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
Introduction

- Member of the Allergen Bureau Board and Technical Manager of DTS FACTA.
- DTS is an Australian company that provides expert advice and consultative services in the area of food borne allergens.
- Provide training in food allergen awareness, analysis services for food borne allergens and consultation in strategies for allergen control within factory and food service environments.
- We have over 10 years experience in this area and are Nationally accredited (NATA).
- Work closely with both industry and regulatory laboratories and have been involved in industry working groups both nationally and internationally.
- www.dtsfoodlabs.com.au
- www.factaaustralia.com.au
Overview

A brief outline of food allergy
A review of current resources
Key points for allergen management
Industry Best Practise
HACCP with a twist
Valid validations
Recalls and what they teach
Food Allergy

Due to exposure to a protein that triggers an immune-based response in a sensitive individual.
- typically naturally occurring proteins in foods
  the reaction is not necessarily proportionate to the quantity consumed
- may be life-threatening

• Involve 3 main sets of organs
  – the respiratory tract (rhinitis, asthma, throat swelling)
  – the gastrointestinal tract (nausea, vomiting, diarrhea, abdominal cramping)
  – the skin (hives, itching, tingling dermatitis, eczema)
  – Characterised by being the location of the mast cells
  – Anaphylaxis
Allergic patterns and Incidence

Australia - 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. (Immunologist Professor Katie Allen - Murdoch CRI)

United States - An estimated 4% to 6% of U.S. children of children under age 18 have food allergies
http://www.cdc.gov

China - The overall prevalence of challenge-proven FA in 0- to 1-yr-old children in Chongqing, China, was 3.8% with 2.5% egg allergic and 1.3% cow’s milk allergic
(The prevalence of food allergy in infants in Chongqing, China Jing Chen1, Pediatric Allergy and Immunology)

A Mixed bag - bird's nest soup in Singapore
royal jelly allergy in Hong Kong,
mustard seed allergy in France.
Coeliac Disease

A different picture

- gluten-sensitive enteropathy
- permanent intestinal intolerance to dietary gluten.

The lining of the small bowel (intestine) is damaged. This causes a flattening of the villi (Villous atrophy).

The surface area, which enables the absorption of nutrients and minerals from food, is seriously depleted. This leads to deficiencies in vitamins, minerals and sometimes proteins, carbohydrates and fats.
Harmonisation Challenges

Geographical differences
Population variation
International labelling and safety expectations
Lack of confidence around precautionary labels

“In this era of globalization, it is not only populations that migrate but also foods, as people adopt foreign diets and import exotic products”

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1679775/
<table>
<thead>
<tr>
<th>Cereals containing gluten</th>
<th>Codex</th>
<th>United States</th>
<th>Japan</th>
<th>Canada</th>
<th>The EU</th>
<th>Australia</th>
<th>China</th>
<th>Malaysia</th>
<th>Singapore</th>
<th>Thailand</th>
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<tr>
<td>Crustacea</td>
<td>As per Codex</td>
<td>But states wheat</td>
<td>States</td>
<td>Codex</td>
<td>As per Codex</td>
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<td>Egg</td>
<td>As per Codex</td>
<td>And states wheat</td>
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<td>AS per Codex</td>
<td>Codex</td>
<td>Codex</td>
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<tr>
<td>Fish</td>
<td>As per Codex</td>
<td>And states wheat</td>
<td>States</td>
<td>Codex</td>
<td>As per Codex</td>
<td>As per Codex</td>
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<td>Codex</td>
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<tr>
<td>Peanuts and soybeans</td>
<td>Eternal</td>
<td>Coconuts</td>
<td>States</td>
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<td>Milk</td>
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<tr>
<td>Tree nuts (and all their products)</td>
<td>Eternal</td>
<td>Coconuts</td>
<td>States</td>
<td>Codex</td>
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<td>Eternal</td>
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<td>Sulphites</td>
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</table>

**Recent changes**

- **Codex**: Variation cereal including wheat, rye, barley and oat nut and nut product including peanut and soybean; fish and fish product; milk and milk product (inc lactose) Egg and egg product.
- **Codex Implementation Pending**

