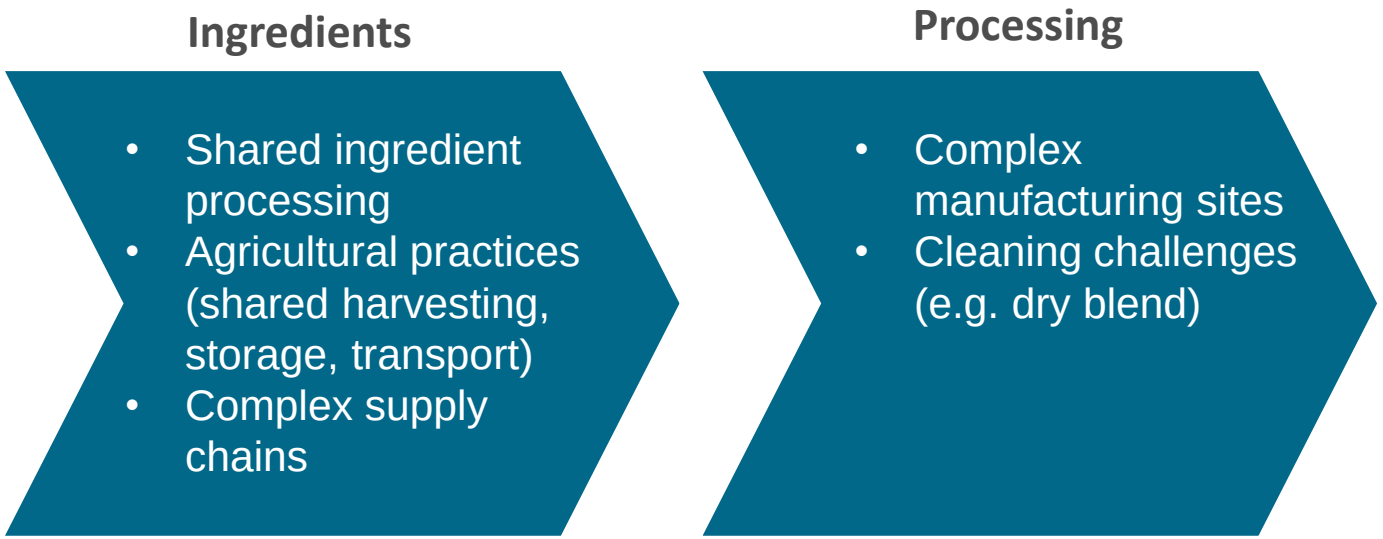
	Intentionally Added Allergens	Unintentionally Added Allergens
Also called....	ingredient, compound ingredient, additive, processing aid	Cross contact
Defined in legislation	Yes	No
Mandatory declaration	Yes Usually in the ingredient list	No - voluntary
Labelling declaration example	Ingredients: Rice, **Egg**, Carrots, **Milk**. **Contains: Egg, Milk**	**•May be present: soy.** **•May contain: soy.** **•Made in a facility that also processes soy.**
Thresholds applicable	No	Yes

HOW DO CROSS CONTACT ALLERGENS GET INTO FOOD?



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INTRODUCTION TO AUSTRALIAN (AND OTHER WESTERN) CONSUMERS

FOOD ALLERGY IS COMMON

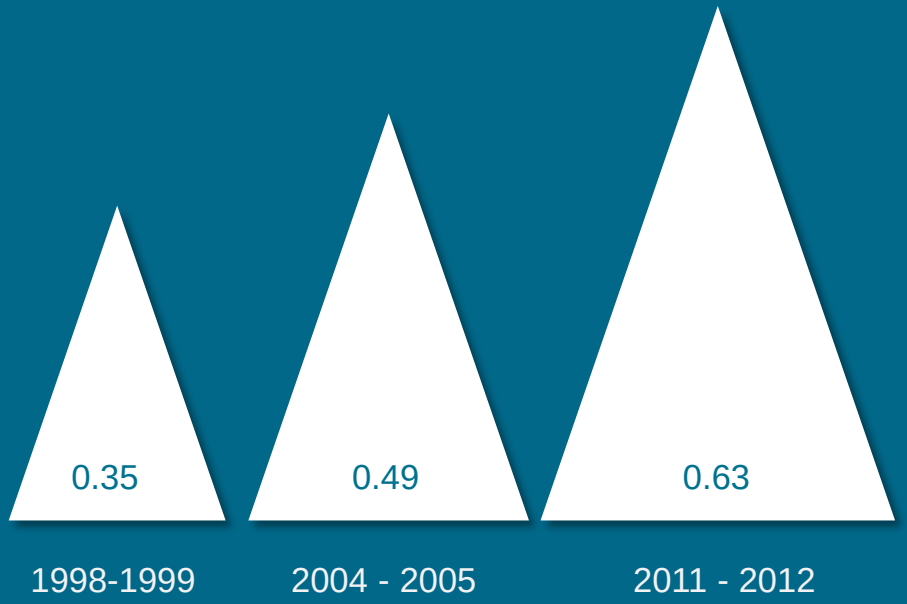
Rapid increase in food allergic disease in last 30 years in mainly Western countries

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

Food allergy rates are increasing in Australia and New Zealand



Mullins JACI 2015 Time trends in Australian hospital anaphylaxis admissions in 1998-1999 to 2011-2012.

AUSTRALIAN CONSUMERS:

Packaged food is as a large portion of the diet

China

Australia

Source: http://www.atchuup.com/a-week-of-groceries-around-the-world/

WHY IS ACCURATE LABELLING IMPORTANT?

- Food allergic patients must avoid foods with the allergen to which they are sensitive
- Products must be labelled accurately
- Food allergic patients are managed by their doctor or specialist – doctors are confused too!
- Many people avoid certain foods for (perceived) health (e.g. Gluten)

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PREDOMINANT FOOD ALLERGENS (WESTERN)

Children

- Peanut
- Tree nuts
- Soy
- Milk
- Eggs
- Wheat

Adults

- Peanuts
- Tree nuts
- Crustacea (shrimp, crab, lobster)
- Fish
- Sesame

WHY WAS THE VITAL PROGRAM DEVELOPED?

