

Allergen  
Bureau

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VITAL

an initiative of the Allergen Bureau

**ILSI Europe 13 & 14 September 2012**



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# VITAL Experience

- **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**



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# 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



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# 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





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## **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



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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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# 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





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# What we Developed – 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



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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)

# 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



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# 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



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## 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 Childrens 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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# 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



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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 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



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# 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



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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 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 means protection for our industry
- *Global recognition* by the scientific community



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# VITAL 2.0

# New Identity



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## **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





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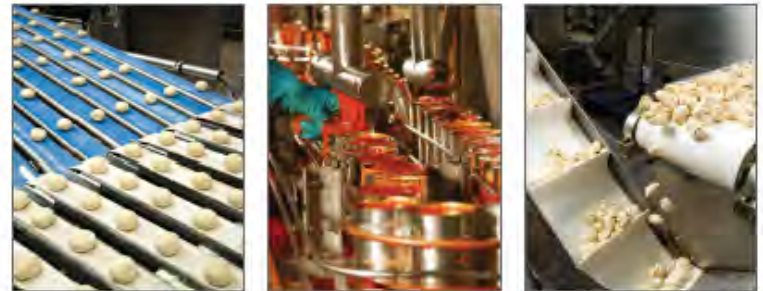
# New VITAL Procedure

- 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



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



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23 April 2012

# 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 **?**  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



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# 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



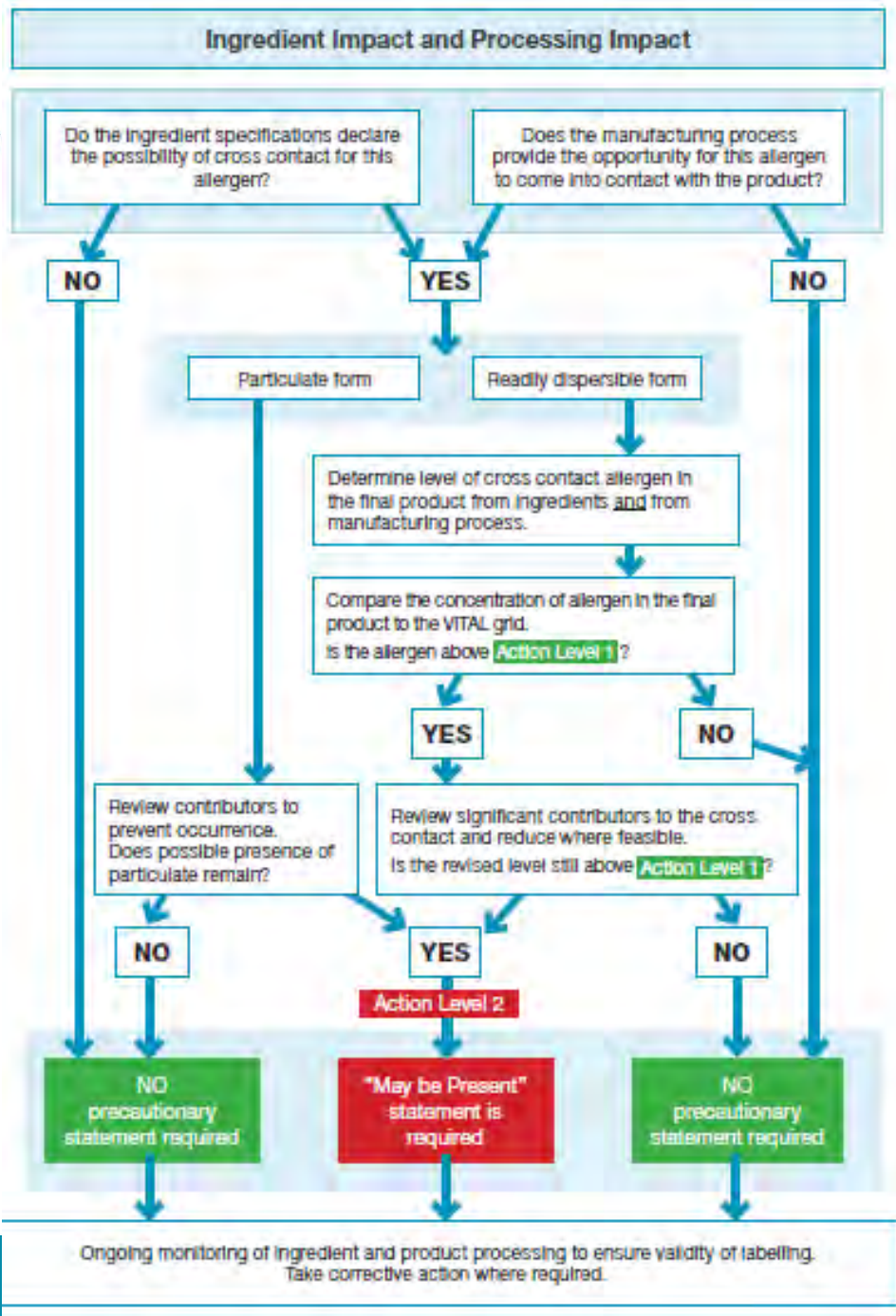
Table 1

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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## **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



