Allergen management ~ it’s all about the consumer safety

Kirsten Grinter
President, Allergen Bureau
Discussion

~ Who is the Allergen Bureau
~ The VITAL Program & PAL
~ VITAL growth - Allergen Bureau Working Groups
~ Cross Contact Anomalies
~ What success looks like
Who we are

~ Established in 2005 due to industry demand, a ‘Not for Profit’ organisation

~ Manage VITAL® Program, continues to invest & engage broadly

~ Our members steer the resources & projects
  - 31 Full members
  - 23 Associate members
  - 21 Individual members

Our reason for being to share information & experience across the food industry on the management of food allergens to ensure consumers receive relevant, consistent & easy to understand food allergen information
Allergen landscape ~ Australia New Zealand

Working together to drive Allergen Management Initiatives

~ Allergen Bureau Industry ‘not for profit’

~ AFGC Allergen Forum

~ FSANZ Allergen Collaboration

~ ASCIA & AAA National Allergy Strategy

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Allergen Bureau - Why

- May contain ........ Inconsistent use of Allergen Risk Assessment
- Proliferation of cross contact statements across the industry, survey of 350 products in 2005 revealed 42 creative statements!
  - Made in the same factory/facility.....
  - Made on the same line.....
- Allergic consumers were ignoring cross contact statements
- Action levels varied between manufacturers, no consistency

So...

Industry Guidance and Standards were needed
The VITAL Program

Voluntary Incidental Trace Allergen Labelling

a standardised allergen risk assessment process for the food industry

Developed by industry for industry and is adopted on a voluntary basis
What is the VITAL Program?

The VITAL Program provides a consistent methodology for food industry to **assess the impact of allergen cross contact** and provide appropriate precautionary allergen labelling on their products.

The VITAL precautionary allergen statement ‘**May be present: XXX**’ for cross contact allergens indicates a defined level of risk based upon scientific principles.
The VITAL® Program

~ consistent approach to assessing cross contact allergen risk
~ clear, consistent and accurate allergen declaration
~ assists consumers in making safer food choices
~ encourages the elimination of cross contact allergens where possible within manufacturing or via material supplier
~ standard precautionary allergen labelling statement is used
Benefits to the allergic consumer

- Cross contact allergens are declared based upon a standardised risk assessment process
- Founded upon scientific principles
- Clear, accurate and consistent information about the allergen status of the product

Allows the consumer to trust the information
Benefits to the food industry

¬ standardised risk review process
¬ labelling outcomes are based upon science
¬ VITAL Online - user-friendly

Provides reassurance by virtue of informed decision making
The VITAL Framework

- VITAL Program
- Tools
- VSEP
- Training Providers
- (WG1) Risk Review
- (WG2) Communication
- (WG3) Certification
- Risk Review Anomalies
- VITAL Online

Allergen Bureau: informing the food industry
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

http://allergenbureau.net/vital/vital-downloads
Allergen Risk Assessment Decision Tree

the fundamental first step

ingredient specification already identifies intended allergens – in Ingredient List

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Allergen Bureau
informing the food industry

ILSI China March 2017
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>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>

* Original VITAL value applied
Action Levels guide labelling recommendations

**Action Level 1**
a low concentration of allergen protein and a low chance of adverse reaction.

No precautionary statement is required.

**Action Level 2**
a significant concentration of allergen protein and a significant chance of adverse reaction.

A precautionary statement is required.
Example of a VITAL® Online Labelling Outcome Summary

VITAL labelling outcomes will appear like this

Table: Summary of labelling outcomes

<table>
<thead>
<tr>
<th>Substances</th>
<th>Reference amount or serving size: 80g</th>
<th>Action level 1</th>
<th>Action level 2</th>
<th>Cross contact amount</th>
<th>Labelling outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals containing gluten (Total)</td>
<td>1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barley</td>
<td>1 &lt; 12.5 ppm</td>
<td></td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oats</td>
<td>1 &lt; 12.5 ppm</td>
<td></td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rye</td>
<td>1 &lt; 12.5 ppm</td>
<td></td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spelt</td>
<td>1 &lt; 12.5 ppm</td>
<td></td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheat</td>
<td>1 &lt; 12.5 ppm</td>
<td></td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cress</td>
<td>10 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eggs</td>
<td>0.03 &lt; 0.375 ppm</td>
<td>≥ 0.375 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fennel</td>
<td>0.1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupin</td>
<td>0.1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Milk</td>
<td>0.1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mustard</td>
<td>0.1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0.1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peanut</td>
<td>0.2 &lt; 2.5 ppm</td>
<td>≥ 2.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sesame</td>
<td>0.2 &lt; 2.5 ppm</td>
<td>≥ 2.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shellfish/Mollusca</td>
<td>0.2 &lt; 2.5 ppm</td>
<td>≥ 2.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soy</td>
<td>1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulphites</td>
<td>0.1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tree nuts (Total)</td>
<td>0.1 &lt; 12.5 ppm</td>
<td>≥ 12.5 ppm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Source: VITAL Online
VITAL growth ~ Allergen Bureau Working Groups