FOOD REGULATIONS SILENT ABOUT CROSS CONTACT ALLERGENS

- No information in Australia about how to label allergens which were present inadvertently – the Allergen Bureau counted 42 different statements
- Cross contact statements were applied to products with no consistency in wording or risk assessment
- Confusion for allergic consumers!
- Concern for food manufacturers!
- The industry needed a consistent way to identify, manage and label cross contact allergens

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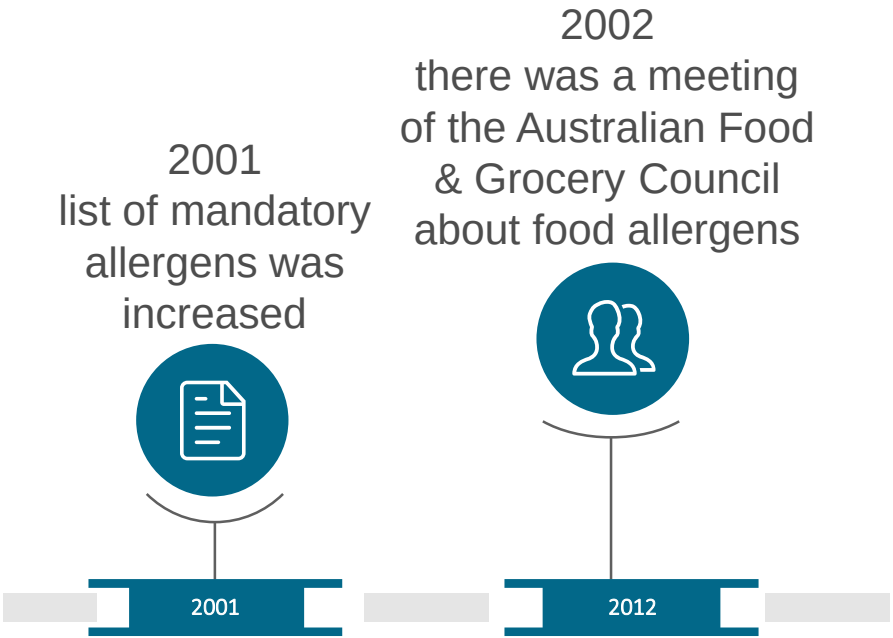
WHY WAS THE VITAL PROGRAM DEVELOPED?



- Australian food industry met and planned to research food allergens and make their research publically available
- From this collaborative, industry process, the first version of the VITAL Program, and the Allergen Bureau were formed.

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THE VITAL PROGRAM

VOLUNTARY INCIDENTAL TRACE ALLERGEN LABELLING

VITAL

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

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

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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

Allergen Bureau

THE VITAL PROGRAM

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 statement**

The VITAL precautionary statement is:
May be present: allergen x, allergen y.

VITAL PROGRAM OVERALL 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.*

APPLYING THE VITAL PROGRAM DEMONSTRATES…

- your due diligence with regard to understanding the risk of cross contact allergens from all ingredients used and from the manufacturing process
- your commitment to consumers
- your commitment to consistent risk review and allergen labelling across industry

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VITAL AND LEGAL PROTECTION

VITAL does not directly offer any legal protection

HOWEVER, the correct implementation of VITAL provides evidence that a company has used best practice in regard to managing allergens

It is the application of due diligence that allows a defence or at least mitigation in product liability actions

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VITAL AND LEGAL PROTECTION

Including an allergen precautionary statement on the label **does not mean** that you no longer have to control that allergen

Allergen management procedures should be followed to eliminate (or when that is not possible reduce) the possibility allergen cross contact

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THE VITAL PROGRAM TOOLS

- VITAL Procedure
- Decision Tree
- Interactive VITAL Action Level Grid
- VITAL Online (web-based calculator)
- VITAL training materials
- Guidance documents & FAQs

Q: WHAT DO YOU NEED TO START VITAL?

***A:** An established and robust Allergen Management Plan*

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

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WHY DO ALLERGEN RISK ASSESSMENT?

Carrying out a VITAL risk assessment using the tools provided ensures a food company understands…

- the allergen status of its ingredients
- impact of allergen cross contact from processing
- the allergen status of its finished products

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Allergen risk assessment contributes towards due diligence

WHAT IS THE SCIENCE BEHIND VITAL?

The VITAL Program determines appropriate precautionary labelling based on risk by using Action Levels that are underpinned by **scientific evidence**

A collaboration of international food allergen experts established the science that underpins the VITAL Program

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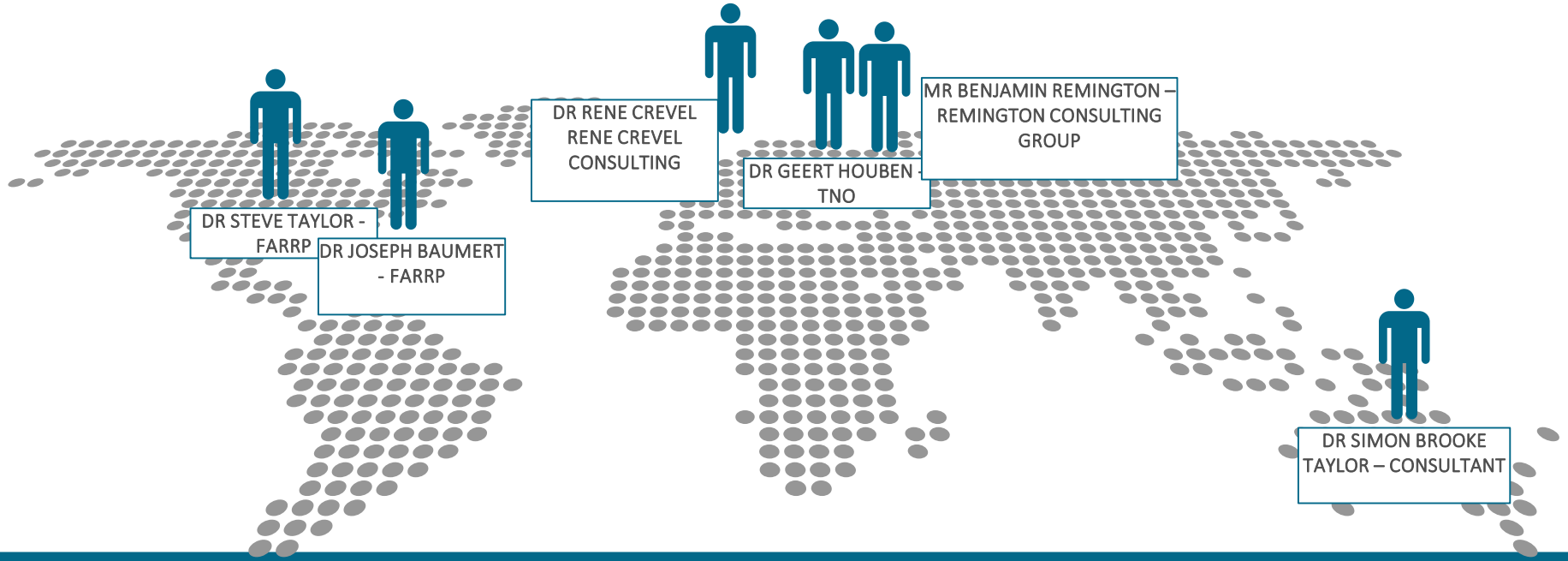

MEET THE VSEP PANEL

Dr Steve Taylor - Food Allergy Research & Resource Program (FARRP) (USA)

Dr Joseph Baumert (FARRP)

Mr Benjamin Remington (REMINGTON CONSULTING GROUP B.V. & adjunct faculty member of FARRP, formerly of TNO) (NL)

Dr Geert Houben - Program Manager Food Safety, Netherlands Org. for Applied Scientific Research (TNO) (NL)

Dr Rene Crevel (RENE CREVEL Consulting Ltd, formerly of Allergy & Immunology, Unilever) (UK))

Dr Simon Brooke Taylor (Food Safety & Risk Analysis Consultant, Allergen Bureau) (AUS)

VITAL 3.0 : SIGNIFICANT UPDATE IN 2019

VITAL 2.0 → **VITAL 3.0**

1

Increased data set from 1815 data points (2011) to 3417 data points (2019)

