

VITAL – An Action Level Based Approach  
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# Overview

- **What is the Allergen Bureau**
- **The “may contain” dilemma**
- **VITAL , the Revival and VITAL 2.0**
- **Lessons Learnt**
- **The VITAL Future**





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## Who are the Allergen Bureau?:

exists to share information and experience within the ANZ food industry on the management of food allergens to ensure consumers receive relevant, consistent and easy to understand information on food allergens.

- Management Committee and Members
  - committee drive the allergen management **projects** for the industry
  - becoming a registered '**Not for Profit**' organisation.
- 
- The Bureau has believed and continues to believe that –  
**Protecting the Allergic Consumer means Protection of our industry**

# Why we had to do something

## The “may contain” dilemma

- FSC silent on labelling of “cross contact” allergens
- Allergic consumers confused and take risks
- Clinicians advising allergic consumers to ignore “may contain” statements
- Industry did not have a uniform process for determining when to use precautionary labelling
- Industry was criticised for the inconsistent and often blanket approach to advisory allergen labelling.
- Medium to small manufacturers lacked the technical resources and expertise and would benefit from a tool to assist with allergen risk assessment.





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# What we Developed - VITAL Program

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



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# Our Dream

**Australia**



**New Zealand**

## Harmonised Action Levels

**Imagine That! Is it Possible?**



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# What it would mean?

- Consistent protection for all stakeholders
- Allergen labelling information would mean something to the allergic consumer, it had to be:
  - Relevant, ***consistent*** and easy to understand
  - Easily recognised by the allergic consumer
  - Cross contact statements would be based on the same action levels



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## Allergen Bureau

The Allergen Bureau is the first point of contact for questions on the management of food allergen risks in food ingredients and food manufacturing in Australia and New Zealand.

The Allergen Bureau shares information within the food industry on the management of food allergens so consumers receive relevant, consistent and easy to understand information on food allergens.

## New Allergen Guide out now

If your company handles food ingredients, manufactures, imports, exports or retails food products you need the new revised 2007 edition of the Allergen Management and Labelling Guide including VITAL (Voluntary Incidental Trace Allergen Labelling).

[More information on the Allergen Guide](#)



## VITAL system launched

The VITAL (Voluntary Incidental Trace Allergen Labelling) system has been launched as part of the new revised 2007 edition of the Allergen Management and Labelling Guide. VITAL is an essential tool for food producers.

[More VITAL information](#)



# JUNE 2007

[www.allergenbureau.net](http://www.allergenbureau.net)





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## The VITAL Difference

Many risk assessment protocols have been developed internationally as a result of the requirement for Mandatory labelling of allergens. The characteristic that set VITAL apart was the incorporation of a three level action grid to assist in determining if the presence of residual protein from cross contact with allergenic substances requires a precautionary labelling statement .



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# The VITAL Grid

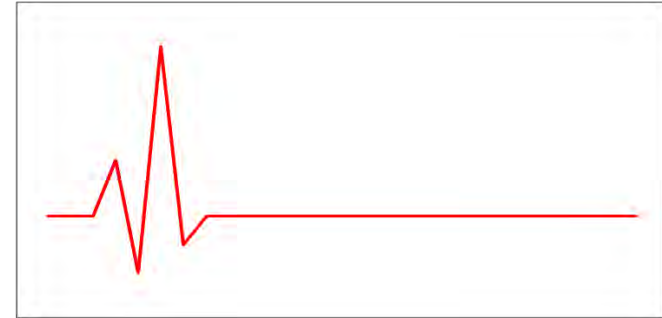
	VITAL GRID								
	Allergen Milk*	Egg*	Soy*^	Fish*	Peanuts*	Tree Nuts*	Sesame Seed*	Crustacea*	Gluten#
Action Level 1 (ppm)	<5	<2	<10	<20	<2	<2	<2	<2	<20
Action Level 2 (ppm)	5 - 50	2 - 20	10 - 100	20 - 200	2 - 20	2 - 20	2 - 20	2 - 20	20 - 100
Action level 3 (ppm)	>50	>20	>100	>200	>20	>20	>20	>20	>100

\* mg/kg (ppm) of total protein  
# Gluten includes all gluten type proteins as defined in the Food Standards Code  
^The Action Level for soy is highly conservative

- Total protein basis
- Expressed as a concentration in food (5g)
- 3 Action Levels, **Green** no label, **Yellow** - may be present, **Red** - contains

# VITAL Flat Lining (2010)

- Limited uptake across the industry
- Numerous barriers to implementation
  - large /small organisation impacts
- Clinicians created an environment of zero tolerance
- Many companies still not getting the fundamentals right
- There was so much more science to consider to underpin the Grid cross contact levels



# VITAL Revival

- VITAL Review initiated in 2010 – International interest
- Decision to look at the entire VITAL program and refresh
- A Scientific Expert Panel was convened to review the science underpinning the action levels in the grid
- Government Feedback & Support
  - FSANZ / Review of Labelling Law & Policy
- Development of a targeted VITAL Communication Strategy



