VITAL 2.0 – What you need to know

April 2012
Allergen Bureau Information Session
Agenda

1. Introducing VITAL 2.0

2. What can be recycled from VITAL Version 1

3. What is new
Introducing VITAL 2.0

• NEW Action Levels
• NEW Concepts
  • Reference Dose
  • Reference Amount/Serving Size
• NEW Definitions
  • Fish
  • Tree nuts
  • Particulates
Introducing VITAL 2.0

- VITAL (Version 1) was launched in 2007

- VITAL has been reviewed including:
  - recommendations from VITAL Scientific Expert Panel, and
  - feedback from VITAL users

- VITAL 2.0 is the updated version of VITAL and will supersede VITAL (Version 1)
Introducing VITAL 2.0

- New procedure (Guidance document)
- New VITAL Calculator
- New VITAL Action Level Grid (incorporated in the VITAL Calculator)
- New FAQ’s
Introducing VITAL 2.0 – New Identity!

an initiative of the Allergen Bureau
What is new in VITAL 2.0?

- New Action Levels
- Reference Dose + Reference Amount/Serving Size
- New VITAL Calculator
- New Allergens
Action Levels

- Action Levels are the concentrations which define how cross contact allergens should be labelled.
- Cross contact allergens are those which are unintentionally incorporated.
- Action Level One = low concentration of allergens, low chance of adverse reaction & no precautionary statement required.
- Action Level Two = significant concentration of allergen protein, significant chance of adverse reaction and a precautionary statement is required.
Action Level Concept

- VITAL 2.0 still uses Action Levels
- Action Levels guide labelling recommendations
- BUT – VITAL 2.0 has only 2 Action Levels and a new interactive VITAL Action Level Grid
Two Action Levels

• Action Level 3 has been removed – no requirement for ingredient labelling

• High levels of cross contact allergen will have “May be present” labelling recommendation

• Consistent with advice to allergic consumers to avoid products, to which they are sensitive, with an allergen precautionary statement
VITAL Action Level Grid

**Action Level 1** - precautionary cross contact statement is **not** required

**Action Level 2** - precautionary cross contact statement is **required**

“May be Present: XXX”
VITAL Action Level Grid

• Interactive

• Specific to each product

• Based on Reference Dose and appropriate Reference Amount/Serving Size
Action Levels

- Action Levels are found in the interactive VITAL Action Levels Grid

- Calculated from Reference Dose and Reference Amount/Serving Size

Transition between Action Levels*

= Reference Dose x (1000 / Reference Amount/Serving Size)

*with the exception of gluten containing cereals where it is either this formula or 20ppm, whichever is smaller
Transition between Action Levels = 
Red Reference Dose \times \left(\frac{1000}{\text{Reference Amount/Serving size}}\right)

Set by VSEP
Reference Dose

- 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

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Peanut</th>
<th>Milk</th>
<th>Egg</th>
<th>Tree nuts</th>
<th>Soy</th>
<th>Wheat</th>
<th>Mustard</th>
<th>Lupin</th>
<th>Sesame</th>
<th>Crustacea (Shrimp)</th>
<th>Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Dose (mg)</td>
<td>0.2</td>
<td>0.1</td>
<td>0.03</td>
<td>0.1</td>
<td>1</td>
<td>1</td>
<td>0.05</td>
<td>4</td>
<td>0.2</td>
<td>1</td>
<td>0.1</td>
</tr>
</tbody>
</table>
Transition between Action Levels = Reference Dose x (1000 / Reference Amount/Serving Size)

Set by User
Reference Amount / Serving Size

Definition:
• the maximum amount of a food eaten in a typical eating occasion;

• may be the same as the “serving size” on the nutrition information panel or;

• the whole product as presented to the consumer

• it is recommended that where serving size is used that the AFGC serving size principles should be applied
Reference Amount / Serving Size

- Entered into VITAL Action Level Grid to determine Action Levels
- Specific for each product
- Determination of Reference Amount / Serving Size is a business decision
- Reference Amount / Serving Size choice can significantly affect Action Levels
VITAL Grid

