VITAL Allergen Risk Assessment

23 September 2008

Fiona Fleming
Overview

- What is Vital?
- What has been achieved to date?
- Next Steps
- Challenges
The “may contain” dilemma

• Industry is criticised for the inconsistent and often blanket approach to precautionary allergen labelling.
• Allergic consumers confused and take risks
• Reduces the value of precautionary labelling as risk management measure
VITAL – launched June 2007
VITAL Allergen Risk Assessment

23 September 2008
What is Vital?

- An Industry solution

- A tool for industry intended to be used as part of a HACCP process when conducting the risk assessment for allergenic hazards

- 3 level grid to assist in determining if the presence of residual protein from allergenic substances requires a precautionary statement

- Intended to be used where cross contact is:
  - Documented using Vital; and
  - Unavoidable; and
  - Sporadic

- A single consistent message to the allergic consumer “May be present: “

- Reflects best evidence currently available
## VITAL - Timeline

|------------|---------------------------------|-------------------------------------|-------------------------------------|
| Project Team formed | Review of current risk assessment protocols | Development of VITAL:  
  - literature review was conducted to develop the levels in the grid  
  - Decision Tree and Procedure developed | Stakeholder consultations & refinement |

**VITAL Allergen Risk Assessment**  
23 September 2008
VITAL – Timeline (continued)

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>VITAL Industry Pilots</td>
<td>Draft for inclusion into revised AFGC Guide</td>
<td>Targeted consultation on Action Level Grid</td>
<td>Finalise for AFGC Guide</td>
<td>Launch of AFGC Allergen Guide</td>
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</tbody>
</table>
The Vital Process

- **assessment** of likely sources of cross contact allergenic substances from raw materials and the processing environment,
- **evaluation** of the amount present,
- **review** of the ability to reduce the allergenic material from all contributing sources,
- **decision** on precautionary labelling statement, and
- **ongoing monitoring and verification.**
VITAL Allergen Risk Assessment

Particulate form

- Determine level of cross contact allergen in ingredient and from manufacturing process, calculate proportion in the finished product as mg per kg of total protein.

- Compare the concentration of allergen in the final product to the VITAL grid. Is the allergen above Action Level 1?
  - YES
    - Review contributors to prevent occurrence. Does possible presence of particulate remain?
      - NO
        - NO CROSS CONTACT STATEMENT REQUIRED
      - YES
        - Action Level 2
          - ALLERGEN CROSS CONTACT STATEMENT IS REQUIRED
  - NO

Readily dispersible form

- Review significant contributors to the cross contact and reduce where feasible. Is the revised level still above Action Level 1?
  - YES
    - Action Level 3
      - ALLERGEN INGREDIENT STATEMENT IS REQUIRED
  - NO

- Ongoing monitoring of ingredient and product processing to ensure validity of labelling. Take corrective action where required.
# Voluntary Incidental Trace Allergen Labelling (VITAL)

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## INDEX

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<tbody>
<tr>
<td>A</td>
<td>B</td>
<td>C</td>
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### VITAL Grid, Explanatory Notes, Decision Tree, Procedure
- Table showing the Allergen Advisory Action Levels
- Links to Explanatory Notes, Decision Tree & Procedure on how to use the Allergen Advisory Action levels

### Guidelines
Guidelines, Instructions and Assumptions about using this worksheet for calculations

### Assumptions
Worksheet to document any key assumptions when running the calculation

#### 1. Raw Material Impact
Worksheet to calculate the allergen impact of the raw materials in the product

#### 2. Raw Material Cross Contact
Worksheet to calculate the potential cross contact allergen impact of the raw materials in the product
# The Vital Action Level Grid

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Milk*</th>
<th>Egg*</th>
<th>Soy**</th>
<th>Fish*</th>
<th>Peanuts*</th>
<th>Tree Nuts+</th>
<th>Sesame Seed+</th>
<th>Crustacea+</th>
<th>Gluten#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action Level 1 (ppm)</td>
<td>&lt;5</td>
<td>&lt;2</td>
<td>&lt;10</td>
<td>&lt;20</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>&lt;20</td>
</tr>
<tr>
<td>Action Level 2 (ppm)</td>
<td>5 - 50</td>
<td>2 - 20</td>
<td>10 - 100</td>
<td>20 - 200</td>
<td>2 - 20</td>
<td>2 - 20</td>
<td>2 - 20</td>
<td>2 - 20</td>
<td>20 - 100</td>
</tr>
<tr>
<td>Action Level 3 (ppm)</td>
<td>&gt;50</td>
<td>&gt;20</td>
<td>&gt;100</td>
<td>&gt;200</td>
<td>&gt;20</td>
<td>&gt;20</td>
<td>&gt;20</td>
<td>&gt;20</td>
<td>&gt;100</td>
</tr>
</tbody>
</table>