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# 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



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## **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



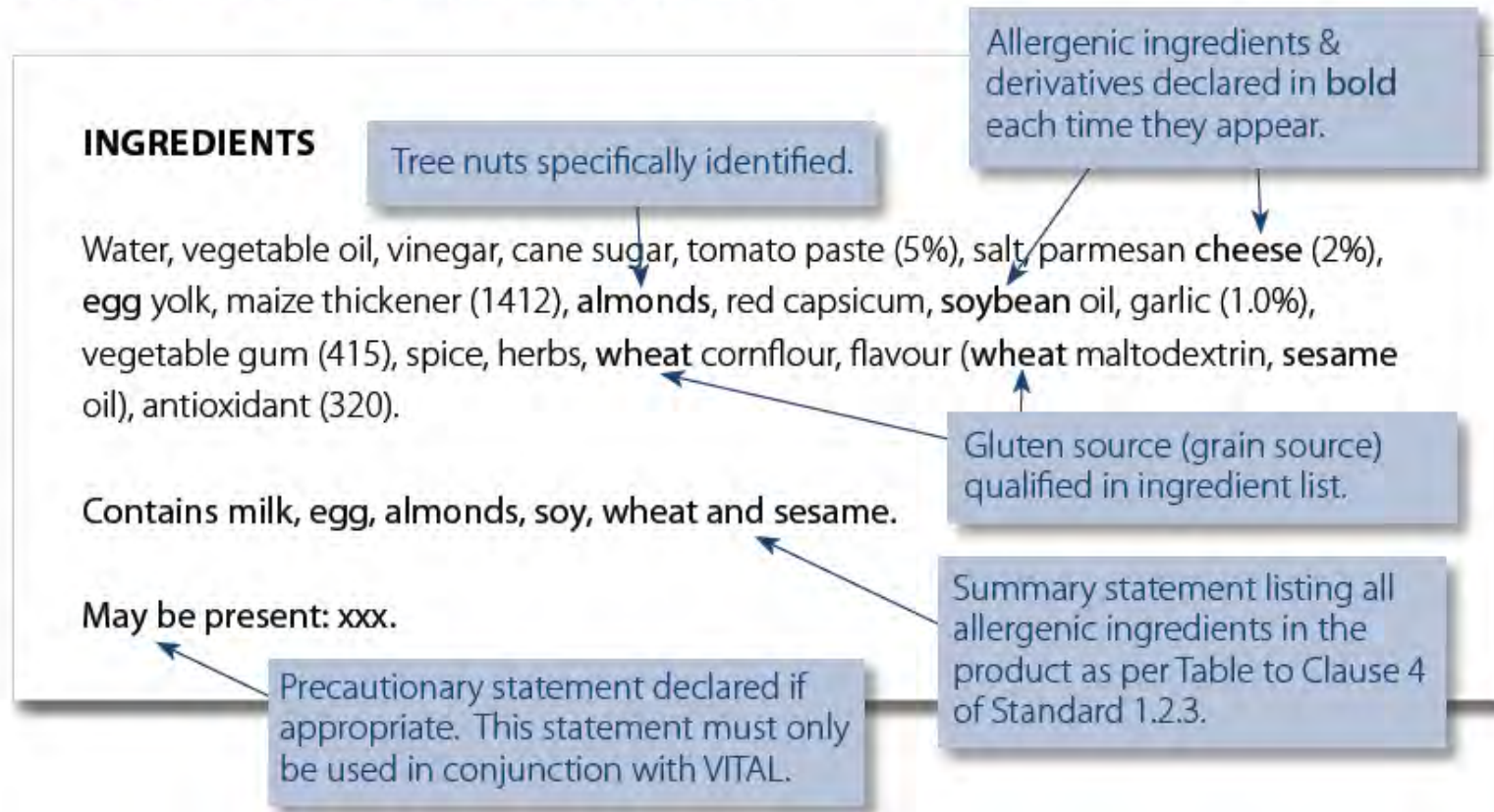
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# What continues to go well

- 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 (**bolding**)
- Training material developed and training providers sourced
- Retailer support is powerful
- Government feedback positive no regulatory outcome

# VITAL Labelling

## RECOMMENDED LABELLING FORMAT EXAMPLE.



## 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!



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# 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!



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# A VITAL Future

**Go back to your primary drivers**

**Substantiate & invest in your platform**

**&**

**Stay Engaged**



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# Thank you

## **Allergen Bureau Management Committee**

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David Henning – Campbell Arnotts

Neil Smith - Kraft

Kirsten Grinter – Nestle

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