2

New statistical modelling approach used: Stacked Model Averaging

3

More information www.allergenbureau.net/vital/vital-science/

VITAL 3.0 launches 24th October 2019

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THE VITAL SCIENTIFIC EXPERT PANEL (VSEP)

VSEP

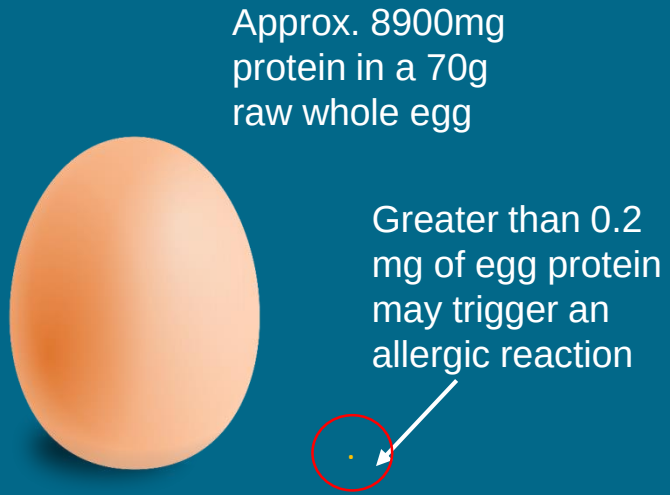
- over 3400 clinical data points were collated
- used statistical modelling called “Stacked Model Averaging” which incorporated 5 different statistical models to produce a single “averaged” distribution
- Reference Doses are set using ED01 – the Eliciting Dose of an allergen at which 1% of the allergic population would be likely to react

World leaders in VSEP Food Allergy Research

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

Cereals containing gluten *	0.7
Barley	0.7
Rye	0.7
Oats	0.7
Spelt	0.7
Wheat	0.7
Crustacea	25
Egg	0.2
Fish	1.3
Lupin	2.6
Milk	0.2
Peanut	0.2
Mollusc	None set
Sesame	0.1
Soy	0.5
Tree nuts (cashew, pistachio)	0.05
Cashew	0.05
Pistachio	0.05
Tree nuts (walnut, pecan)	0.03
Walnut	0.03
Pecan	0.03
Tree nuts	0.1
(almond, Brazil nuts, hazelnuts, Macadamia nuts, pine nuts)	
Almonds	0.1
Brazil nuts	0.1
Hazelnuts	0.1
Macadamia nuts	0.1
Pine nuts	0.1

*(Action Level transition maximum point is 20ppm)

REFERENCE DOSE

Only applicable for the allergens within the VITAL Action Level Grid

- no Reference Dose for mollusc

Not applicable for people who have heightened sensitivity to food allergens

- foods for infants
- food for special medical purposes

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VALIDATING THE REFERENCE DOSES

J Allergy Clin Immunol. 2017 May;139(5):1583-1590. doi: 10.1016/j.jaci.2017.01.030. Epub 2017 Feb 24.

Peanut Allergen Threshold Study (PATS): Novel single-dose oral food challenge study to validate eliciting doses in children with peanut allergy.

Hourihane JO[1], Allen KJ[2], Shreffler WG[3], Dunngalvin G[4], Nordlee JA[5], Zurzolo GA[6], Dunngalvin A[4], Gurrin LC[7], Baumert JL[5], Taylor SL[5].

- 378 people aged 1-18yrs participated
- they ate **1.5mg peanut protein** = 6mg whole peanut = 1/100th of a peanut kernel = ED05
- Reference Dose for peanut in the VITAL Program is 0.2 mg
  So, in this study, the peanut-allergic participants were fed an amount of peanut protein that is more than **7 times greater than the Reference Dose**.

378 people aged
1-18yrs participated

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VALIDATING THE REFERENCE DOSES

- 8 (2.1%) people met the criteria of an objective and likely allergic reaction. (The reactions were mild.) This is less than the predicted 5%
- These results suggest that the use of 0.2mg peanut protein in the VITAL Program is conservative
- Studies repeating this experiment & validation studies for other allergens are planned & are helpful to support the VITAL Program

8 people met the criteria of an objective and likely allergic reaction.

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ACTION LEVELS

Are the concentrations (of protein) which define the labelling outcomes from a cross contact allergen

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

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ACTION LEVELS GUIDE LABELLING RECOMMENDATIONS

Action Level 1
a low concentration of allergen protein and a low chance of adverse reaction.

No precautionary statement is required.

Action Level 2
a significant concentration of allergen protein and a significant chance of adverse reaction.

A precautionary statement is required.

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EXAMPLE –

CALCULATING ACTION LEVELS FOR PRODUCT WITH PEANUT CROSS CONTACT

Peanut Reference Dose = 0.2 mg protein

5g Reference Amount or Serving Size:

(Transition = 0.2 x 1000/5 = 40ppm)

Action Level 1:<40ppm

Action Level 2:≥40ppm

50g Reference Amount or Serving Size:

(Transition = 0.2 x 1000/5 = 4ppm)

Action Level 1 :<4ppm

Action Level 2 :≥4 ppm

REFERENCE AMOUNT

The Reference Amount is used to calculate the quantity of cross contact allergen a person would consume in a typical eating occasion.

Can significantly affect Action Levels!

What about foods or ingredients that have no specific Reference Amount?

VITAL ACTION LEVEL GRID

A table stating the Action Level transition points (in ppm total protein) of each allergen for a specific product

VITAL
an initiative of the Allergen Bureau

VITAL Action Level Grid Report

Substances	Reference Dose(mg)	Action Level (ppm) where reference amount/serving size is 80g	
		Action Level 1	Action Level 2
Cereals containing gluten (Total)	0.7	< 8.75 ppm	≥ 8.75 ppm
Barley	0.7	< 8.75 ppm	≥ 8.75 ppm
Oats	0.7	< 8.75 ppm	≥ 8.75 ppm
Rye	0.7	< 8.75 ppm	≥ 8.75 ppm
Spelt	0.7	< 8.75 ppm	≥ 8.75 ppm
Wheat	0.7	< 8.75 ppm	≥ 8.75 ppm
Crustacea	25	< 312.5 ppm	≥ 312.5 ppm
Eggs	0.2	< 2.5 ppm	≥ 2.5 ppm
Fish	1.3	< 16.25 ppm	≥ 16.25 ppm
Lupin	2.6	< 32.5 ppm	≥ 32.5 ppm
Milk	0.2	< 2.5 ppm	≥ 2.5 ppm