**General STD for Labelling of Prepackaged Foods**

- Food Allergen and Consumer Protection Act 2004
- Codex Alimentarius
- Law concerning Standardization and Proper Quality Labeling of Agricultural and Forestry Products April 2002 (Law No.175 of 1950, hereinafter referred to as "JAS Law"), Amendment to Food Allergen Labelling regulations published in 2011. in force in August 2012
- FSANZ 2000 (enforced in 2002)
- General Administration of Quality Supervision, Inspection and Quarantine

**Links**

- [Regulation 11](http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/26460/2web_FoodRegulations_3Sep2013.pdf)
- [Regulation 4 (ea)](http://www.wtocenter.org.tw/SmartKMS/fileviewer?id=135404)
- [Regulation 20 (6) for sulphites](http://www.wtocenter.org.tw/SmartKMS/fileviewer?id=135404)
- [Regulation 11](http://fsq.moh.gov.my/v4/images/filepicker_users/Sec35272cb-78/Perundangan/Akta%2020dan%20Peraturan/Food_Regs_1985/Regulation%202011.pdf)
- [Regulation 11](http://fsq.moh.gov.my/v4/images/filepicker_users/Sec35272cb-78/Perundangan/Akta%2020dan%20Peraturan/Food_Regs_1985/Regulation%2011.pdf)
International View Points

Nut Allergy Alert:
Nuts are used on the premises of our bakery and equipment. All French Macarons are made with nut flours and some menu items contain various nuts.

Please Contact Staff if you have any Allergens.

Almost Gluten Free
$1.50 each 14.95 dozen.
DON'T EAT WHOLE GRAINS IF YOU DON'T KNOW HOW TO EAT THEM.

PROTEIN BUILDS YOU OR KILLS YOU: PLANT PROTEINS TURN TO GLUTEN & DAMAGE YOUR INTESTINAL LINING. THE MORE YOU EAT, THE SOONER YOU ARE DEAD.
International Views

ILSI papers

- Advances in the risk management of unintended presence of allergenic foods in manufactured food products – An overview
- Development and evolution of risk assessment for food allergens
- Translating reference doses into allergen management practice: Challenges for stakeholders

Others

Globally consistent use of precautionary allergen labelling.

Katie Allen (et al) calling for an international framework to drive global consistency in allergen labelling, particularly precautionary allergen labelling (PAL).
International Tools

FDF Guide-

http://www.foodallergens.info/Manufac/Guidelines.html

Allergen Management in the Food Industry – Edited by Joyce Boye and Samuel Benrejeb Godefrey

Risk Management for Food Allergy (Food Science & Technology International (Hardcover Academic) Charlotte Madsen (Editor), Rene Crevel (Editor), Clare Mills Dr. (Editor), Steve Taylor (Editor)
Guides

FSA _ Providing allergen information for non pre-packed foods
Voluntary best practice advice to help food retailers and caterers selling food that is not pre-packed provide allergen information on the food they sell.
http://www.food.gov.uk/business-industry/guidancenotes/labelregsguidance/nonprepacked#.U6a9wPmSzAQ

BRC guideline to meet allergen management
21-Mar-2014
The British Retail Consortium (BRC) Global Standards has published a guideline to help manufacturers identify allergens and ensure best practices are met and risks reduced.

BRC Global Standard for Food Safety – Guidelines for Allergen Management
Allergen Management - 12 Point Plan

1. Supplier approval
2. Ingredients
3. Consumer profile
4. Sanitation
5. HACCP plan
6. Employee awareness and training
12 Point Plan

7. Rework
8. Reformulation
9. Product research and development
10. Labelling and claims
11. Engineering and maintenance
12. Action plan
HACCP for allergens

1. Approved supplier program
2. Raw Material control
3. Sanitation
   Segregation
   Scheduling
4. Training and awareness
5. Labelling

http://www.foodprotection.org/resources/food-allergen-icons/
A word about cleaning validations

What’s important in a validation
Risk assessment
  What allergen
  What form
Swab before and after cleaning
Finished Product with risk based sampling strategy
Repeatable – minimum of three events
Modelling

No place for stripping!
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
Techniques applicable for routine analysis - Fit for purpose

Non specific
- ATP – bioluminescence
- Protein

Specific
- Target either the allergen itself or a marker that indicates the presence of the allergenic food.
  - Markers include
    - Specific proteins
    - DNA fragments
- ELISA variants
- PCR
Role of testing in allergen control:

