

**Allergen
Bureau**

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VITAL[®]

an initiative of the Allergen Bureau

Incidental Trace Allergen Labelling

Roger Bektash & Julie Newlands

'Food Allergens – Science & Challenges'

ILSI SEAR April 2015



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Allergen Bureau

Our Objective

Protecting the allergic consumer
Protecting the food industry

Our Challenge

Consistency & industry alignment

Our Engagement

One Program, Harmonised Action Levels
Scientific Validity, Training and Support





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Why Allergen Bureau?

- Inconsistent use of Allergen Risk Assessment
- Proliferation of cross contact statements across the industry, survey of 350 products in 2005 revealed 42 creative statements!
 - May contain Made on the same line.....
Made in the same factory/facility.....
- Allergic consumers were ignoring cross contact statements
- ***Action levels varied between manufacturers, no consistency***
- SO → Industry Guidance and Standards were needed



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VITAL[®] Experience

- Allergen Bureau – Industry initiative 10 years ago
- Allergen Risk Assessment tool
 - Fundamental, Science based and Pragmatic
 - sound basis for Industry self-regulation
- VITAL - developed ACTION LEVELS
- The VITAL Scientific Expert Panel - VSEP
- VITAL 2.0 – VITAL Online, Training, Identity
- Future – Global engagement



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Allergen Bureau – Who we are

- Established in 2005 due to industry demand, Management Committee, now a 'Not for Profit' organisation
- The food industry are our Members! We have 27 Full Members plus 11 Associate and 8 Individual members
- The Members steer the resources & projects

Our reason for being

Share information & experience in the management of food allergens by developing tools to support industry with the needs of the allergic consumer at the forefront

Allergen Bureau Management

Allergen Bureau ('Not for Profit')

The Board of Directors

- Robin Sherlock (DTS)
- Roger Bektash (MARS)
- Julie Newlands (Unilever)
- Kirsten Grinter (Nestlé)



Our support network

- VITAL[®] Coordinator /support (Georgina Christensen & Lisa Warren)
- Technical expertise (Simon Brooke Taylor & Lyn Davies)
- VITAL[®] Scientific Expert Panel (VSEP)
- Allergen Bureau advisors – (David Henning & Fiona Fleming)

Funded Secretariat

What we Developed - VITAL[®] Program

- Voluntary Incidental Trace Allergen Labelling
- VITAL is a risk assessment process to determine appropriate precautionary labelling which uses action levels underpinned by scientific evidence
- VITAL Program comprises:
 - Is a risk assessment process, decision tree, grid (Action Levels) & calculator;
 - Promotes consistent labelling across industry by prescribing when a precautionary label statement is to be applied / avoided
 - Delivers one consistent labelling approach '**May be present**'
- VITAL was developed *BY* industry *FOR* industry and is voluntary

