

# From Thresholds to Action Levels :VITAL2.0 and the Australian Food Industry

16th International Congress on Dietetics

Sydney, NSW, Australia

INDANA Symposium 2012

Risk Management for Food Allergens: The VITAL Approach



*informing the food industry*

# What's the fuss

## The Allergy Epidemic or should we call it plague ??

Epidemic warning: The study found Australian children have record levels of food allergies  
Immunologist Professor Katie Allen from the Murdoch Children's Research says  
Australian children have the highest recorded rate of food allergies in the world .  
An Australian study involving 5,000 infants has found one in 10 has a food allergy, with  
the highest rates found among children in Melbourne.

## Global markets and the sales team's dream

Global growth means the market for food allergy and intolerance products will surpass  
\$26 billion US dollars (11.2 billion euro) by 2017, according to new forecasts from Global  
Industry Analysts. massive investment in “ free from foods “

<http://www.foodnavigator.com/Financial-Industry/Global-allergy-and-intolerance-> market-to-hit-11.2bn-euro



*informing the food industry*

# Allergen Bureau – Who we are

- Established in 2005 due to industry demand
- An outcome of the industry's desire to deal wisely with regulatory changes
- a mixture of large multinationals , smaller consumer focused companies , retailers, consultants and analysts .
- The Members steer the resources & projects
- Provides a website that is a powerful method of communication  
<http://allergenbureau.net>



*informing the food industry*

## **Our Rationale**

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

## **Our Drivers**

Protecting the allergic consumer

Protecting the food industry

## **Our Challenge**

Consistency & industry alignment

## **Our Engagement**

One Program or One system

Harmonised Action Levels



informing the food industry

# Why we had to do something!

- Initial development of risk hierarchy and associated statements
  - Made on the same line.....Made in the same factory/facility.....
- Proliferation of cross contact statements across the industry, survey of 350 products in 2005 revealed 42 creative statements!
- Allergic consumers were ignoring cross contact statements
- Some statements weren't about allergens at all!
  - May contain traces of ***vitamins and water***
- ***Action levels varied between manufacturers, no consistency***

# Cautionary labelling!



# Voluntary Incidental Trace Allergen Labelling (VITAL) Procedure

- A stake holders industry designed tool for a standardised approach to the area of precautionary labelling
- A risk based methodology for food producers
- Assessing the impact of allergen cross contact and provide appropriate precautionary allergen labelling.
- Aims to avoid inappropriate use of precautionary labelling and to preserve the most valuable consumer risk management tool.
- Minimise risk to allergic consumers.



*informing the food industry*

# The VITAL Program

- 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 and is adopted on a voluntary basis





*informing the food industry*

# 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
  - Communicating accurately and consistently to the allergic consumer



informing the food industry

# The Grid – the VITAL Difference

	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



*informing the food industry*

# 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)

# Limited uptake across the industry

- Initial scientific review used only publicly available allergen data to determine Action Levels for the grid
- Numerous barriers to implementation
  - Large /small organisation impacts
  - Difficult to leverage wider support at the time
  - Potential financial burden
  - Clinicians had contributed to an environment of zero tolerance
- Many companies not getting the fundamentals right ,limited training
- Limited support tools and industry engagement
- There had been rapid growth in the science around thresholds and risk modelling
- Process for evaluation of risks & the role of analysis not clear



*informing the food industry*

# Getting Back on Track



- VITAL Review initiated in 2010-
  - Allergen Bureau committed to a review of VITAL to ensure that it can be considered to be the best available tool for cross contact allergen risk management
- Scientific review of the data
- Government Feedback & Support
  - FSANZ / Review of Labelling Law & Policy
- VITAL Program overhaul
- VITAL - Training project to drive engagement



*informing the food industry*

## VSEP Collaboration

- Significant collaboration
  - The Allergen Bureau;
  - FARRP (Food Allergy Research and Resource Program (University of Nebraska) and;
  - TNO (The Netherlands Organisation for Applied Scientific Research)
- Initial meeting (2011) focus, 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)



*informing the food industry*

# Philosophy behind the VSEP

What we needed to facilitate consistency in process !