Peanut Reference Dose = 0.2 mg protein

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

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

• New allergens added to VITAL Action Level Grid

• Lupin

• Mustard
Particulates

Definition: a particulate is a separate and distinct particle of material (eg sesame seeds, slithered nuts, grated cheese). For the purpose of VITAL, a particulate refers to an entity of food which either

1. Does not mix homogenously with other parts of the food; or

2. May consist of, or are likely to aggregate into an entity which contains equal to or greater than the relevant Reference Dose.
Tree nuts definitions

FSANZ (Schedule 4 of Standard 1.4.2):

Almonds;
Beech nuts;
Brazil nut;
Cashew nut;
Chestnuts;
Hazelnuts;
Hickory nuts;
Japanese horse-chestnut;
Macadamia nuts;
Pecan;
Pine nuts;
Pili nuts;
Pistachio nuts;
Sapucaia nut;
Walnuts.

VITAL 2.0

Almonds;
Brazil nut;
Cashews nut;
Hazelnuts;
Macadamia nuts;
Pecans;
Pine nuts (pignolias);
Pistachio nuts;
Walnuts.
Fish Definitions

FSANZ:
Fish = Fin fish + Molluscs

VITAL 2.0:
Fish = Fin fish
Gluten Representation

- Units for measuring gluten cross contact have changed from:

  mg gluten per kg; to

  mg total protein from gluten containing cereal per kg

- Action Level for gluten will depend on Reference Amount / Serving Size but will be locked to a maximum of 20ppm
Gluten Representation

- VITAL cannot be used as justification NOT to label highly refined ingredients from an allergen source.
- Clarification in VITAL 2.0 with regard to “gluten-containing cereals.”
What can be retained from existing VITAL assessments to help with implementing VITAL 2.0?

Scope / Pre-requisites

Risk assessment
**GRAND TOTAL - RM & Processing Cross Contact, & Concentration / Dilution Impact (As Consumed)**

<table>
<thead>
<tr>
<th>Units</th>
<th>Milk</th>
<th>Egg</th>
<th>Soy</th>
<th>Fish</th>
<th>Peanut</th>
<th>Tree Nut</th>
<th>Sesame</th>
</tr>
</thead>
<tbody>
<tr>
<td>ppm</td>
<td>0.0</td>
<td>0.0</td>
<td>221.7</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Labelling</td>
<td>Must label</td>
<td>No Label</td>
<td>Must Label</td>
<td>No Label</td>
<td>No Label</td>
<td>No Label</td>
<td>No Label</td>
</tr>
</tbody>
</table>

| Action level 1 (ppm) | 5 | 2 | 10 | 20 | 2 | 2 | 2 |
| Action level 3 (ppm) | 50 | 20 | 100 | 200 | 20 | 20 | 20 |
Scope and Pre-requisites - Retained

• **Scope**
  – processed foods (excluding those specifically formulated for infants)

• **Pre-requisites**
  • HACCP based food safety program
  • in depth knowledge of manufacturing plant and ingredients
Risk Assessment

• Identification and quantification of cross contact allergens are retained from VITAL (version 1) *
  * except for gluten

• For existing VITAL risk assessments, information about cross contact from suppliers and calculations on concentration of cross contact from processing, can be retained
New VITAL Procedure

- Now called Guidance Document – more detailed
- New definitions and expanded explanations
- Attempts to avoid common mistakes
- Includes detailed information about allergen analysis
- Currently DRAFT format only – we welcome your comments!
New VITAL Calculator

- New version more detailed and follows new procedure
- Point and Click
- Summary page for customers
- Current DRAFT format only – we welcome your comments!
Summary of changes:

• Determine Reference Amount / Serving Size for each product

• VITAL Action Level Grid must be calculated for each product

• Conversion from VITAL (Version 1) to VITAL 2.0 is possible

• Review labelling outcomes from VITAL (Version 1) as they may be changed
Thank you

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