~ National Allergy Strategy – Food service working group

~ Phase 3 – Certification (pursuing a VITAL certification process)

~ Phase 2 – Risk Communication (labelling & pursuing exemptions)

~ Phase 1 – Risk Review (expanding & enhancing)

~ Risk Review Anomalies working with the Ai group
Phase 1 ~ Risk Review Working Group

~ Expanding guidance on how to do risk review & what that means

~ New team using the foundations already built by the initial WG1

~ Implementing strategies to communicate this new information to the food industry
VITAL Phase 2 ~ Risk Communication (Labelling) Working Group

~ 2016 success

~ Allergen labelling exemptions in regulation

~ VITAL Best Practice Labelling Guide for Australia and New Zealand launched

http://allergenbureau.net/vital/
VITAL Phase 3 ~ Certification Working Group

- Has developed a VITAL Verification Model and Foundation Elements as part of the certification investigation
- Project completed a draft the VITAL Program into the ‘VITAL Scheme’ under ISO 17065

- auditable ‘VITAL Standard’ plus
- rules and processes to be followed by accredited certification bodies (to meet ISO 17065)
Working Group ~ Risk Review Anomalies

A working group collaboration between

~ Allergen Bureau
~ Australian Industry Group (Ai Group representing the Confectionary Sector; and
~ in consultation with the AFGC

Developing best practice guidance specifically with regard to allergen risk review anomaly & food labelling

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Working Group ~ Risk Review Anomalies

Addressing what to do when cross contact is identified at levels above Action Level 2 where even under conditions of Good Manufacturing Practice (GMP) allergen cross contact may be difficult to eliminate

Anomalies where allergens are known to be present but are:

~ not formulated as an ingredient; and

~ inappropriate to label as cross contact, such as VITAL ‘May be present: XXX’
The Anomaly

Are allergens present in product recipe as ingredient, food additive, processing aid or components of these?  

Yes → Declare as per the ANZ Food Standards Code

No → Is there an allergen impact through ingredients / raw materials or processing?

No → No Precautionary Allergen Labelling required (note: keep risk review updated)

Yes → Apply VITAL® Program in conjunction with HACCP & GMP

Is cross contact below Action Level 1?  

No → Is cross contact at Action Level 2 controlled & managed through HACCP & GMP?

No → Is allergen present above Action Level 2 & level is unable to be controlled or managed via GMP?

Yes → Cross contact statement “May be present: XXX”

No → No Precautionary Allergen Labelling required

Yes → Food Safety Anomaly How to declare?
Examples ~ cross contact anomalies

~ Background cross contact level of allergens are not sporadic (and can be at levels quite high); or

~ Sporadic cross contact level of allergens where initial levels are high but deplete; or

~ Sporadic cross contact level of allergens higher than the level that triggers PAL (VITAL® Action Level 2)
Cross contact anomalies ~ confectionery

~ Example: dark chocolate products manufactured on same equipment following milk chocolate manufacture

~ Representatives from The Australian Industry Group (Ai Group) Confectionery Sector Technical Committee:
  • Mondelez International,
  • Mars Chocolate Australia,
  • Nestle Confectionery & Snacks
  • Fyna Foods Australia
Driving consistency and safety

How should this type of allergen cross contact be declared to protect consumer safety?

Options

Ingredient list declaration?

- first consumer touch point for allergen information
- the definition of ‘ingredient’ has been removed from the regulation

Industry Best Practice?

- key guiding principles
What success looks like

~ The VITAL Program, with its tools, support material & services, that is globally relevant

~ The science that underpins the reference dose/action levels remains current through VSEP ongoing interaction

~ Growth through global partners & training collaborations

~ Continuous development of VITAL as the industry and the program evolves
Allergen Bureau Management

Allergen Bureau (‘Not for Profit’)

The Board of Directors

∼ Kirsten Grinter (Nestlé)
∼ Robin Sherlock (DTS)
∼ Julie Newlands (Unilever)
∼ Karen Robinson (Invited Director)
∼ David Henning (Invited Director)

Our support network

∼ VITAL® Coordinator /support (Georgina Christensen & Lisa Warren)
∼ Technical expertise (Simon Brooke Taylor & Lyn Davies)
∼ VITAL® Scientific Expert Panel (VSEP)

Funded Secretariat
For further engagement & information

~ Visit the Allergen Bureau website www.allergenbureau.net

~ Join us & enjoy the benefits of the Allergen Bureau membership www.allergenbureau.net/about-us/join-us/

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~ Access the Allergen Bureau Helpline
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