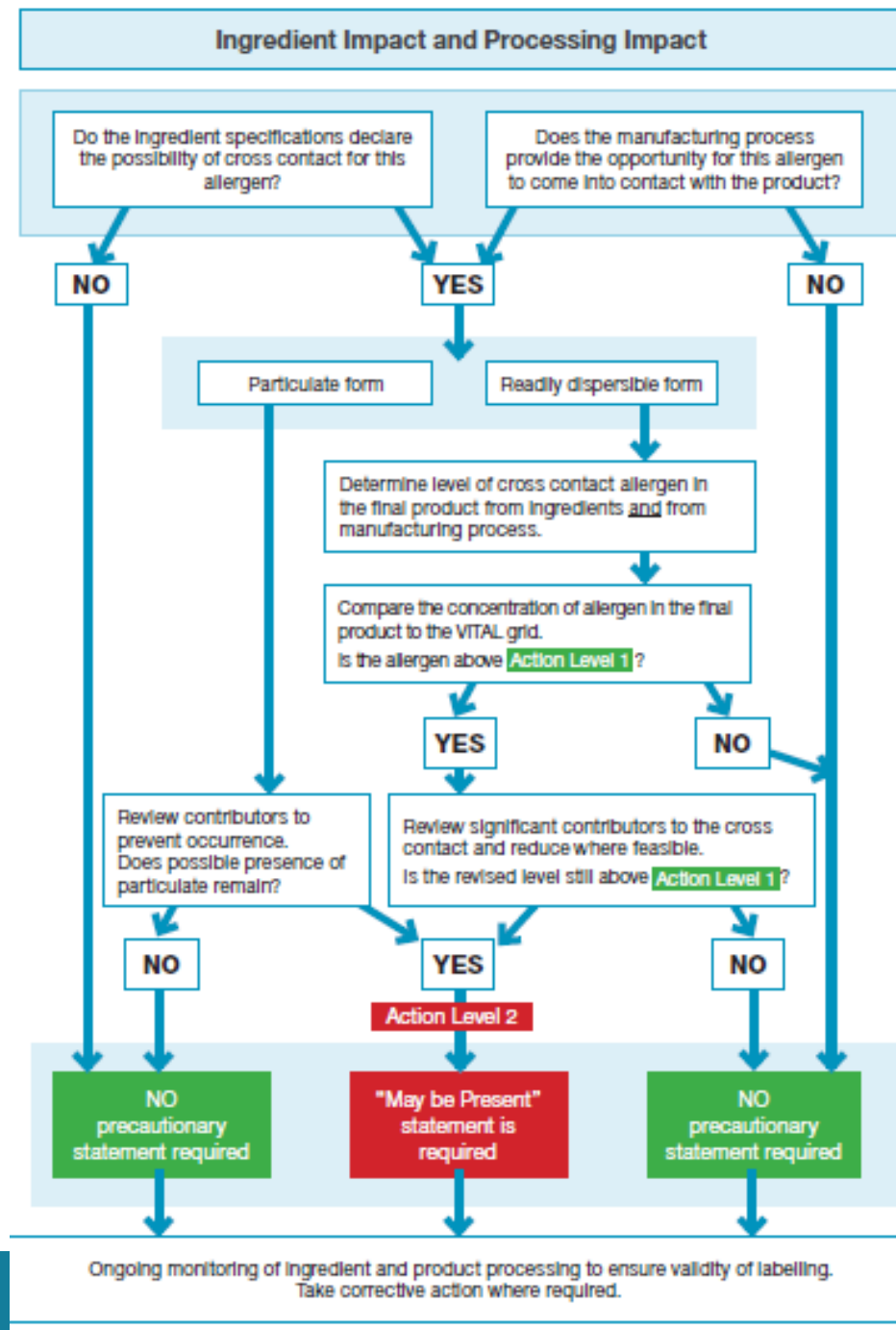


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Allergen Risk Assessment Decision Tree

- the fundamental first step

Ingredient specification already identifies Intended Allergens – in Ingredient List





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Getting to the Heart of VITAL®!

- Knowledge of all parts of the supply chain
 - From raw materials, storage, manufacturing & distribution
 - Harnessing the value of physical risk review and analysis to validate management decisions and assumptions
 - To Communicate accurately and consistently to the allergic consumer



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Scientific Expert Panel

- VSEP collaboration
 - The Allergen Bureau;
 - FARRP (Food Allergy Research and Resource Program (University of Nebraska) and;
 - TNO (Netherlands Organisation for Applied Scientific Research)
- **Action Levels in the VITAL Grid & Underpinning science**





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VITAL[®] Scientific Review

- Established the **Level of acceptable risk**, protection for vast majority
 - Reiterated that exquisitely allergic consumers are not accounted for in VITAL, continue to assume they do not eat processed foods
- Established **Principles to determine Action Levels** that are;
 - Scientifically & clinically sound, defensible and transparent
- Established the **Importance of Portion/Serving Size**
 - Allergen protein expressed as mg of protein as well as a concentration in reference quantities or serving size
- **Review Action Levels**
 - The more data the more confidence in the model
 - Lack of data drives further research