Source: VITAL Online

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VITAL ACTION LEVEL GRID

Reference Dose

Action Level 1

Action Level 2

- The Action Level Grid must be calculated for each individual product

- The calculation uses the Reference Amount and the allergen's Reference Dose

VITAL Action Level Grid Report

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Fish	1.3	< 16.25 ppm	≥ 16.25 ppm
Lupin	2.6	< 32.5 ppm	≥ 32.5 ppm
Milk	0.2	< 2.5 ppm	≥ 2.5 ppm
Molluscs			
Peanut	0.2	< 2.5 ppm	≥ 2.5 ppm
Sesame	0.1	< 1.25 ppm	≥ 1.25 ppm
Soy	0.5	< 6.25 ppm	≥ 6.25 ppm
Tree nuts (Cashews & Pistachios) (Total)	0.05	< 0.62 ppm	≥ 0.62 ppm
Pistachio nuts	0.05	< 0.62 ppm	≥ 0.62 ppm
Cashews	0.05	< 0.62 ppm	≥ 0.62 ppm
Tree nuts (Walnut & Pecans) (Total)	0.03	< 0.38 ppm	≥ 0.38 ppm
Walnuts	0.03	< 0.38 ppm	≥ 0.38 ppm
Pecans	0.03	< 0.38 ppm	≥ 0.38 ppm
Tree nuts (Almond, Brazil nuts, Hazelnuts, Macadamia nuts, Pine nuts) (Total)	0.1	< 1.25 ppm	≥ 1.25 ppm
Almonds	0.1	< 1.25 ppm	≥ 1.25 ppm
Brazil nuts	0.1	< 1.25 ppm	≥ 1.25 ppm
Hazelnuts	0.1	< 1.25 ppm	≥ 1.25 ppm
Macadamia nuts	0.1	< 1.25 ppm	≥ 1.25 ppm
Pine nuts	0.1	< 1.25 ppm	≥ 1.25 ppm

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THE VITAL PROGRAM: EXAMPLE

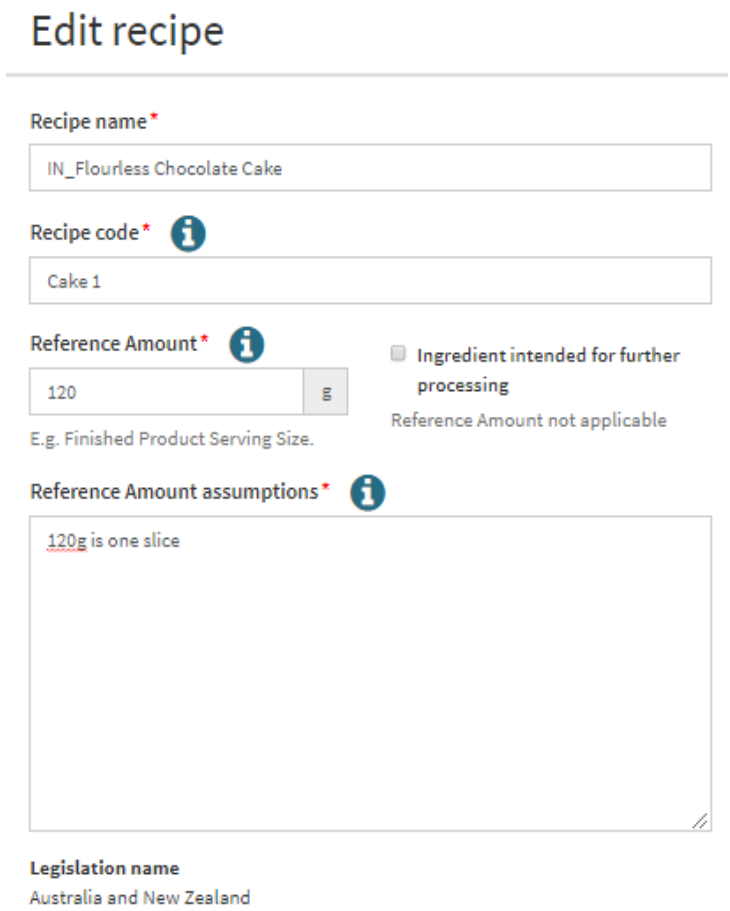
- Recipe & Raw Material Allergen Status Flourless Chocolate Cake
- Yield 85% (Water loss is 15%)
- Serving size is 120g

			Allergen Status	
Reference	Raw Material	Ingoing %	Intentional	Cross Contact
RM1	Liquid whole egg	30	Egg	
RM2	Cooking fat	30		Milk (3ppm), fish (80ppm)
RM3	Sugar	30	None declared	
RM4	Dark compound chocolate	10	Soy	Peanut pieces (particulate)

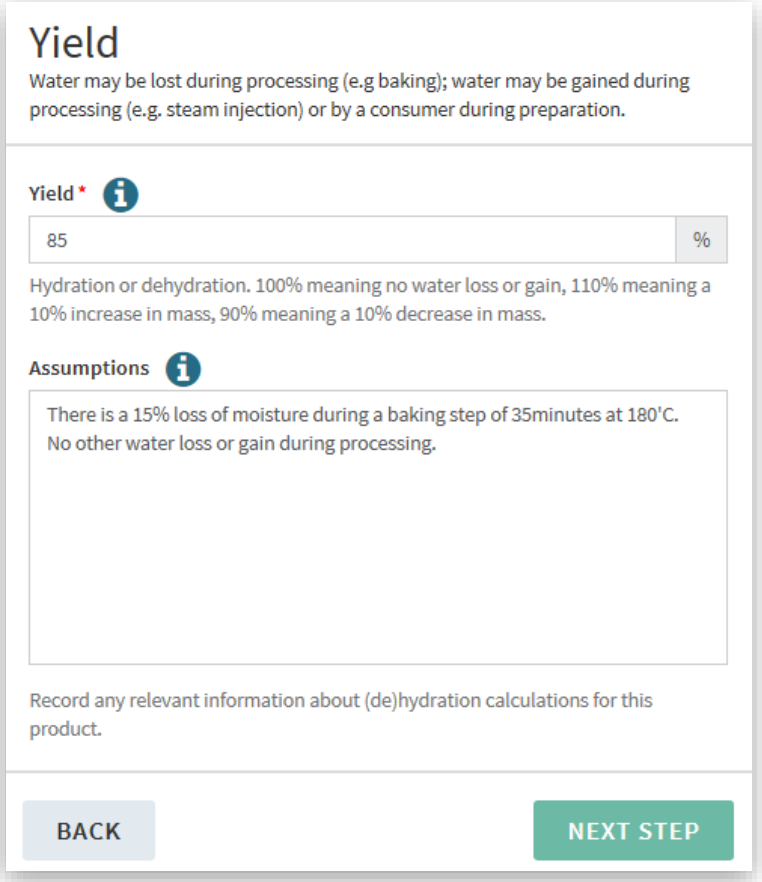
Processing Cross Contact
Hang-up is 2kg
Batch size exposed to hang-up is 200kg

Raw Vegan Cake contains whole sesame seeds
Honey Almond Cake contains almond flour (40% almond in cake, 20.4% protein in almond)

