• Allergen Bureau – Who we are in 2012

• Back to the VITAL start

• 2007 - What we Developed

• VITAL - Losing its Way & Lessons Learnt

• VSEP - breathing life back into VITAL

• VITAL 2.0 launch - Identity & Training

• The VITAL Future – Sustainable engagement
Allergen Bureau – Who we are

• Established in 2005 due to industry demand

• The food industry are our Members!

• We have 24 Members and 15 Associate 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
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*
Inconsistent approach to food
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
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
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
What we Developed – VITAL Grid

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Milk*</th>
<th>Egg*</th>
<th>Soy**</th>
<th>Fish*</th>
<th>Peanuts*</th>
<th>Tree Nuts*</th>
<th>Sesame Seed*</th>
<th>Crustacea*</th>
<th>Gluten#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action Level 1 (ppm)</td>
<td>&lt;5</td>
<td>&lt;2</td>
<td>&lt;10</td>
<td>&lt;20</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>&lt;2</td>
</tr>
<tr>
<td>Action Level 2 (ppm)</td>
<td>5 - 50</td>
<td>2 - 20</td>
<td>10 - 100</td>
<td>20 - 200</td>
<td>2 - 20</td>
<td>2 - 20</td>
<td>2 - 20</td>
<td>2 - 20</td>
<td>20 - 100</td>
</tr>
<tr>
<td>Action Level 3 (ppm)</td>
<td>&gt;50</td>
<td>&gt;20</td>
<td>&gt;100</td>
<td>&gt;200</td>
<td>&gt;20</td>
<td>&gt;20</td>
<td>&gt;20</td>
<td>&gt;20</td>
<td>&gt;100</td>
</tr>
</tbody>
</table>

* 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
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)
Lessons Learnt
The Mistakes & Learning's

- Did not anticipate the impact of International organisations
- 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
- Process for evaluation of risks & the role of analysis not clear
- Limited support tools and industry engagement
VITAL losing its Way 2010

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

- VITAL Review initiated in 2010
- Scientific review of the data
- Government Feedback & Support
  - FSANZ / Review of Labelling Law & Policy
- VITAL Program overhaul
- VITAL - Training project to drive engagement
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 (VSEMP)

- 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 Childrens Hospital, University of Melbourne), supported by Ms Jennifer Koplin
- Dr Simon Brooke Taylor (Food Safety & Risk Analysis Consultant, Allergen Bureau)

- The VSEMP received significant support from Astrid Kruizinga (TNO), Ellen Dutman (TNO) & Harrie Buist (TNO)
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
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 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
<table>
<thead>
<tr>
<th>Allergen</th>
<th>Protein Level (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut</td>
<td>0.2</td>
</tr>
<tr>
<td>Milk</td>
<td>0.1</td>
</tr>
<tr>
<td>Egg</td>
<td>0.03</td>
</tr>
<tr>
<td>Hazelnut</td>
<td>0.1 * (VITAL – Level used as generic tree nut value)</td>
</tr>
<tr>
<td>Soy</td>
<td>1.0 * (VITAL – Soy flour derivatives not soy milk)</td>
</tr>
<tr>
<td>Wheat</td>
<td>1.0 * (VITAL – GCC (Coeliac &amp; wheat allergic population))</td>
</tr>
<tr>
<td>Cashew</td>
<td>2.0 * (VITAL – Hazelnut as generic tree nuts value)</td>
</tr>
<tr>
<td>Mustard</td>
<td>0.05</td>
</tr>
<tr>
<td>Lupin</td>
<td>4.0</td>
</tr>
<tr>
<td>Sesame</td>
<td>0.2</td>
</tr>
<tr>
<td>Shrimp</td>
<td>10.0</td>
</tr>
<tr>
<td>Celery</td>
<td>NA</td>
</tr>
<tr>
<td>Fish</td>
<td>NA * (VITAL – original VITAL value applied)</td>
</tr>
</tbody>
</table>
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 means protection for our industry
- *Global recognition* by the scientific community
VITAL 2.0
New Identity

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
New VITAL Procedure

- Now called Guidance Document – more detailed
- New definitions and expanded explanations
- Attempts to avoid common mistakes
- Includes detailed information about allergen analysis
- Available on our website
**Action Level Concept**

- VITAL 2.0 still uses Action Levels

- Action Levels guide labelling recommendations

- BUT – VITAL 2.0 has only 2 Action Levels and a new interactive VITAL Action Level Grid
## VITAL Action Level Grid

Reference Amount / Serving Size: 40 g

<table>
<thead>
<tr>
<th></th>
<th>Action Level 1</th>
<th>Action Level 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almond</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Brazil nut</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Cashew</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Hazelnuts</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Macadamia nut</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Pecan</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Pine nut</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Pistachio nut</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Walnut</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Wheat</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
</tr>
<tr>
<td>Rye</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
</tr>
<tr>
<td>Barley</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
</tr>
<tr>
<td>Oats</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
</tr>
<tr>
<td>Spelt</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
</tr>
<tr>
<td>Egg</td>
<td>&lt;0.75 ppm</td>
<td>≥0.75 ppm</td>
</tr>
<tr>
<td>Crustacea</td>
<td>&lt;25 ppm</td>
<td>≥25 ppm</td>
</tr>
<tr>
<td>Fish</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Milk</td>
<td>&lt;2.5 ppm</td>
<td>≥2.5 ppm</td>
</tr>
<tr>
<td>Peanut</td>
<td>&lt;5 ppm</td>
<td>≥5 ppm</td>
</tr>
<tr>
<td>Sesame seed</td>
<td>&lt;5 ppm</td>
<td>≥5 ppm</td>
</tr>
<tr>
<td>Soy</td>
<td>&lt;25 ppm</td>
<td>≥25 ppm</td>
</tr>
<tr>
<td>Lupin</td>
<td>&lt;100 ppm</td>
<td>≥100 ppm</td>
</tr>
<tr>
<td>Mustard</td>
<td>&lt;1.25 ppm</td>
<td>≥1.25 ppm</td>
</tr>
</tbody>
</table>
VITAL Calculator

