

Update on the VITAL approach



VITAL

an initiative of the Allergen Bureau

Food Allergens

Fresenius Mainz 29th and 30th October
2012



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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
- Provides a website which is a powerful tool for communication
 - www.allergenbureau.net
- 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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VITAL (Voluntary Incidental Trace Allergen Labelling)

Developed in conjunction with industry, regulatory and consumer stake holders in Australia and New Zealand.

Shaped by a regulatory background where the labelling of incidental cross contact allergens is not mandated.



A Risk Assessment Tool

Used to assess the impact of allergen cross contact

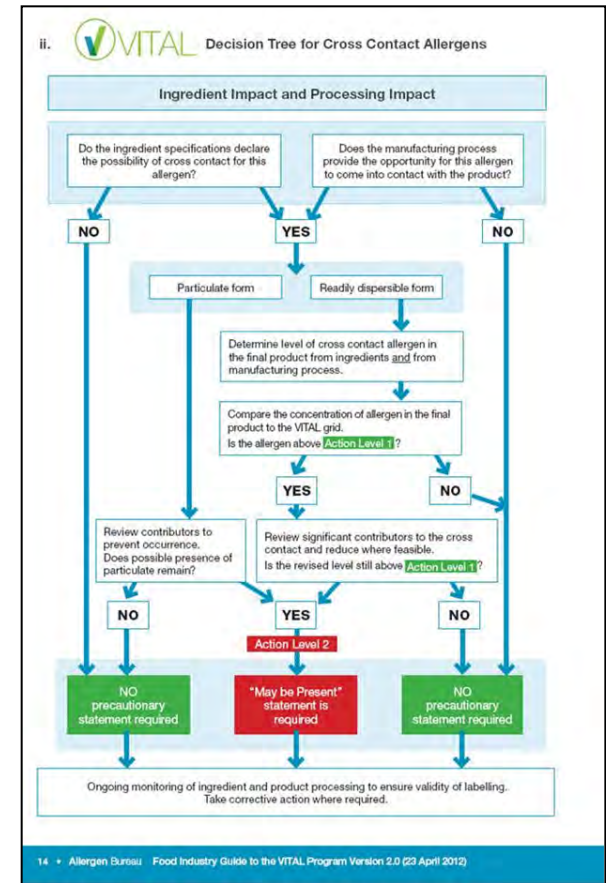
Stipulates a consistent precautionary allergen labelling statement

Uses an action level grid to determine if the presence of residual protein from allergenic substances through cross contact requires precautionary labelling

The VITAL Program

VITAL is a

- a process
- decision tree,
- grid (action levels)
- calculator
- 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



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 concerns regarding threshold levels had a significant impact of industry decision making
 - Many companies not getting the fundamentals right
- 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



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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



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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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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)

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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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



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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



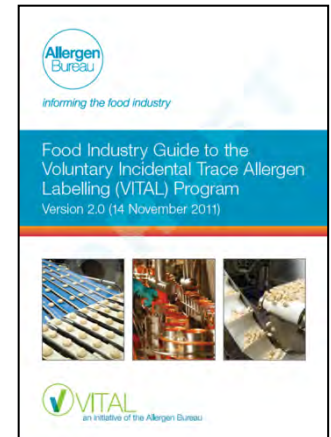
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VSEP Recommendations – Reference Doses & VITAL Application

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 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 (VITAL – initially 1ppm)
Celery	NA
Fish	NA (VITAL – original VITAL 0.1 mg value applied)

Introducing VITAL 2.0

- New procedure (Guidance document)
 - Provides more information and support
 - Aimed at reducing misunderstandings and inconsistencies
 - New Decision tree and Calculator
- New VITAL Action Level Grid (incorporated in the Calculator) (VSEP Reference Dose)
- New FAQ's and support documentation
- Development of facilitator's guide
- Recognition of training providers
- Industry engagement & connection





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VITAL Action Level Grid

- Embedded in the Calculator
- Specific to each product
- Based on Reference Dose and appropriate Reference Amount/ Serving Size
- Action levels guide labelling
- Can be applied to ingredients

VITAL Action Level Grid		
Reference Amount / Serving Size	<input type="text" value="5 g"/>	<input type="button" value="Update"/>
	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



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VITAL 2.0 – Consistency in Training

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



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What continues to go well

- All tools and information available for entire industry globally
- 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

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?
 - Risk Communication Group





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Monitoring 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 “

Workshops



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VITAL

- Always more than the grid
- Numbers alone can be misleading
- Requires knowledge of all parts of the supply chain
 - From raw materials, storage, manufacturing & distribution
- Harnesses the value of physical risk review and analysis to validate management decisions and assumptions
- Results in consistent and accurate communication to the allergic consumer



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VITAL Difference

Not a regulatory response

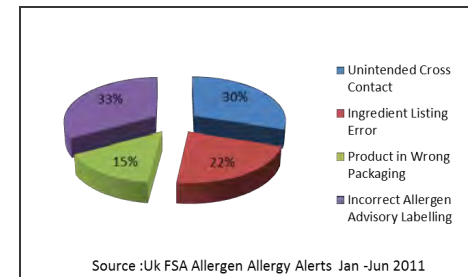
Supported but not endorsed by government

Allows rapid response to changing science

Recognise that not all bodies and organisations will follow the same approach

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
- A significant proportion of allergen recalls globally are related to non cross contact issues.





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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 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 2 - journey continues nationally and internationally



Cow named Daisy makes reduced-allergy milk

Daisy the transgenic cow makes reduced-allergy milk.
Genetically modified to produce Beta free milk !!!



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Thank you

Allergen Bureau Management Committee

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Kirsten Grinter – Nestle

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