## VSEP January 2011 Collaboration

- The first VITAL Scientific Expert Panel (VSEP) meeting was held in Sydney on January 19-20, 2011
- Significant collaboration was required to ensure the event could proceed:
  - The Allergen Bureau;
  - FARRP (Food Allergy Research and Resource Program (University of Nebraska) and;
  - TNO (The Netherlands Organisation for Applied Scientific Research)
- Meeting focus & objective was to review and discuss Action Levels in the VITAL Grid
  - Underpinning science

# VITAL Scientific Expert Panel (VSEP)

- Scientific Expert Panel

Panel Members are:

- Dr Steve Taylor (FARRP)
- Dr Joseph Baumert (FARRP) , supported by Mr Benjamin Remington (FARRP),
- Dr Geert Houben (Program Manager Food Safety, TNO. NL)
- Dr Rene Crevel (Allergy & Immunology, Unilever)
- Dr Katie Allen (Paediatric Gastroenterologist/Allergist , Royal Children's Hospital, University of Melbourne), supported by Ms Jennifer Koplin
- Dr Simon Brooke Taylor (Food Safety & Risk Analysis Consultant, Allergen Bureau)
- The VSEP received significant support from Astrid Kruizinga (TNO), Ellen Dutman (TNO) & Harrie Buist (TNO)





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## **VITAL Scientific Review**

- The Panel established principles to be used in selecting Action Levels;
  - scientifically & clinically sound, defensible and transparent
- Determined that the current Action Levels in VITAL were:
  - appropriate based on available science at that time
- Portion/Serving Size
  - allergen protein expressed as mg of protein . In this context serving size or reference quantity plays a significant role
- Exquisitely allergic consumers will not be accounted for in the VITAL grid, continue to assume they do not eat processed foods

## VITAL Scientific Review

- Level of Acceptable Risk
  - protection for vast majority of allergic individuals
- Action levels set with highest degree of safety
  - Increasing availability of clinical data enables the model to be applied with increasing confidence
  - Acknowledges & drives research to fill the data gaps
- Potentially opens up choice to a larger number of 'safe' foods
  - Consistent approach across industry
  - Precautionary labels will only be applied when appropriate
- Plan is for the Action Levels to be subject to ongoing review



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## Original VITAL Scientific Approach

- Key information taken from the FDA Threshold Working Group Report of 2006
- Used LOAELs from FDA table
- Applied an uncertainty factor (UF) to action levels set
- Expressed action levels in concentration (ppm) rather than amount of protein(mg); based on 5 g serving size (**teaspoon/mouthful**)
- Most VITAL min levels set at >2 ppm (exceptions fish, milk, soy, gluten)

# The VSEP Overarching Scientific Approach

## Quantitative Risk Assessment

- The threshold needs to be *predictive* for the *entire allergic population*
  - Representative population weighted to include individuals who react to very low amts & their counterparts who require large amts
- Statistically based risk assessment provides the ideal approach to the establishment of a population thresholds for allergenic foods
  - This type of risk assessment requires *individual threshold doses* from a sufficiently *large* number of allergic individuals
- Analysis of the clinical literature was conducted to determine if the **quantity** and **quality** of published and unpublished data was sufficient,
  - to apply RA modelling & prediction of population based thresholds



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## VSEP Recommendations – Reference Doses

<b>Allergen</b>	<b>Protein Level (mg)</b>
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 protein isolates 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 & Risk

- VITAL approach used all of the existing published data plus some unpublished data - **Unpublished data needs to be published**
- VITAL grid levels will protect 95-99% of allergic consumers (99% is desirable when sufficient data exists to allow statistically sound estimates at this level)
- Exquisitely sensitive allergic consumers may not be fully protected by the VITAL grid levels (assume do not consume packaged foods)
- No additional uncertainty factors needed because of use of ED01 or lower 95% confidence interval of ED05
- Risk of mild, transitory objective reactions typically requiring no pharmacological intervention
- Allergic populations studied appear to be representative or skewed toward more highly sensitive (referral clinics, immunotherapy studies)





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## VSEP outcomes

- Reference doses determined for each of the top food allergens, Research gaps continue to be addressed
- Standardised methodology or approach to determine appropriate reference dose information, consistent application
- The relevance and importance of Reference Amounts or Serving Size in determining Action Levels, clarity around actual consumption data
- Food industry adoption and implementation of the reference dose, reference amount, action level precautionary labelling risk assessment
- Consistent application globally to drive safe food choices, protection for the allergic consumer means protection for our industry'
- International recognition by the scientific community



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# What went well

- All tools and information available for entire industry
- Dedicated VITAL support, single point of contact
- Consumer group collaboration was key – AAI, Allergen NZ & Coeliac Society
- VITAL was developed at the same time that the allergen labelling format was developed with the AFGC Allergen Guide (e.g. **bolding**)
- Training material developed and training providers sourced
- Penetration of the PIF, support provided to industry
- Government feedback positive no regulatory outcome