- New calculator – currently version 2.0.5
- "point and click"
- Compatible with PC only
- Long term plan to move to a web-based application when funding available
- Report produced in pdf format which can be saved & emailed
- For ingredients: no Action Levels are created – supplier is recommended to advise customer of ppm cross contact allergens & details of particulate cross contact allergens
<table>
<thead>
<tr>
<th>Substances</th>
<th>Reference Dose (mg)</th>
<th>Action Level (ppm) where Reference Amount / Serving Size is 50g</th>
<th>Cross Contact Amount</th>
<th>Labelling Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Action Level 1</td>
<td>Action Level 2</td>
<td>Particulate</td>
</tr>
<tr>
<td>Tree Nuts (Total)</td>
<td></td>
<td>0.1</td>
<td>&lt;2 ppm</td>
<td>≥22 ppm</td>
</tr>
<tr>
<td>Almond</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brazil nut</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cashew</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hazelnuts</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macadamia nut</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pecan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pine nut</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pistachio nut</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walnut</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gluten-containing cereals (total)</td>
<td></td>
<td>1</td>
<td>&lt;20 ppm</td>
<td>≥220 ppm</td>
</tr>
<tr>
<td>Wheat</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rye</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barley</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oats</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spelt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Egg</td>
<td>0.03</td>
<td>&lt;0.6 ppm</td>
<td>≥0.6 ppm</td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>1</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td>0.1</td>
<td>&lt;2 ppm</td>
<td>≥2 ppm</td>
<td>160</td>
</tr>
<tr>
<td>Milk</td>
<td>0.1</td>
<td>&lt;2 ppm</td>
<td>≥2 ppm</td>
<td></td>
</tr>
<tr>
<td>Peanut</td>
<td>0.2</td>
<td>&lt;4 ppm</td>
<td>≥4 ppm</td>
<td>0.1</td>
</tr>
<tr>
<td>Sesame seed</td>
<td>0.2</td>
<td>&lt;4 ppm</td>
<td>≥4 ppm</td>
<td>YES</td>
</tr>
<tr>
<td>Soy</td>
<td>1</td>
<td>&lt;20 ppm</td>
<td>≥22 ppm</td>
<td>0.5</td>
</tr>
<tr>
<td>Lupin</td>
<td>Not assessed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mustard</td>
<td>Not assessed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3 Months After the launch of VITAL 2.0

• VITAL 2.0 has been well accepted

• Feedback from industry has helped to make the calculator run more smoothly

• The food industry is beginning to train in VITAL 2.0 & transition to VITAL

• The Allergen Bureau will continue to provide resources & support the industry through the transition stage
Training

Engagement
VITAL 2.0 – Consistency in Training

- Critical to long term success
- Development of facilitator’s guide & training slides and support material
- Recognition of training providers
- Industry engagement & connection
VITAL 2.0 - Training

• Phase out the original version of VITAL

  • Support offered for the original VITAL until end October 2012

• All training from today should be VITAL 2.0

• Global presence ? Next Steps for the Allergen Bureau
What continues to go well

- All tools and information will be available for entire industry
- Dedicated VITAL support, single point of contact
- Consumer group collaboration was key – AAI, & Coeliac Society
- Standardised allergen labelling format across industry
- Training material developed and training providers sourced
- Retailer support is powerful
- Government feedback positive no regulatory outcome
VITAL Labelling

RECOMMENDED LABELLING FORMAT EXAMPLE.

INGREDIENTS

Tree nuts specifically identified.

Water, vegetable oil, vinegar, cane sugar, tomato paste (5%), salt, parmesan cheese (2%), egg yolk, maize thickener (1412), almonds, red capsicum, soybean oil, garlic (1.0%), vegetable gum (415), spice, herbs, wheat cornflour, flavour (wheat maltodextrin, sesame oil), antioxidant (320).

Contains milk, egg, almonds, soy, wheat and sesame.

May be present: xxx.

Allergenic ingredients & derivatives declared in bold each time they appear.

Gluten source (grain source) qualified in ingredient list.

Summary statement listing all allergenic ingredients in the product as per Table to Clause 4 of Standard 1.2.3.

Precautionary statement declared if appropriate. This statement must only be used in conjunction with VITAL.
What Now

• Partner Organisations & Training providers to facilitate uptake

• VITAL calculator Project
  • Seeking Government Funding, web based tool, 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?

• Ongoing critical review – what we know about how VITAL is used!
The VITAL Journey

**2005**

- Industry in Australia & New Zealand would use same process and information to drive precautionary labelling

**2008 - 2010**

- External forces impacted heavily, Corporate drivers began to impact our dream, sustainability in question

**2011 until Now**

- Drive toward industry globally using the same process and information for precautionary labelling
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 did lose its way!

- 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 will continue!
A VITAL Future

Go back to your primary drivers

Substantiate & invest in your platform

&

Stay Engaged
Thank you

Allergen Bureau Management Committee
Robin Sherlock - FACTa
David Henning – Campbell Arnotts
Neil Smith - Kraft
Kirsten Grinter – Nestle

Allergen Bureau Mangement
management@allergenbureau.net

VITAL Co-ordinator
Georgina Christensen
vital@allergenbureau.net

Information
info@allergenbureau.net