- Transparent approach to drive credibility
- Established parameters to be shared far and wide
- Penetration into the market
- We needed to access best science and we recognised that the only way was through collaborative partners
- We needed to not only maintain but grow our connection with the food allergic community





*informing the food industry*

# VITAL Scientific Review

- Established that 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 be used in selecting 'Action Levels' that are;
  - Scientifically & clinically sound, defensible and transparent
- Set 'Action Levels' with the highest degree of safety
  - The more data the more confidence in the model
  - Lack of data drives research

# VITAL Scientific Review

- 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
- Determined that the current 'Action Levels' in VITAL were:
  - appropriate based on available science at that time
- Science underpinning the 'Action Levels' needs to be subject to ongoing review to remain relevant



informing the food industry

## 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 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)

## VSEP – What Success looks like?

- *Standardised methodology* to determine allergen reference dose
- *A reference dose* determined for each of the top food allergens
- *Research data gaps* continue to be addressed
- That the importance of the *Reference Amount or Serving Size* to determine Action Levels is understood and there is clarity around actual *consumption data*
- Wide food industry adoption of a sound *allergen risk based process*
- *Consistent application globally* that drives safe food choices, protection for the allergic consumer
- *Global recognition* by the scientific community



*informing the food industry*



VITAL

an initiative of the Allergen Bureau

## Introducing VITAL 2.0

- New procedure (Guidance document) & decision tree
- New VITAL Calculator
- New VITAL Action Level Grid (incorporated in the VITAL Calculator) (VSEP Reference Dose)
- New FAQ's and support documentation

## **VITAL 2.0 – Engagement and Consistency in Training**

- Risk based program
- Critical to long term success
- Development of facilitator' s guide
- Recognition of training providers
- Industry engagement & connection



