Allergen Bureau

informing the food industry

Eighth Workshop on Food Allergen Methodologies

May 2014 Vancouver, BC, Canada

A VITAL Approach

Rob Sherlock

ALLERGEN Bureau

Allergen Bureau

Established in 2005 due to industry demand

Not for profit , Non government , incorporated

We have 27 full members

17 Associate members

The Members steer the resources & projects

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

Provides a website that is a powerful method of communication

http://allergenbureau.net

Oversee VITAL and continue to engage with national and international bodies and consumer stake holders

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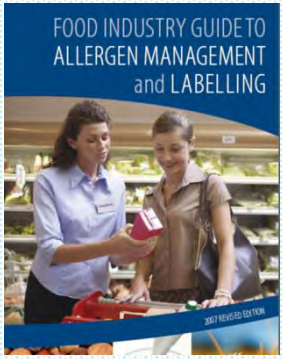

Australia and New Zealand's Industry Tools

AFGC Food Industry Guide to Allergen Management and Labelling

- Under review

Product Information Form

- A 2 edged sword

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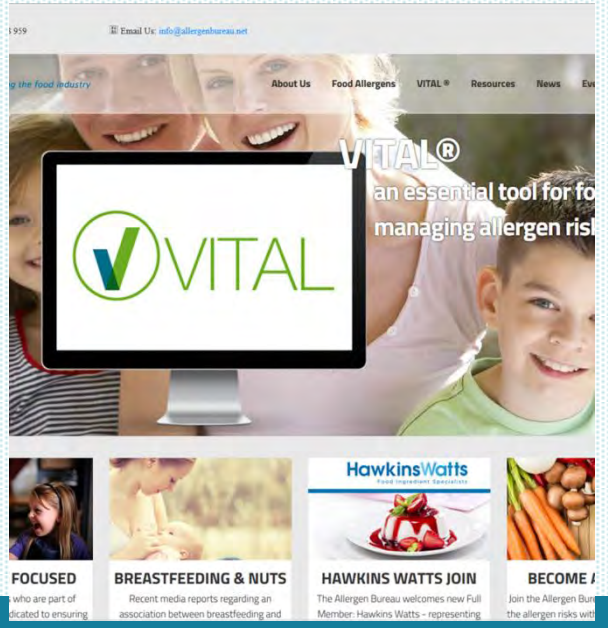
VITAL® and VITAL® support tools



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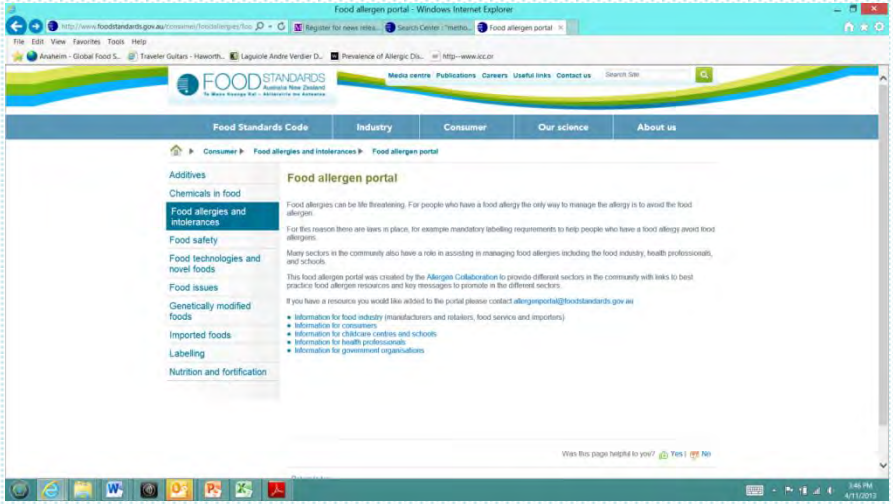
Allergen Collaboration -The Portal



http://www.foodstandards.gov.au/consumer/foodallergies/food%20allergen%20portal/Pages/default.aspx

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VITAL® -A Risk Assessment Tool

Used to assess the impact of allergen cross contact

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

Stipulates a consistent precautionary allergen labelling statement – “may be present “

Aims to avoid indiscriminate use of precautionary labelling and preserve a valuable risk management tool.