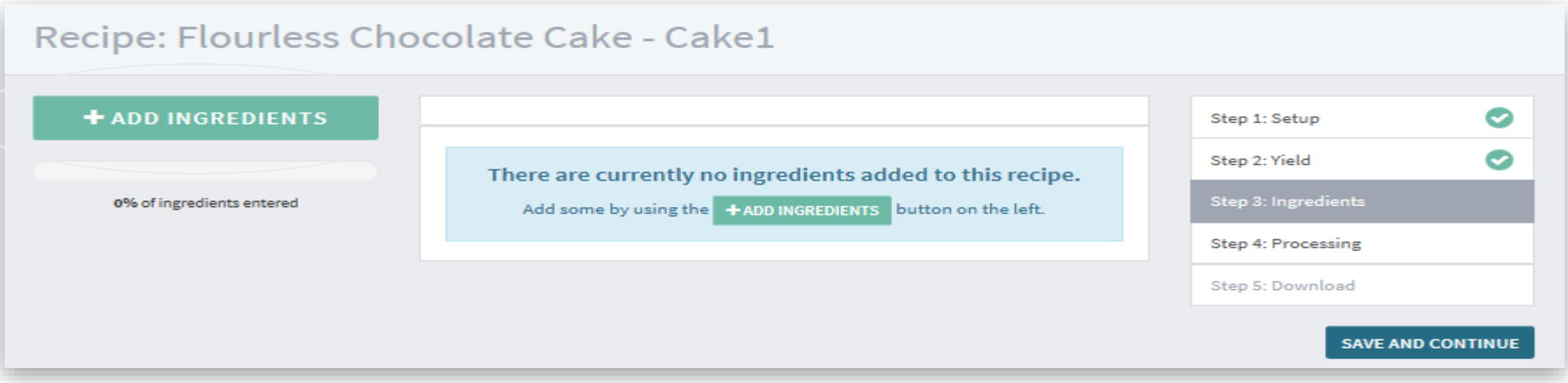
Step 1: Setup


Edit recipe
Recipe name*
IN_Flourless Chocolate Cake
Recipe code*
Cake 1
Reference Amount*
120
g
E.g. Finished Product Serving Size.
Ingredient intended for further processing
Reference Amount not applicable
Reference Amount assumptions*
120g is one slice
Legislation name
Australia and New Zealand