# Our Learnings

- How does the consumer know if VITAL has been used if the product carries no precautionary label?
- Initial scientific review used only publicly available allergen data to determine Action Levels for the Grid
  - Difficult to leverage wider support at the time
  - Where to obtain information & expertise?
  - Potential financial burden
- Grid stipulating 3 Action Levels, added complexity & went too far
- Did not anticipate the impact of International organisations
- Process for evaluation of risks & the role of analysis not clear



## Learnings

- VITAL itself does not convey safety
- VITAL must be part of a total allergen management package
- VITAL requires a robust risk assessment process and risk management strategies





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# VITAL Communication Strategy

- Industry communication, what we are doing today; what has changed
- Obtaining stakeholder input
  - Pilot phase (Calculator, Guidance Document & Procedure)
- Communication plan targeted at the allergic consumer, current advice:
  - “Don’t eat products which have a precautionary statement with an allergen to which you are sensitive”
- Health Care Professional stakeholder communication and management program



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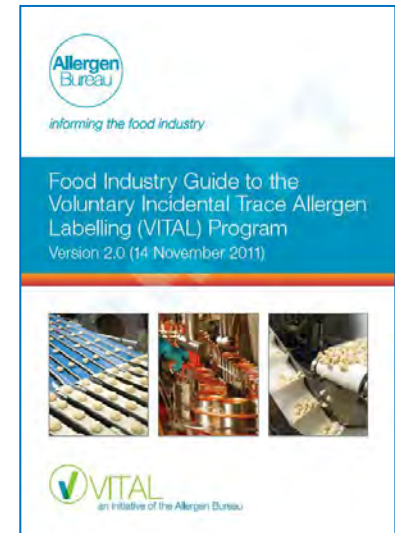
# Introducing VITAL 2.0



# VITAL

an initiative of the Allergen Bureau

- NEW Identity
- NEW Action Levels
- NEW Concepts
  - Reference Dose
  - Reference Amount/Serving Size
- NEW Definitions
  - Fish
  - Tree nuts
  - Particulates
- New procedure (Guidance document)
  - New VITAL Calculator
- New VITAL Action Level Grid (incorporated in the VITAL Calculator)
- New FAQ's



an initiative of the Allergen Bureau



# VITAL 2.0 Action Level Grid

- VITAL 2.0 still uses Action Levels
- Action Levels guide labelling recommendations
- Embedded in the guidance document
- Interactive
- Based on Reference Dose and appropriate Reference Amount/Serving Size



**VITAL Action Level Grid**

Reference Amount / Serving Size  g

	Action Level 1	Action Level 2
Almond	<20 ppm	≥20 ppm
Brazil nut	<20 ppm	≥20 ppm
Cashew	<20 ppm	≥20 ppm
Hazelnuts	<20 ppm	≥20 ppm
Macadamia nut	<20 ppm	≥20 ppm
Pecan	<20 ppm	≥20 ppm
Pine nut	<20 ppm	≥20 ppm
Pistachio nut	<20 ppm	≥20 ppm
Walnut	<20 ppm	≥20 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	<6 ppm	≥6 ppm
Crustacea	<200 ppm	≥200 ppm
Fish	<20 ppm	≥20 ppm
Milk	<20 ppm	≥20 ppm
Peanut	<40 ppm	≥40 ppm
Sesame seed	<40 ppm	≥40 ppm
Soy	<200 ppm	≥200 ppm
Sulphites	<10 ppm	≥10 ppm
Lupin	<800 ppm	≥800 ppm
Mustard	<10 ppm	≥10 ppm

# A VITAL Future

- Launch the updated VITAL Procedure, Grid (Action Levels) and Decision Tree (May 2012)
- Launch of the updated VITAL tools:
  - VITAL calculator,
  - FAQ's, examples and other supporting information
  - VITAL Training program
- VITAL calculator - a sub project of the VITAL revival
  - Updated excel based tool
  - Longer term project , working with GS1 to produce a sustainable tool that is web based, easy to use with a global footprint
- E-Commerce & Extended Labelling



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# Continuing the VITAL Scientific Journey

- The Allergen Bureau plan is to maintain the VSEP ongoing and continue to invest in the VITAL future
- New science and data needs to continue to be considered
- The Allergen Bureau objective is to support initiatives, projects and collaborations where possible to drive the research gaps
- Currently reviewing the possibility of collaboration with the EU
- The Allergen Bureau continue to stay closely linked in to the ILSI Thresholds to Action Levels Group



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# Summary

- VITAL was developed to ensure a consistent approach to precautionary labelling across industry
- It has been a successful and positive collaboration between industry and consumer groups and we continue to collaborate
- VITAL Revival encompasses, Procedure & Decision Tree, Action Level Grid – Scientific Review, VITAL calculator
- The scientific expert panel work has been instrumental
  - it underpins the credibility of the system and ensures there is a VITAL future
- Completion of the VITAL Revival project is the end of May 2012



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# Summary

VITAL is not a regulatory response

Supported but not endorsed by government bodies

Recognise that not all bodies and organisations will follow the same approach but if we are all starting from the same point we can work for a common and agreed outcome



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# **Dream becoming a Reality**



**Global Harmonised Action Levels**  
**Watch this space**



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