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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 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

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

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

Science underpinning the 'Action Levels' needs to be subject to ongoing review to remain relevant

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Reference Dose

- As recommended by the VSEP
  - Based on the total protein from an allergic food below which only the most sensitive individual (between 1 and 5% depending on the quality of the data) in the allergic population are likely to experience an adverse reaction

Allergen	Peanut	Milk	Egg	Tree nuts	Soy	Wheat	Mustard	Lupin	Sesame	Crustacea (Shrimp)	Fish
Reference Dose (mg)	0.2	0.1	0.03	0.1	1	1	0.05	4	0.2	10	NA

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Publications

Allergen reference doses for precautionary labeling (VITAL 2.0): Clinical implications

Contents lists available at ScienceDirect

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

Establishment of Reference Doses for residues of allergenic foods: Report of the VITAL Expert Panel

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ABSTRACT

In 2011, an expert panel was assembled to establish appropriate Reference Doses for allergenic food residues as a part of the VITAL (Voluntary Incidental Trace Allergen Labeling) program of The Allergen Bureau of Australia & New Zealand (ABA). These Reference Doses would guide advisory labeling decisions for use on food labels. Individual NOAELs and LOAELs were obtained from clinical challenges of food-allergic subjects. Statistical dose-distribution models (log-normal, log-logistic, Weibull) were applied to the individual NOAELs and LOAELs for each allergenic food. The Reference Doses, in terms of mg of total protein from the allergenic food, were based upon either the ED_{01} (for peanut, cow's milk), the 95% lower confidence interval of the ED_{05} (for wheat, soybean, cashew, shrimp, sesame seed, mustard, and lupine), or both (egg, hazelnut) using all appropriate statistical dose-distribution models. Reference Doses were established for 11 allergenic foods ranging from 0.03 mg for egg protein to 10 mg for shrimp protein. Reference Doses were not established for fish or celery due to poor model fits with existing data. Reference Doses were not established for other tree nuts beyond hazelnut and cashew because of the absence of data on NOAELs and LOAELs from individual subjects.

1. Introduction

Over the past few decades, food allergies have emerged as a significant public health issue in terms of prevalence and severity. Accordingly, public health authorities and the food industry have placed increasing priority on the protection of food-allergic consumers. Food-allergic individuals must adhere to specific avoidance diets to prevent the occurrence of allergic reactions (Arshad et al., 2007). The labeling of the presence of allergenic foods is critical to the implementation of safe and effective avoidance diets (Sheth et al., 2010). The unintended presence of residues of allergenic foods that are not declared on product labels (undeclared allergens) poses a risk to food-allergic individuals. The implementation of risk assessment approaches is needed to quantify the level of risk and exercise risk management strategies that would protect food-allergic consumers without being overly burdensome and reducing their quality of life. In particular, it is now well recognized that excessive use of precautionary (advisory) labeling results in unintended consequences, in particular risk-taking which negates the original intent of the labeling (Barnett et al., 2011).

The same principles and approaches of quantitative risk assessment as used for chemical residues in foods also apply to allergenic foods (Spanjersberg et al., 2007, 2010; Madsen et al., 2009). However, in contrast with risk assessment done with chemical residues that rely on toxicological data from experimental animals, useful data exist for food allergens from the actual subset of the human population that have food allergies. Data on individual no-observed adverse effect levels (NOAELs) and lowest-observed adverse effect levels (LOAELs) have emerged from low-dose oral clinical challenge studies with food-allergic individuals that allow the application of quantitative risk assessment approaches and the potential development of population thresholds for specific allergenic foods (Taylor et al., 2010).

Despite the increasing availability of NOAELs and LOAELs determined in food-allergic individuals, public health authorities have

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The VITAL® Process

A systematic approach to processes and allergenic contributors

part of a HACCP based food safety program.