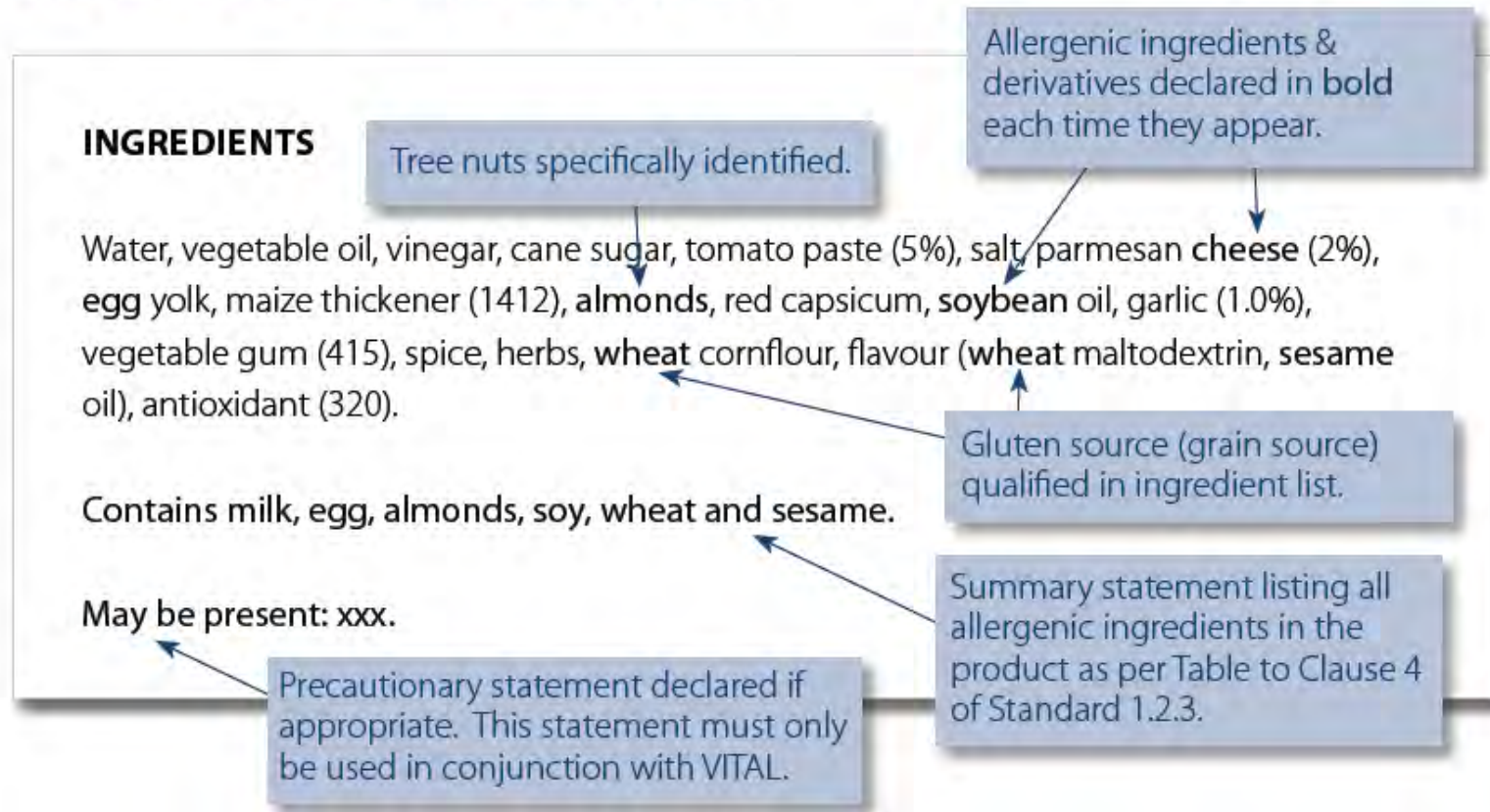
*informing the food industry*

# What continues to go well

- All tools and information will be available for entire industry
- Dedicated VITAL support, single point of contact
- Continued Consumer group collaboration – AAI, & Coeliac Society, ASCIA
- Standardised allergen labelling format across industry (**bolding**)
- Training material developed and training providers sourced
- Retailer support is powerful

# VITAL Labelling

## RECOMMENDED LABELLING FORMAT EXAMPLE.







*informing the food industry*

# Uptake

Implementation in 2007

2009 - Allergen Bureau Allergen Labelling Survey

7 % of surveyed product

“ may be present”

2011 - Survey - Zurzolo GA et al “ The Prevalence of  
Precautionary Allergen Labelling “( Murdoch  
Children's Research Institute )

12.7% of surveyed product

“may be present “

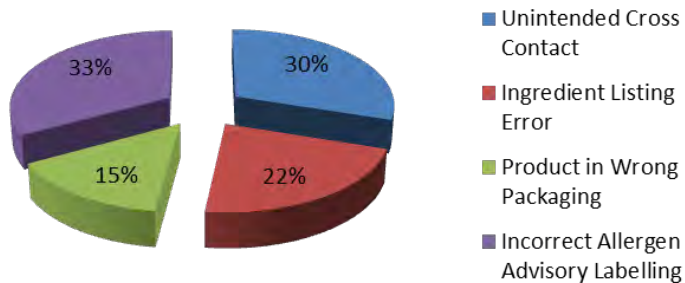
## What Now

- Partner Organisations & Training providers to facilitate uptake
- VITAL calculator Project
  - Seeking Government Funding
  - 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, connecting with the allergic consumer
- How does the consumer know if VITAL has been used if the product carries no precautionary label?



## 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



Source :UK FSA Allergen Allergy Alerts Jan -Jun 2011

70 % of all allergy recalls due to incorrect labelling  
Unintended Cross Contact 30%  
Product in Wrong Packaging 15%  
Incorrect Allergen Advisory Labelling 33%  
Ingredient Listing Error 22%

Andrew Sheard  
Campbells



*informing the food industry*

# 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 Review encompassed, Procedure & Decision Tree, Action Level Grid – Scientific Review, VITAL calculator
- The VSEP work was a game changer and was instrumental
  - it underpins the credibility of the system and ensures there is a VITAL future
- VITAL journey continues nationally and internationally



*informing the food industry*

# Thank you

## **Allergen Bureau Management Committee**

Kirsten Grinter ( Chair) - Nestle

Robin Sherlock - FACTa/DTS

David Henning – Campbell Arnotts

Neil Smith - Kraft

**Allergen Bureau Mangement**  
[management@allergenbureau.net](mailto:management@allergenbureau.net)

**VITAL Co-ordinator**  
Georgina Christensen  
[vital@allergenbureau.net](mailto:vital@allergenbureau.net)

**Information**  
[info@allergenbureau.net](mailto:info@allergenbureau.net)