VSEP - Reference Doses

Allergen	Protein Level (mg)
Peanut	0.2
Milk	0.1
Egg	0.03
Hazelnut	0.1 (VITAL – Level used as generic tree nut value)
Soy	1.0 (VITAL – Soy flour derivatives not soy milk)
Wheat	1.0 (VITAL – GCC (Coeliac & wheat allergic population))
Cashew	2.0 *(VITAL - Hazelnut as generic tree nuts value)
Mustard	0.05
Lupin	4.0
Sesame	0.2
Shrimp	10.0
Celery	NA
Fish	NA (VITAL – original VITAL value applied)



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VITAL[®] 2.0

- Procedure (Guidance document) & decision tree
- VITAL Calculator (*on-line from July 2015*)
- VITAL Action Level Grid (incorporated in the VITAL Calculator) (VSEP Reference Dose)
- FAQ's and support documentation



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VITAL[®] Program

- Guidance Document – more detailed
- Definitions & expanded explanations
- Attempts to avoid common mistakes
- Includes detailed information about allergen analysis
- Available on our website

<http://allergenbureau.net/>



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Food Industry Guide to the
Voluntary Incidental Trace Allergen
Labelling (VITAL) Program
Version 2.0



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an initiative of the Allergen Bureau

23 April 2012

Action Level Concept

- VITAL 2.0 uses Action Levels
- Action Levels guide labelling recommendations
- VITAL 2.0 has 2 Action Levels and an interactive VITAL Action Level Grid

Action Level 1 - precautionary cross contact statement is not required

Action Level 2 - precautionary cross contact statement is required

“May be Present: XXX”



VITAL Action Level Grid

Reference Amount / Serving Size  g

	Action Level 1	Action Level 2
Almond	<2.5 ppm	≥2.5 ppm
Brazil nut	<2.5 ppm	≥2.5 ppm
Cashew	<2.5 ppm	≥2.5 ppm
Hazelnuts	<2.5 ppm	≥2.5 ppm
Macadamia nut	<2.5 ppm	≥2.5 ppm
Pecan	<2.5 ppm	≥2.5 ppm
Pine nut	<2.5 ppm	≥2.5 ppm
Pistachio nut	<2.5 ppm	≥2.5 ppm
Walnut	<2.5 ppm	≥2.5 ppm
Wheat	<20 ppm	≥20 ppm
Rye	<20 ppm	≥20 ppm
Barley	<20 ppm	≥20 ppm
Oats	<20 ppm	≥20 ppm
Spelt	<20 ppm	≥20 ppm
Egg	<0.75 ppm	≥0.75 ppm
Crustacea	<25 ppm	≥25 ppm
Fish	<2.5 ppm	≥2.5 ppm
Milk	<2.5 ppm	≥2.5 ppm
Peanut	<5 ppm	≥5 ppm
Sesame seed	<5 ppm	≥5 ppm
Soy	<25 ppm	≥25 ppm
Lupin	<100 ppm	≥100 ppm
Mustard	<1.25 ppm	≥1.25 ppm