Considers

Ingredient and processing impact

Consider the form of allergenic material

Determine the amount of cross contact allergen in the finished product (in terms of protein content)

Consider the VITAL® grid and determine the appropriate allergen labelling statement

Review significant contributors and reduce cross contact

Ongoing Monitoring

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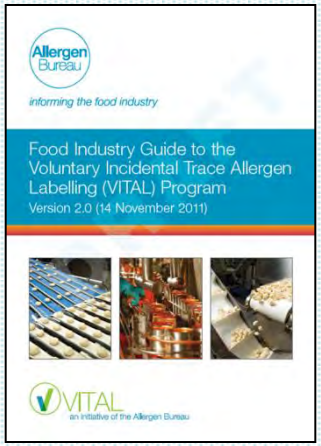

VITAL® 2.0

- New procedure (Guidance document)
  - Provides more information and support
  - 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
  - Trademarked VITAL® and the logo in Australia
  - Trademark registration in EU

VITAL an initiative of the Allergen Bureau

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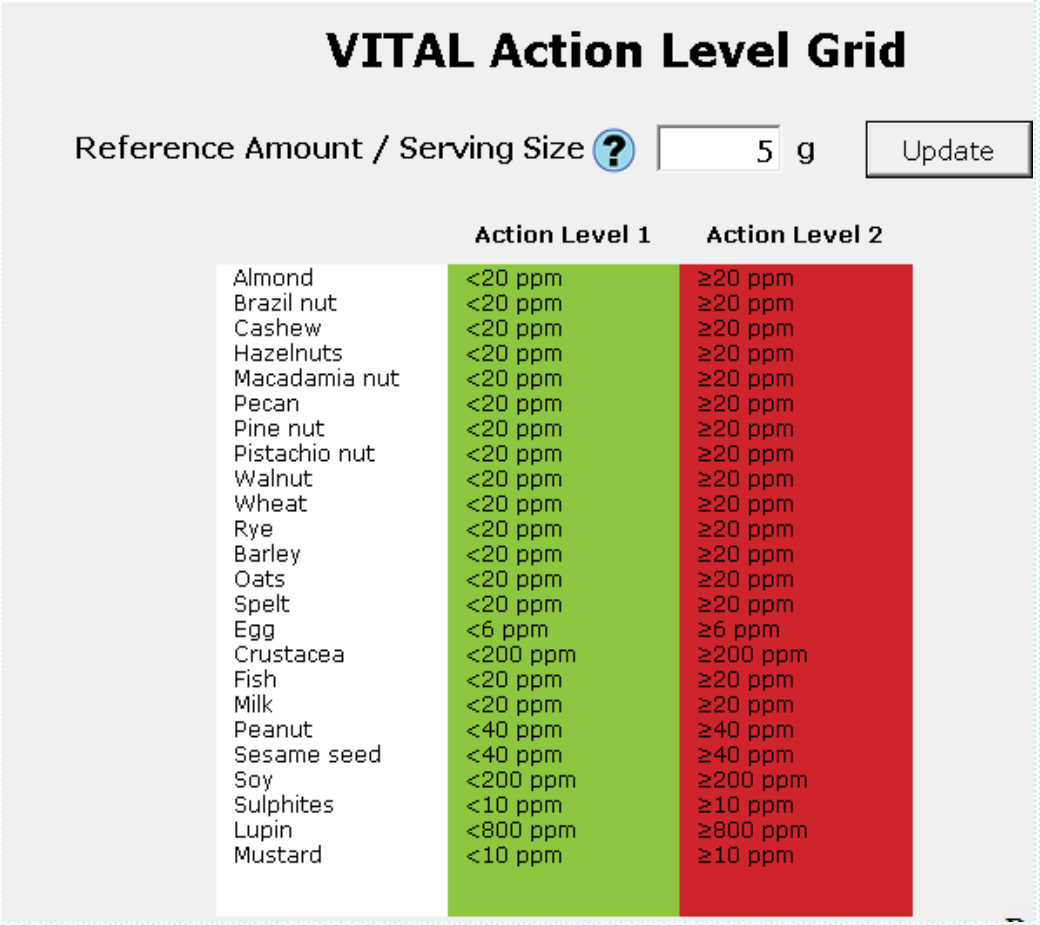
VITAL® 2.0 Action Level Grid

- Embedded in the Calculator
- Specific to each product
- Based on Reference Dose and appropriate Reference Amount/Serving Size
- Sensitivity



VITAL Action Level Grid

Reference Amount / Serving Size ? 5 g 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 – it's a sensitive issue !