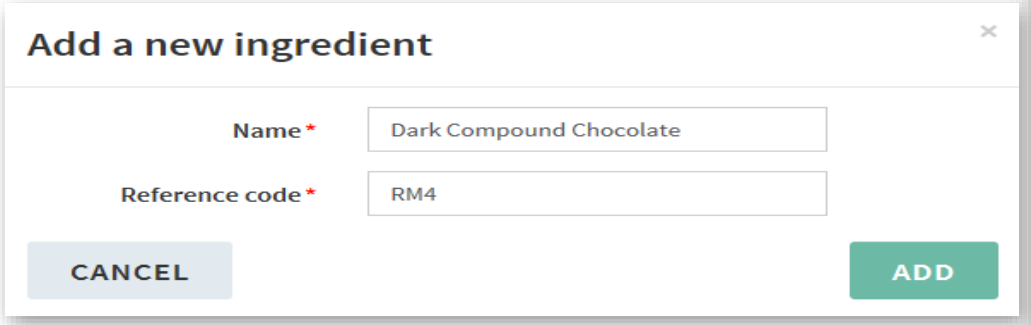
Enter in the yield

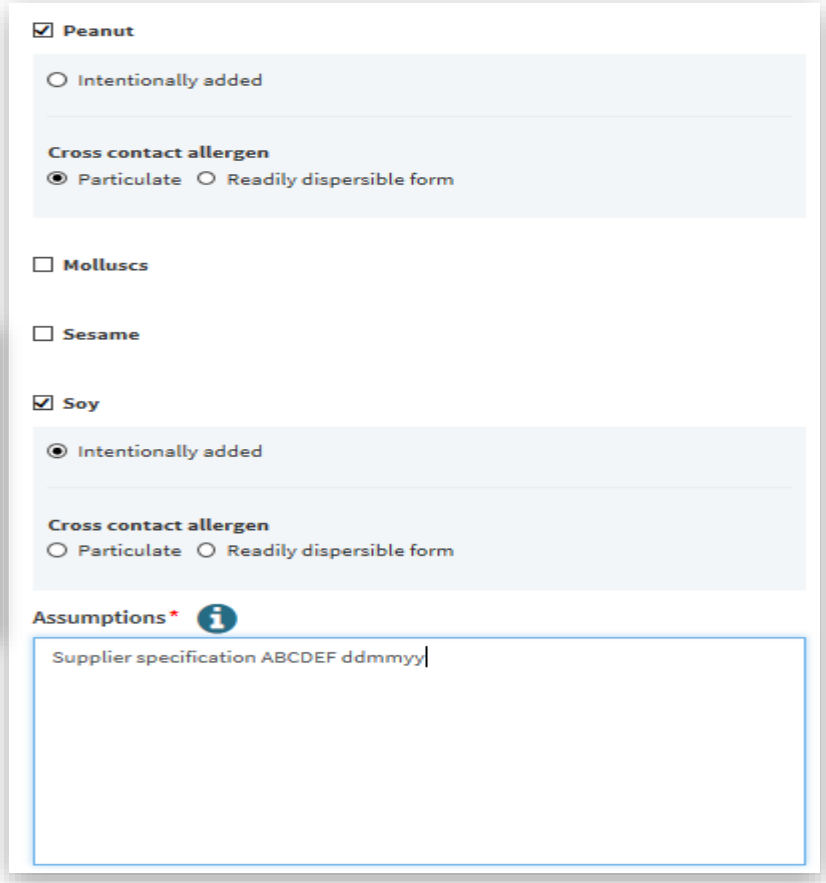


Add ingredients to the recipe

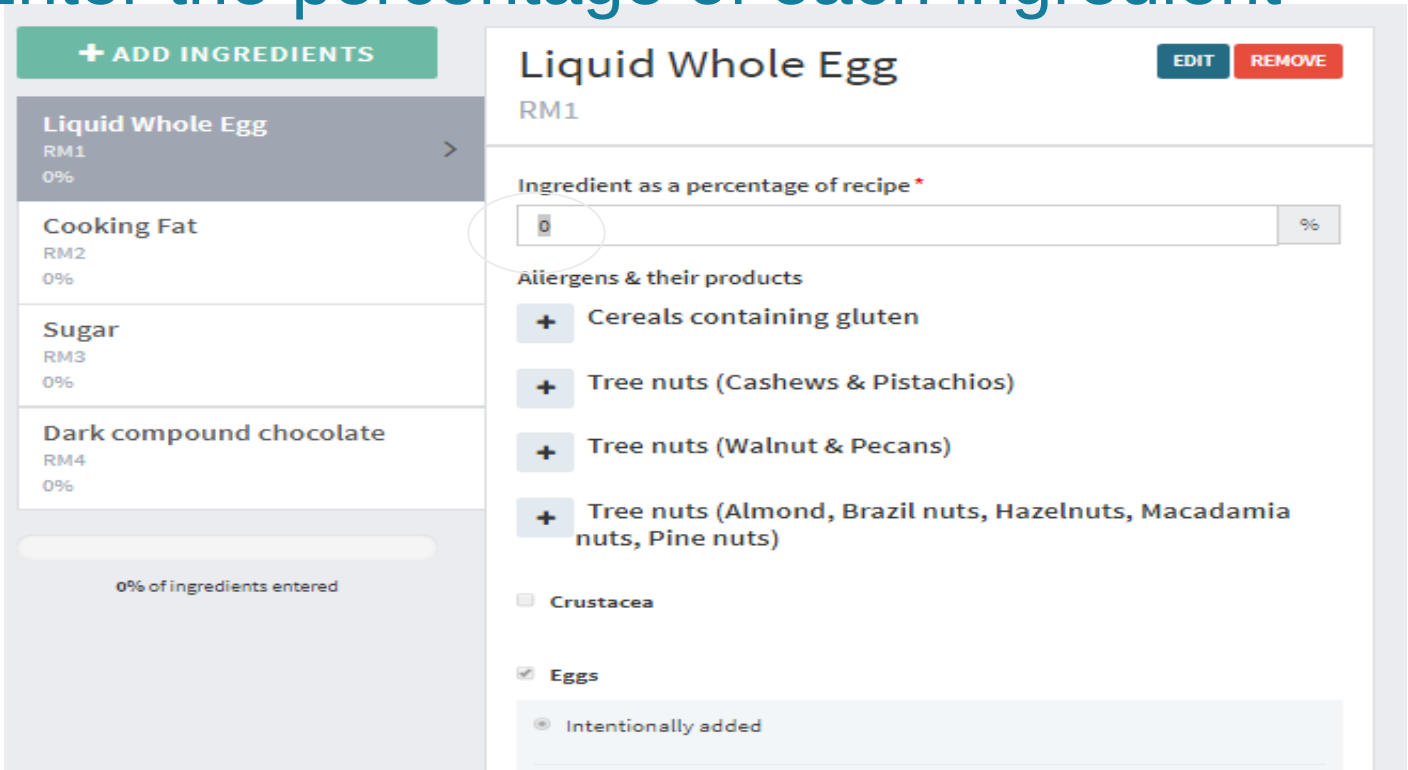


Enter the allergen information for RM4

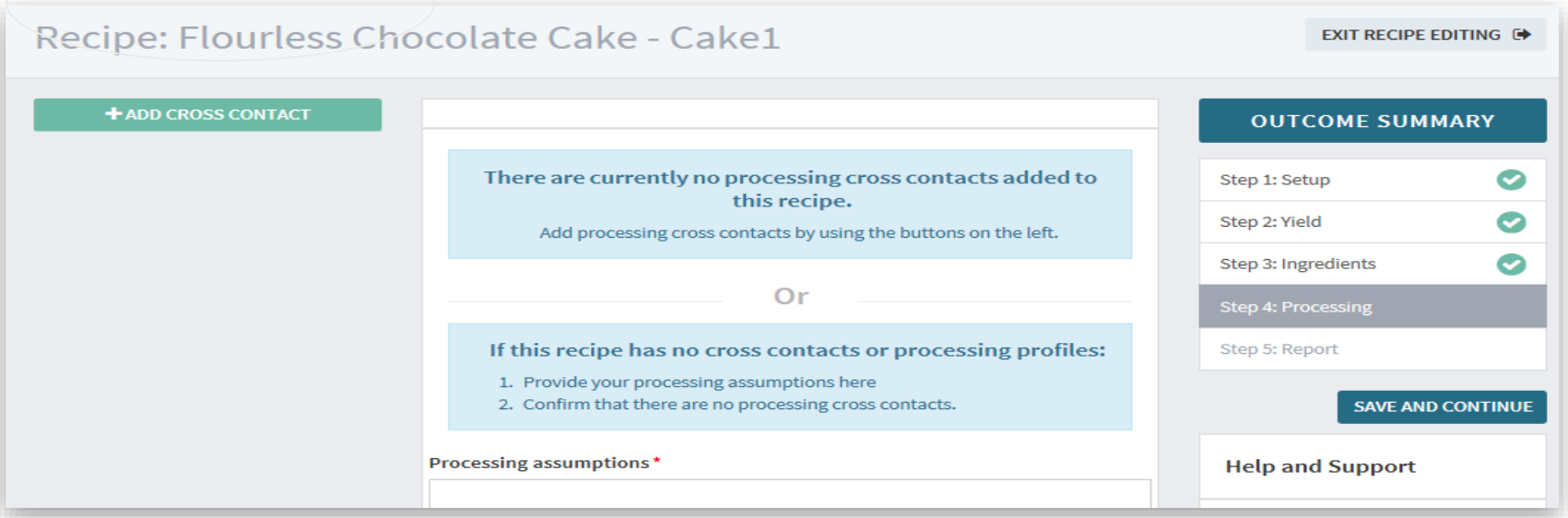




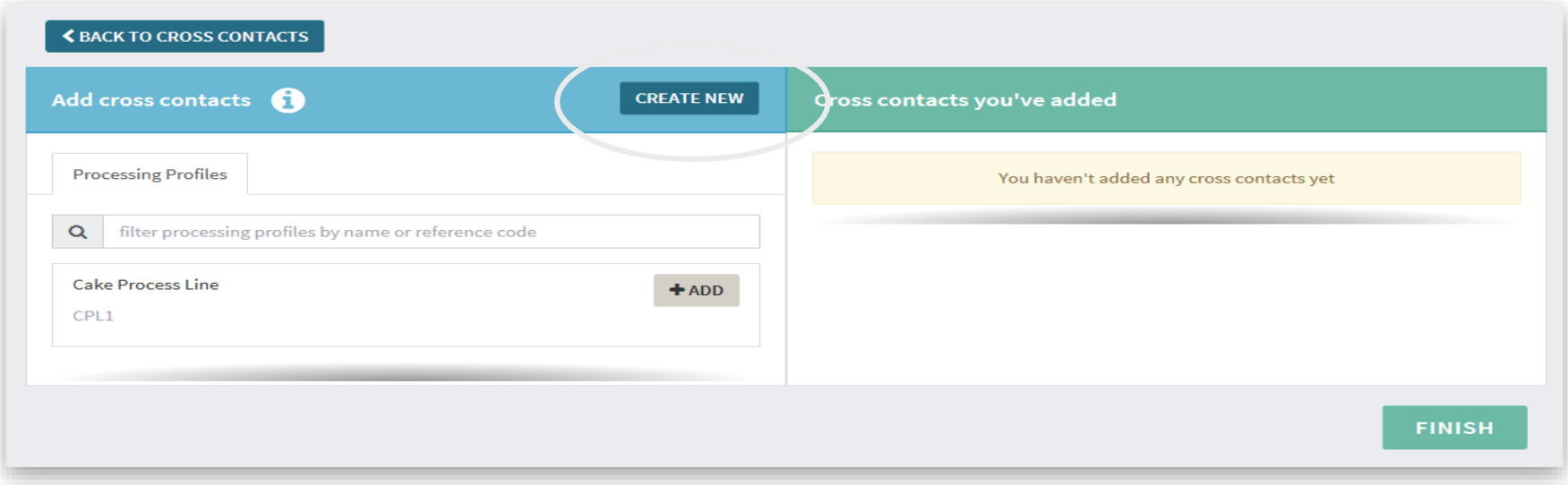
Enter the percentage of each ingredient

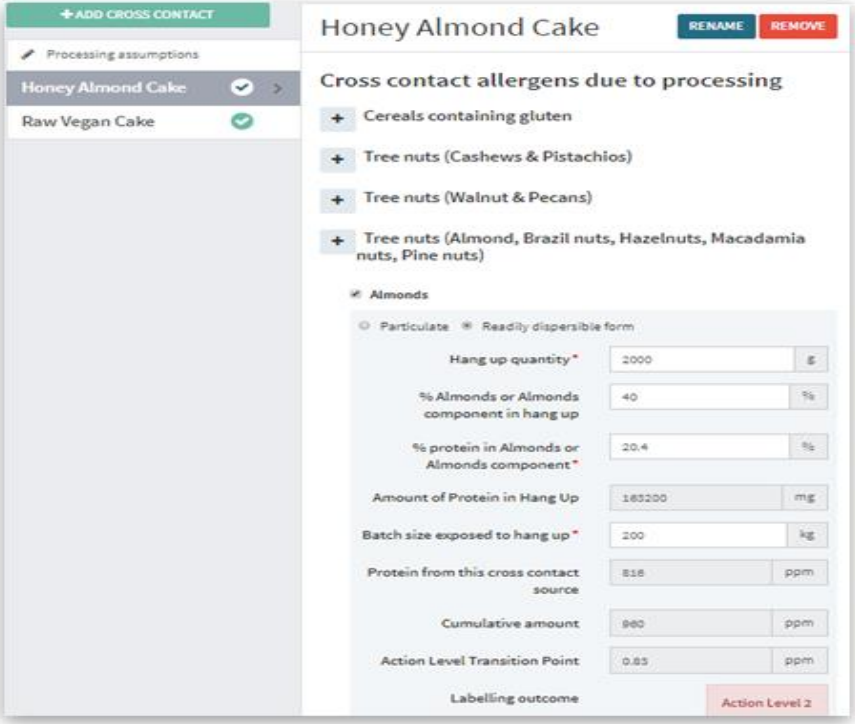


Add cross contact allergens due to processing



Select “Create New”




+ ADD CROSS CONTACT
Processing assumptions
Honey Almond Cake
Raw Vegan Cake
Honey Almond Cake
RENAME
REMOVE
Cross contact allergens due to processing