Table 1

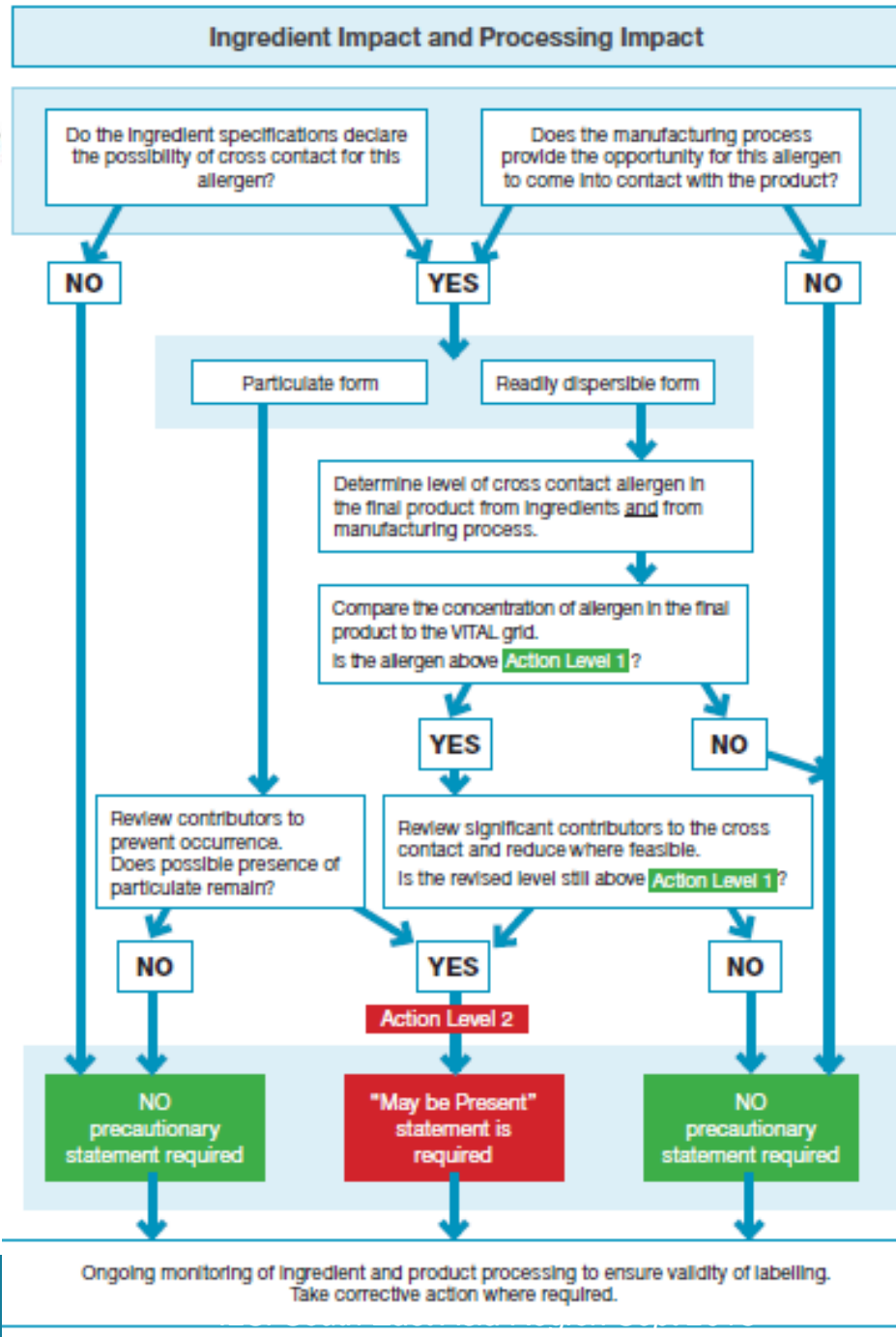
Summary of Labelling outcomes



Substances	Reference Dose (mg)	Action Level (ppm) where Reference Amount / Serving Size is 50g		Cross Contact Amount		Labelling Outcome
		Action Level 1	Action Level 2	Particulate	Readily Dispersible (ppm)	
Tree Nuts (Total)	0.1	<2 ppm	≥2 ppm			
Almond						
Brazil nut						
Cashew						
Hazelnuts						
Macadamia nut						
Pecan						
Pine nut						
Pistachio nut						
Walnut						
Gluten-containing cereals (total)	1	<20 ppm	≥20 ppm			Intentionally Added
Wheat						Intentionally Added
Rye						
Barley						
Oats						
Spelt						
Egg	0.03	<0.6 ppm	≥0.6 ppm			Intentionally Added
Crustacea	1	<20 ppm	≥20 ppm		0	Action Level 1
Fish	0.1	<2 ppm	≥2 ppm		160	Action Level 2
Milk	0.1	<2 ppm	≥2 ppm			Intentionally Added
Peanut	0.2	<4 ppm	≥4 ppm		0.1	Action Level 1
Sesame seed	0.2	<4 ppm	≥4 ppm	YES	8.8	Action Level 2
Soy	1	<20 ppm	≥20 ppm		0.5	Action Level 1
Lupin	Not assessed					
Mustard	Not assessed					