Peanut Reference Dose = 0.2 mg protein

Example (**5g** Reference Amount/Serving Size):
Action Level 1 : < 40ppm (Transition = 0.2 x 1000/5 = 40ppm)
Action Level 2 : ≥ 40ppm

Example (**50g** Reference Amount/Serving Size):
Action Level 1 : < 4 ppm (Transition = 0.2 x 1000/50 = 4ppm)
Action Level 2 : ≥ 4 ppm

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10 Steps of VITAL

1. Determination of relevant allergens
2. Identification of intentionally added allergens
3. Identification and quantification of cross contact allergens due to ingredients
4. Identification and quantification of cross contact allergens due to processing
5. Calculation of total cross contact allergen in finished product
6. Determination of Action Levels
7. Review of labelling recommendations and sources of cross contact
8. Recording of Assumptions
9. Validation of VITAL assessment
10. Ongoing Monitoring

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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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Role of Allergen Testing in a VITAL® Context – to Ensure Analysis Informs Risk Assessment

- Establishing Allergen profile of raw material
- Examination of potential raw material cross contact
- Targeted analysis of problem pieces of processing equipment;
- Confirming assumptions made during the implementation of VITAL (such as validation of cleaning)

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Role of Allergen Testing in a VITAL® context

- Testing allergen status of the final product to compare with calculated results from VITAL assessment - especially relevant to high risk environments
- Monitoring the effect of critical changes
- Examining allergen status of production surfaces
- Monitoring of cleaning solutions and flushing
- On going monitoring of production performance and compliance

- Validation of the VITAL risk assessment

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A word about cleaning validations

What's important in a validation

- What allergen
- What form
- Swab before and after
- Finished Product with risk based sampling strategy
- Repeatable – minimum of three events

Modelling

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Robust Sampling Plans

Risk Based !

Distribution usually not homogenous

- May concentrate in first part of the run due to presence of previous product
- Hang ups in the system may result in random dumping of allergen
- May be particulate and therefore distributed irregularly in the sample itself

Test multiple samples at different points of production run

Avoid batching of samples for analysis as dilution will prevent identification of push through allergen from previous product run.

Sanitation swabs for aerial contamination

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Analysis , Risk Assessment and VITAL

Need to consider

- Sensitivity
- Suitability i.e. Fit for purpose
- Matrix effect
- Extraction efficiency
- Calibrators and Reporting Units

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Learning from FDA Food Allergen Recalls and Reportable Foods

many recalls were caused by simple problems

- regular review process to look for formulation changes in products and ingredients,
- checks of packages and labels before they are used to ensure that they match the product being produced
  packing and label controls are as important for allergen control as sanitation and Good Manufacturing Practices

GMP is a significant factor in reducing the nintended presence of allergens through cross-contact

Correct labelling is key

Cause	Number of Recalls
Wrong package or label	82
Terminology	59
Failure to carry forward information from an ingredient to final label	41
Cross-contact	28
Ingredient mislabeled from supplier	21

Table 3: Causes of Food Allergen Recalls

» Process is a critical risk factor

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What Now

Partner Organisations & Training providers to facilitate uptake

- Development of International Trainers guide and review of the Trainer resource

VITAL calculator Project

- Sourcing development funding
- produce a sustainable tool that is web based, easy to use with a global footprint
- Adaptable to further input

- IFAAM
  - Associate Partner
- ATSIG

  consensus papers

IFAAM

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VITAL Evolving

VITAL : 3 phases

Phase 1 – Risk Review

Phase 2 – Risk Communication (Labelling)

Phase 3 – Certification Investigation

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Thank you

DTS FACTA Staff and colleagues

Allergen Bureau Board

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