(A) Monitor Ingredients
- ensure raw material allergen profile is as specified
- handling/storage appropriate

(B) Investigate, validate cleaning procedures

(C) Targeted analysis of problem pieces of processing equipment

(D) Environmental swabs and finished product samples to determine effectiveness of cleaning protocols

(E) End product to verify effectiveness of, and adherence to, control procedures
Role of testing in allergen control:

(F) Investigation of complaints related to undeclared food allergens

(G) Monitoring of change impact

(H) Confirm assumptions made during risk assessment process
    E.g. VITAL® (Voluntary Incidental Trace Allergen Labelling)

(I) Free From ...........

(J) Regulatory Compliance
Enzyme Linked Immuno Sorbent Assays Available

<table>
<thead>
<tr>
<th>Category</th>
<th>Allergen</th>
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<tbody>
<tr>
<td>Gluten</td>
<td>Gluten</td>
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<td>Competitive gluten</td>
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<tr>
<td>Milk</td>
<td>Total milk</td>
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<td></td>
<td>Casein</td>
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<td></td>
<td>Beta lactoglobulin</td>
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<td>Soy</td>
<td>Soy</td>
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<td>Lysozyme</td>
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<td>Peanut</td>
<td>Peanut</td>
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<td>Tree-nuts</td>
<td>Hazelnut</td>
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<td></td>
<td>Almond</td>
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<td>Walnut</td>
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<td>Macadamia</td>
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<td>Pistachio</td>
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<td>Cashew</td>
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<td>Sesame</td>
<td>Sesame</td>
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<tr>
<td>Crustacean</td>
<td>Crustacean</td>
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<td>Fish</td>
<td>Cod species</td>
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<td></td>
<td>Lupin</td>
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<td></td>
<td>Buckwheat</td>
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<td></td>
<td>Mustard</td>
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<td></td>
<td>Coconut</td>
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<tr>
<td>Gaps to Plug</td>
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<table>
<thead>
<tr>
<th>Category</th>
<th>Allergen</th>
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</thead>
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<tr>
<td>Grains</td>
<td>Wheat</td>
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<td></td>
<td>Oats</td>
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<tr>
<td></td>
<td>Barley</td>
</tr>
<tr>
<td></td>
<td>Rye</td>
</tr>
<tr>
<td>Nuts</td>
<td>Brazil</td>
</tr>
<tr>
<td></td>
<td>Pecan</td>
</tr>
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<td></td>
<td>Pine Nuts</td>
</tr>
<tr>
<td></td>
<td>Celery</td>
</tr>
<tr>
<td></td>
<td>Molluscs</td>
</tr>
</tbody>
</table>

Increasing number of reputable kit producers responsive to industry needs
Key Analytical Considerations

What laboratory
What method
What calibrator
What matrix
Reference materials and proficiencies
Company pedigree and available information
External publication and Approvals
Sensitivity, Cross Reactivity and Related products
Current testing trends

Overall increase in analysis
Increase non risk based analysis
Increased use of strip based tests

Surface and product
ELISA remains most common method
Increased interest in PCR in some jurisdictions
International push towards Mass Spectrometry in various forms

May become gold standard although currently few fully validated methods (egg, milk validated by the instrument producer)

Fit for purpose - quick and dirty
Australia and New Zealand's Industry Tools

AFGC Food Industry Guide to Allergen Management and Labelling
Under review

Product Information Form
Allergen Bureau
VITAL® and VITAL® support tools
http://www.allergenbureau.net
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.
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
Establishment of Reference Doses for residues of allergenic foods: Report of the VITAL Expert Panel


*Food Allergy Research & Resource Program, University of Nebraska, Lincoln, NE, USA.
†R&D, Protexera, Inc.
‡Agriculture & Food Safety, Ministry of Health and Welfare, Amsterdam, the Netherlands.

Department of Allergy & Immunology, Royal Children’s Hospital, Melbourne, VIC, Australia.

A R T I C L E   I N F O

Keywords: Allergy; Labeled; Food; Allergen; Evaluation; Reference dose.