* 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
Recommended Allergen Labelling

**INGREDIENTS**

- Allergic ingredients & derivatives declared in bold each time they appear
- Tree nuts specifically identified
- Gluten source (grain source) qualified in ingredient list
- Contains milk, egg, almonds, soy, wheat and sesame
- May be present: xxx, xxx, xxx
- Summary statement listing all allergenic ingredients in the product as per the table to clause 4 Statement should start with ‘Contains...’
- Cross contact statement declared if appropriate. This statement must only be used in conjunction with the VITAL Tool

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VITAL Allergen Risk Assessment  
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VITAL – Post Launch June 2007
VITAL Pickup – Registration

To date: 200+ registrations

- Australia
- NZ
- US
- India
- Belgium
- UK
- Israel
- France
- Netherlands
Training – Advancing Food Safety (AFS)

Total VITAL training
March – Aug 08 = 365

www.haccptown.com
Key Stakeholders

WQA Version 5 Requirements:

• VITAL: endorsed in June 2008 with release of WQA version 5

• 1 Sept 2008 all Trade Partners supplying WOW Brand implemented WQA

• What does this mean to our supply base:
  - Training
  - Rework of existing specifications
  - Raw Material specification review
750 + supermarkets nationwide
20 – 30,000 SKUs on shelf
92,000 employees
Housebrand private label (2500 + Suppliers)
Focus quality product + innovation
Leading market share private label sales
(Latest Nielson Qtr report)
Products in the market

Noble Rise

Maltesers® contains 75% milk chocolate and 7.5% malt extract. Ingredients: sugar, milk solids, cocoa butter, cocoa mass, glucose syrup (sources include wheat), barley malt extract, vegetable fat, emulsifier (soy lecithin), wheat gluten, raising agents (500, 501), salt, pectin, natural vanilla extract. Milk chocolate contains a minimum of 25% cocoa solids and 22% milk solids. May be present: peanuts

Mars® bar contains milk chocolate 40%, nougat 33% and caramel 27%. Ingredients: sugar, glucose syrup (sources include wheat), milk solids, vegetable fat, cocoa butter, cocoa mass, barley malt extract, cocoa powder, emulsifier (soy lecithin), salt, egg white, natural vanilla extract. Milk chocolate contains a minimum of 25% cocoa solids and 22% milk solids. May be present: peanuts and tree nuts.
Next steps
VITAL Co-ordinator

- Develop and maintain VITAL-related FAQ's and case studies
- Manage the VITAL review process
  - Conduct research to support the action levels on which VITAL is based
- Develop the vitalallergen.com website
- Maintain and develop VITAL documentation
- Maintain and develop the VITAL calculator
- Liaise with food industry retailers with respect to implementation of VITAL
- Liaise with our training provider with respect to VITAL training
- Develop an Auditor Guide for VITAL
- Conduct benchmarking on VITAL

Timeframe: September 08
VITAL Q&A

Q. What is VITAL?
Q. What is the benefit to industry to use VITAL
Q. What is the benefit to allergic consumers if industry uses VITAL
Q. Is it mandatory?
Q. Who is using it – what sort of take up has occurred in the food industry?
Q. Is there some way to indicate to consumers that the vital tool has been used to determine the risk – e.g. “V” for Vital?
Q. Is there a Certification system for those who are using vital?

Timeframe: September 08
VITAL Review

Project description:

Outcomes:
- Update "Development of VITAL Allergen Actions Levels Grid Explanatory Notes" to include references published since June 2007 through a comprehensive literature review
- Update values in VITAL Grid based on findings of literature review
- Review VITAL Decision Tree and Procedure

Timeframe: January 09
Market Survey – Outcome

After each survey combine the data from the 3 sites and provide a written report with:

- A list of all products carrying the allergen labelling; and
- Assesses the proportion of product correctly using the AFGC labelling guide and Vital.

Timeframe: February 09
Consultations

- FSANZ Allergen Issues Paper
- FDA – Public Hearing

*Food Labelling; Current Trends in the use of Allergen Advisory Labelling: Its Use, Effectiveness, and Consumer Perception*

- The FDA is developing a long-term strategy to assist manufacturers in using allergen advisory labelling that is truthful and not misleading, conveys a clear and uniform message, and adequately informs food allergic consumers and their care-givers

http://www.cfsan.fda.gov/~lrd/fr080808.html
Challenges

- Cross contact information from suppliers of ingredients (PIF)
- Robustness of the Action Level numbers
- Assume homogenous distribution of “cross contact” allergen
- Imported products
- Does the use of the process need to be audited to ensure compliance?
- How do consumers know which companies are using the process?
- Who will manage and update?
The Journey continues...

...will you join us?
Fiona Fleming
Chair
Allergen Bureau Management Committee

Submit a Review
review@allergenbureau.net

Technical Support
support@allergenbureau.net

Management