AOAC DALLAS

The VITAL ® approach to risk-based precautionary allergen labelling

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The Allergen Bureau and me

- Established in 2005 due to industry demand, Management Committee, now a ‘Not for Profit’ organisation
- 10 years experience
- The food industry are our Members
  - 31 Full Members;
  - 20 Associate members; and
  - 19 Individual members
- The Members steer the resources & projects

- DTS FACTA-over 10 years' experience in the area and hold the broadest range of NATA accreditation for the performance of allergen analysis
VITAL® Framework:

- VITAL Program
- VITAL Working Groups
- VITAL Scientific Expert Panel (VSEP)
- VITAL Training Providers
- VITAL Communication
The VSEP overarching scientific approach

~ analysed existing published clinical data and some unpublished data

~ statistically based risk assessment

~ scientifically and clinically sound, defensible and transparent

~ protection for vast majority of people with food allergy
### Reference Doses

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Reference Dose (mg of total protein)</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>Tree nuts</td>
<td>0.1</td>
</tr>
<tr>
<td>Soy</td>
<td>1</td>
</tr>
<tr>
<td>Wheat</td>
<td>1</td>
</tr>
<tr>
<td>Mustard</td>
<td>0.05</td>
</tr>
<tr>
<td>Lupin</td>
<td>4</td>
</tr>
<tr>
<td>Sesame</td>
<td>0.2</td>
</tr>
<tr>
<td>Crustacea (shrimp)</td>
<td>10</td>
</tr>
<tr>
<td>Fish *</td>
<td>0.1</td>
</tr>
</tbody>
</table>

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.

* Original VITAL value applied
The VITAL® Program

~ Provides a consistent risk based methodology to thoroughly review the allergen status of all the ingredients and the processing conditions that contribute towards the allergen status of the finished product.

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

~ Delivers one consistent labelling approach where determined appropriate: ‘May be present’

~ Aims to preserve a valuable risk management tool for allergic consumers.
The VITAL® Program

- VITAL Procedure
- Decision Tree
- Interactive VITAL Action Level Grid
- VITAL Online (calculator)
- VITAL training materials and endorsed trainers
- Guidance documents & FAQs
The 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 & 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
Robust Allergen Management Plan

• What is the allergen status of each ingredient?
  2\textsuperscript{nd} party allergen audit, supplier relationship, questions

• Where can cross contact occur in my factory?
  How can this be eliminated or practically reduced?

• How much cross contact? Quantification.
VITAL® Online

~ The user-friendly, web-based VITAL Calculator

~ Input the results of a VITAL risk assessment

~ Output a finished product labelling outcome

~ Training package to support new look VITAL® Online

~ Advisory Group & a VITAL® User Group have been pivotal
Reference Amount in VITAL®
Online

Create recipe

Recipe name*
Flourless Chocolate Cake

Recipe code*  
Cakes

Reference Amount*  
80
E.g. Finished Product Serving Size,
Reference Amount not applicable

Reference Amount assumptions*  
Represents one slice of cake

Legislation*  
Australia and New Zealand

Legislation description  
ANZFC Allergens

Use this field for preparing a PIF for a customer, or when combining recipe components

Use this field for products sold to consumers
VITAL ® Online

**ADD INGREDIENTS**

- Sugar: RM3
  - 30.000000%
- Cooking fat: RM2
  - 30.000000%
- Liquid whole eggs: RM1
  - 30.000000%
- Dark compound Chocolate: RM4
  - 10.000000%

**Ingredient as a percentage of recipe**

- 30.00000

**Allergens & their products**

- Gluten containing cereals
- Tree nuts
  - Celery
  - Crustacea
  - Eggs
  - Finfish

**Help and Support**

Add the individual ingredients, their allergens and their percentage of this recipe. Choose from your pre-entered ingredient library, or enter them manually.
Example of a VITAL® Online Labelling Outcome Summary