Abstract

In 2011, an expert panel was assembled to establish appropriate Reference Doses for allergenic food residues as part of the VITAL (Vigilance Tool for Allergen Labeled information) project of the Allergen Bureau of Australia & New Zealand. The Reference Doses were intended to provide a basis for developing reference dose tables for allergenic foods that contain food allergens. These tables can be used by the food industry, regulatory agencies, and healthcare providers to develop food labeling and reference dose tables for allergenic foods. The Reference Doses were established to provide a scientifically valid basis for the development of food labeling and reference dose tables for allergenic foods.

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 prevention of food-allergic consumption errors. Food labeling is a key tool in this regard, as it helps to prevent the occurrence of allergic reactions in food allergic individuals. The labeling of the presence of allergenic foods is critical to the implementation of safe and effective avoidance by food allergic individuals. The identification of allergenic foods that are not declared on product labels (undisclosed 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 unmeasured consequences, including potential risk-taking which negates the original intent of the labeling (Barrett et al., 2011).

The aim of the project was to establish reference dose tables for allergenic foods that contain food allergens. These tables can be used by the food industry, regulatory agencies, and healthcare providers to develop food labeling and reference dose tables for allergenic foods.

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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
**VITAL® 2.0 Action Level Grid**

**Reference Amount / Serving Size**: 5 g  
**VITAL Action Level Grid**

<table>
<thead>
<tr>
<th>Product</th>
<th>Action Level 1</th>
<th>Action Level 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almond</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
</tr>
<tr>
<td>Brazil nut</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<tr>
<td>Cashew</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<tr>
<td>Hazelnuts</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<tr>
<td>Macadamia nut</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<tr>
<td>Pecan</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<td>Pine nut</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<td>Pistachio nut</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<tr>
<td>Walnut</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<td>Wheat</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<td>Rye</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<td>Barley</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<td>Oats</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<td>Spelt</td>
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<td>≥20 ppm</td>
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<td>Egg</td>
<td>&lt;6 ppm</td>
<td>≥6 ppm</td>
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<td>Crustacea</td>
<td>&lt;200 ppm</td>
<td>≥200 ppm</td>
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<td>Fish</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<tr>
<td>Milk</td>
<td>&lt;20 ppm</td>
<td>≥20 ppm</td>
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<tr>
<td>Peanut</td>
<td>&lt;40 ppm</td>
<td>≥40 ppm</td>
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<td>Sesame seed</td>
<td>&lt;40 ppm</td>
<td>≥40 ppm</td>
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<tr>
<td>Soy</td>
<td>&lt;200 ppm</td>
<td>≥200 ppm</td>
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<tr>
<td>Sulphites</td>
<td>&lt;10 ppm</td>
<td>≥10 ppm</td>
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<tr>
<td>Lupin</td>
<td>&lt;800 ppm</td>
<td>≥800 ppm</td>
</tr>
<tr>
<td>Mustard</td>
<td>&lt;10 ppm</td>
<td>≥10 ppm</td>
</tr>
</tbody>
</table>

*Embedded in the Calculator*

*Specific to each product*

*Based on Reference Dose and appropriate Reference Amount/Serving Size*

*Analytical Sensitivity*
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

http://allergenbureau.net/vital/vital-downloads
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
VITAL® Evolving

VITAL®: 3 phases

Phase 1 – Risk Review

Phase 2 – Risk Communication (Labelling)

Phase 3 – Certification Investigation
iFAAM – Integrated Approaches to Food Allergen and Allergy Risk Management

- EU supported project builds on EuroPrevall
- involves leading experts from UK, Europe, Australia and US.
- will produce a standardised management process for food manufacturing companies.
- develop tools regulations and produce evidence-based health advice on nutrition.
- build risk models to support management of allergens in a factory environment to minimise the use of precautionary labels.
- Investigate tools to measure allergens to allow validation and monitoring of allergen management plans.
- Investigate nutritional approaches and dietary implications for allergic community
Are we there yet - Recalls

4-year Recalls Comparison (As of July 2014)

2011-2014 Food Recalls - Allergens (As of July 2014)
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

» Process is a critical risk factor

» http://allergenbureau.net/tag/food-safety-magazine/
The Future
Packaging smarter than we are?

Thank you

Presenter

Rob Sherlock
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www.dtsfoodlabs.com.au
www.factaaustralia.com.au

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