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Status Today of VITAL[®] 2.0

- VITAL 2.0 has been well accepted - by Industry, Allergic Consumer Associations & Authorities
- Being adopted Internationally
- Feedback from industry has helped to make the calculator run more smoothly
- The food industry training providers use VITAL 2.0
- The Allergen Bureau continues to provide resources & support for the industry – and VITAL On-line web-based calculator

Project - VITAL[®] Online

- Wizard-style input, user-friendly
- Multiple platform compatibility (eg. PC & Mac; tablet & iPad)
- Online or offline storage
- Updated centrally, updates easily applied to existing calculations
- Companies can create users and control access in the system
- Create and save ingredients online
- Store process flows and recipes

Recipe: Flourless Chocolate Cake - Cake001

Edit recipe

Recipe name*
Flourless Chocolate Cake

Recipe code* *i*
Cake001

Finished product serving size* *i* Ingredient intended for further processing
80.000000 Serving Size not applicable
(Reference Amount)

Legislation*
Australia and New Zealand *v*

Legislation description
null

CANCEL NEXT STEP

ADD CROSS CONTACT

ADD PROCESSING STEP

Raw Vegan Cake *✓*

Honey Almond Cake *✓* >

Honey Almond Cake

RENAME REMOVE

Sources of processing cross contact

Gluten containing cereals *+*

Tree nuts *-*

Almonds

Particulate Readily dispersible form

Percent of allergen source in product manufactured prior %

Quantity of residual previous product* g

Protein residue of previous product* %

Quantity of protein in residue mg

Batch size exposed to residue* kg

Protein from this cross contact source ppm

Cumulative amount ppm

Labelling outcome



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Training

How you can be Engaged

Global Partners & Training Collaborations

- Partners to support and facilitate VITAL implementation
 - BRC & FDF interest in being an Allergen Bureau Partner
- Goal is for Trainers to be managed through our Partners
- Training collaborations growing very quickly
Currently 16 <http://allergenbureau.net/vital/vital-training/>
- Ongoing industry engagement & connection
- Critical to long term success
(Global consistency in approach & labelling)





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VITAL[®] 2.0 – What Success Looks Like

- A VITAL Procedure, tools & support material and services that are ***globally relevant***
- The ***science*** that underpins the reference dose/action levels remains ***current*** through VSEP ongoing interaction
- Growth through global partners and training collaborations
- Continuous development of VITAL as the industry and the program evolves

Summary

- VITAL was developed to ensure a consistent approach to Risk Assessment and precautionary labelling across industry
- It has been a successful and positive collaboration between industry and consumer groups and we continue to collaborate
- VITAL program provides: Risk assessment Procedure & Decision Tree, Action Level Grid – Scientific Review, VITAL calculator
- The VSEP underpins the scientific credibility of the system
- A basis for strong Industry Self-regulation
- VITAL journey will continue!





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A VITAL Future

Go back to your primary Risk Assessment

Substantiate & invest in your platform

&

Stay Engaged





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Thank you

For further engagement and information:

- Visit the Allergen Bureau website www.allergenbureau.net
- Join Us and enjoy the benefits of the Allergen Bureau membership www.allergenbureau.net/about-us/join-us/
- Subscribe to our free monthly Allergen Bureau eNews www.allergenbureau.net/news/
- Access the Allergen Bureau HelpLine
 - email: info@allergenbureau.net
 - Phone: +61 437 918 959 (International)
- Attend our Allergen Management & VITAL[®] Training Day, 11 May 2015, Sydney, Australia
- Register for the Food Allergen Management Symposium 2015 (FAMS2015) 12-14 May 2015, Sydney www.fams2015.com.au/