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Reference amount (mg)</th>
<th>Action level 1</th>
<th>Action level 2</th>
<th>Partial or Complete</th>
<th>Labeling outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereal containing gluten (wheat)</td>
<td>1 &lt; 12.5 ppm</td>
<td>&lt; 12.5 ppm</td>
<td>&gt; 12.5 ppm</td>
<td>Partial</td>
<td>Intentionally added</td>
</tr>
<tr>
<td>Oats</td>
<td>1 &lt; 12.5 ppm</td>
<td>&lt; 12.5 ppm</td>
<td>&gt; 12.5 ppm</td>
<td>Partial</td>
<td>Intentionally added</td>
</tr>
<tr>
<td>Rice</td>
<td>1 &lt; 12.5 ppm</td>
<td>&lt; 12.5 ppm</td>
<td>&gt; 12.5 ppm</td>
<td>Partial</td>
<td>Intentionally added</td>
</tr>
<tr>
<td>Rye</td>
<td>1 &lt; 12.5 ppm</td>
<td>&lt; 12.5 ppm</td>
<td>&gt; 12.5 ppm</td>
<td>Partial</td>
<td>Intentionally added</td>
</tr>
<tr>
<td>Spelt</td>
<td>1 &lt; 12.5 ppm</td>
<td>&lt; 12.5 ppm</td>
<td>&gt; 12.5 ppm</td>
<td>Partial</td>
<td>Intentionally added</td>
</tr>
<tr>
<td>Wheats</td>
<td>1 &lt; 12.5 ppm</td>
<td>&lt; 12.5 ppm</td>
<td>&gt; 12.5 ppm</td>
<td>Partial</td>
<td>Intentionally added</td>
</tr>
<tr>
<td>Oatcakes</td>
<td>12 &lt; 125 ppm</td>
<td>&lt; 125 ppm</td>
<td>&gt; 125 ppm</td>
<td>Complete</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Figs</td>
<td>0.001 &lt; 0.275 ppm</td>
<td>&lt; 0.275 ppm</td>
<td>&gt; 0.275 ppm</td>
<td>Partial</td>
<td>Action Level 1</td>
</tr>
<tr>
<td>Fennel</td>
<td>0.1 &lt; 1.26 ppm</td>
<td>&lt; 1.26 ppm</td>
<td>&gt; 1.26 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Lovage</td>
<td>0.1 &lt; 1.26 ppm</td>
<td>&lt; 1.26 ppm</td>
<td>&gt; 1.26 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Milk</td>
<td>0.1 &lt; 1.26 ppm</td>
<td>&lt; 1.26 ppm</td>
<td>&gt; 1.26 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Mustard</td>
<td>0.1 &lt; 1.26 ppm</td>
<td>&lt; 1.26 ppm</td>
<td>&gt; 1.26 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Other</td>
<td>0.1 &lt; 1.26 ppm</td>
<td>&lt; 1.26 ppm</td>
<td>&gt; 1.26 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Pecan</td>
<td>0.2 &lt; 2.56 ppm</td>
<td>&lt; 2.56 ppm</td>
<td>&gt; 2.56 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Sesame</td>
<td>0.2 &lt; 2.56 ppm</td>
<td>&lt; 2.56 ppm</td>
<td>&gt; 2.56 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Shefflaid/White</td>
<td>0.2 &lt; 2.56 ppm</td>
<td>&lt; 2.56 ppm</td>
<td>&gt; 2.56 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Soy</td>
<td>1 &lt; 12.5 ppm</td>
<td>&lt; 12.5 ppm</td>
<td>&gt; 12.5 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
<tr>
<td>Guajillo</td>
<td>0.1 &lt; 5.06 ppm</td>
<td>&lt; 5.06 ppm</td>
<td>&gt; 5.06 ppm</td>
<td>Partial</td>
<td>Action Level 2</td>
</tr>
</tbody>
</table>

These Action Levels will change depending on the product’s Reference Amount.

VITAL labelling outcomes will appear like this.
Role of analysis in VITAL

Monitor ingredients to ensure raw material allergen profile is as specified and handling/storage appropriate

Investigate, validate and verify cleaning procedures

Perform targeted analysis of problem pieces of processing equipment

Monitor change impact

Confirm assumptions made during risk assessment process
VITAL Phase 1 – Risk Review (expanding & enhancing) Working Group

- How to perform and interpret an allergen risk assessment
- Guidance documents exist but **risk review** is not well articulated in VITAL guidance
- Intention to provide further guidance and industry specific examples
VITAL Phase 2 – Risk Communication (Labelling) Working Group

~ Allergen labelling exemptions
  ~ gazetted in the Food Standards Code in May 2016
  ~ example of the food industry working together pre-competitively for mutual benefit

~ The new Food Allergen Labelling VITAL® Best Practice Guide
  ~ assist industry in accessing allergen labelling guidance from one place
  ~ provide a link between VITAL Program labelling outcomes and existing allergen labelling information
  ~ provide five examples showing best practice for declaring food allergens
VITAL Phase 3 – Certification Investigation Working Group

- Overarching Allergen Management Principles to support use of VITAL
- VITAL Verification Module (Product specific) designed to be used with existing overarching Standards
- Development of an ISO standard under consideration
- Certification mark based on verification of appropriate VITAL® implementation
  - Consumer communication key
Risk review anomalies – Working Group

- Allergens are known to be present but are:
  - Not formulated as an ingredient; and
  - Inappropriate to label as per VITAL ‘May be present’

- The group will consider options and approaches

- Representatives from The Australian Industry Group (Ai Group) Confectionery Sector Technical Committee: Mondelēz International, Mars Chocolate Australia, Nestlé Confectionery & Snacks & Fyna Foods Australia
Expanding VITAL Online to the world

Challenge – global differences in

• mandatory allergens
• allergen definitions
• labelling exemptions
• language
• obtaining cross contact information from ingredient suppliers
Contact Details

Allergen Bureau

- VITAL® Coordinator /support (Georgina Christensen & Lisa Warren)
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DTS FACTA

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