+ Cereals containing gluten
+ Tree nuts (Cashews & Pistachios)
+ Tree nuts (Walnut & Pecans)
+ Tree nuts (Almond, Brazil nuts, Hazelnuts, Macadamia nuts, Pine nuts)
Almonds
Particulate
Readily dispersible form
Hang up quantity* 2000 g
% Almonds or Almonds component in hang up 40 %
% protein in Almonds or Almonds component* 20.4 %
Amount of Protein in Hang Up 163200 mg
Batch size exposed to hang up* 200 kg
Protein from this cross contact source 816 ppm
Cumulative amount 960 ppm
Action Level Transition Point 0.83 ppm
Labelling outcome
Action Level 2

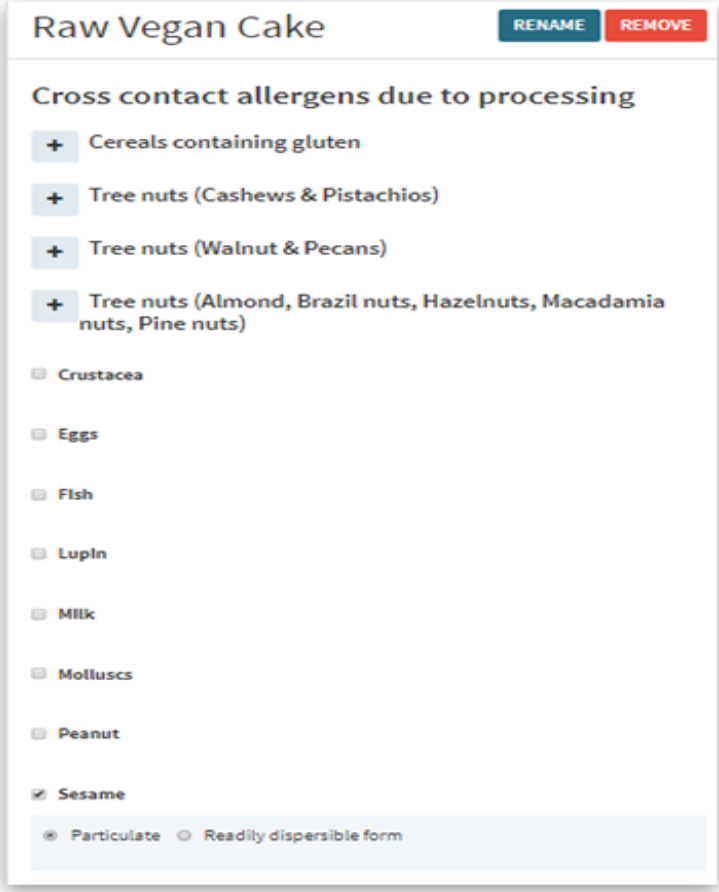
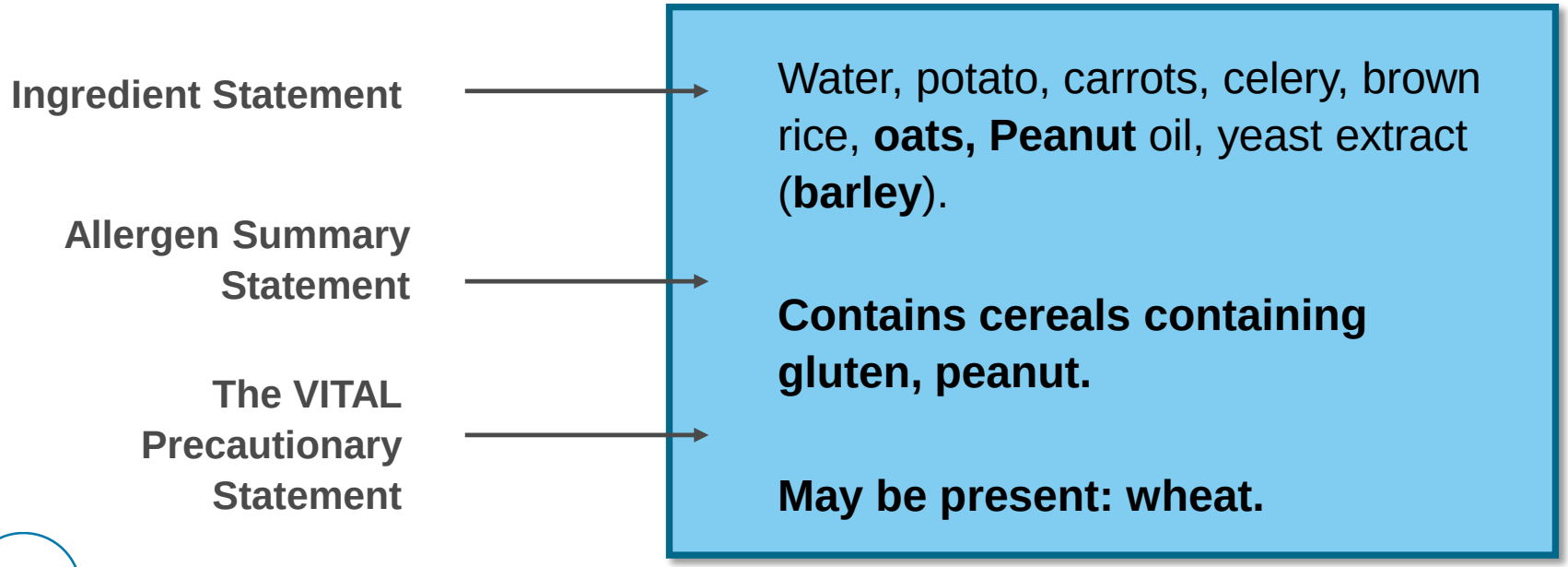

Raw Vegan Cake
RENAME
REMOVE
Cross contact allergens due to processing
+ Cereals containing gluten
+ Tree nuts (Cashews & Pistachios)
+ Tree nuts (Walnut & Pecans)
+ Tree nuts (Almond, Brazil nuts, Hazelnuts, Macadamia nuts, Pine nuts)
Crustacea
Eggs
Fish
Lupin
Milk
Molluscs
Peanut
Sesame
Particulate
Readily dispersible form

Table 1: Summary of labelling outcomes

Reference Amount information
Reference Amount: 120g
Assumptions: 120g is one slice

Substances	Reference Dose (mg)	Action Level 1	Action Level 2	Cross contact amount		Labelling outcome
				Particulate	Readily dispersible (ppm)	
Eggs	0.2	< 1.67 ppm	≥ 1.67 ppm			Intentionally added
Fish	1.3	< 10.83 ppm	≥ 10.83 ppm		28.235294	Action Level 2
Milk	0.2	< 1.67 ppm	≥ 1.67 ppm		1.058824	Action Level 1
Peanut	0.2	< 1.67 ppm	≥ 1.67 ppm	Yes		Action Level 2
Sesame	0.1	< 0.83 ppm	≥ 0.83 ppm	Yes		Action Level 2
Soy	0.5	< 4.17 ppm	≥ 4.17 ppm			Intentionally added

EXAMPLE OF ALLERGEN LABELLING USING VITAL



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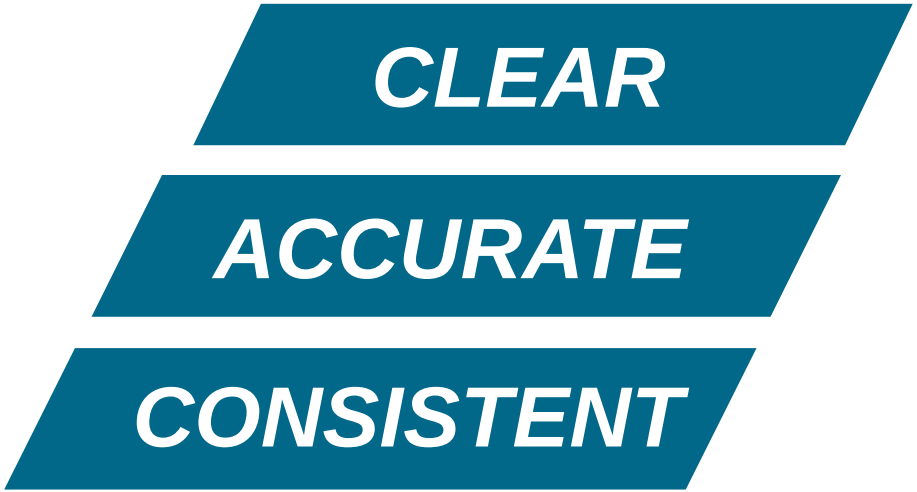
VITAL PRECAUTIONARY STATEMENT



- promotes consistency in allergen labelling
- standardised format
- clear, accurate and relevant
- assists in making safer food choices

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THE VITAL PROGRAM IS NOT:

- For **INTENTIONALLY** added allergens
- For infants and ‘foods for special medical purposes’ who have heightened sensitivity
- For “allergen-free” claims
- To justify poor allergen management practices (allergens must be controlled, even if they are declared in a precautionary allergen label)
- A government program
- Designed to be used with analytical analysis (it is designed to be used with physical risk assessment)

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THE VITAL PROGRAM IS:

- Helpful to determine when a precautionary allergen label should be used e.g. May be present: allergen x, allergen y
- A precautionary allergen label should only be used when the cross contact allergen cannot be eliminated.
- When a precautionary allergen label is used then:
    - The allergen should be reduced and controlled at the lowest level practicable
    - The allergen should continue to be controlled

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WHAT ABOUT ALLERGEN TESTING?

- If you use allergen testing, a laboratory specialising in allergen testing should be used
- Limitations of allergen testing are many E.g. only tests a tiny sample (one gram)
- When would you use allergen testing – validation of an assumption in your allergen management plan
  For example: to check cleaning of equipment between different products

RESOURCES

INTRODUCING THE VITAL STANDARD

- An auditable VITAL Scheme under ISO 17065
- Designed as an extra module for GFSI-recognised certified sites with HACCP based Allergen Management Programs
- VITAL certification is product specific
- Products certified under the VITAL Standard can use a VITAL logo
- Similar but not identical to the VITAL Program
- For more information, see allergenbureau.net

ALLERGEN RISK REVIEW WEBSITE

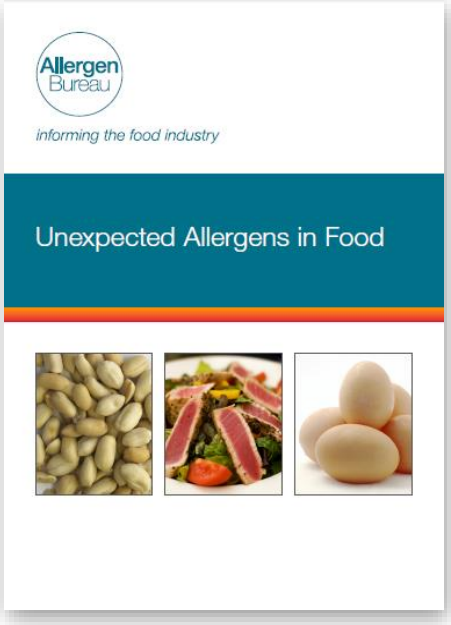
- detailed information and guidance for conducting each aspect of allergen risk review
- includes each aspect that an allergen risk review should address
- use ‘Factory Map’ to navigate
- updated regularly

www.allergenbureau.net/risk-review/

ALLERGEN BUREAU RESOURCES

The **Unexpected Allergens in Food** is a useful resource to identify allergens

Beta-carotene	Does it contain tocopherols and what are they derived from (e.g. **soy**). Is it microencapsulated? If so, is the capsule derived from **fish**?
Beta-galactosidase	Does it contain **milk**?
Beverage Whitener	Does it contain **wheat**, maize, **casein** etc?
Bran	Does it contain **wheat**, **oats**, **rye**, **barley**, **spelt**?
Breadcrumbs	Do they contain **sesame** seeds?
Brine	Check for allergens (e.g. **casein** – milk protein).



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FURTHER ENGAGEMENT AND RESOURCES

The Allergen Bureau

- Visit the website www.allergenbureau.net
- Subscribe to our free monthly Allergen Bureau eNews www.allergenbureau.net/news/
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