

The Implications for Analysis of the VSEP Reviewed VITAL Grid

VITAL 2.0 – it's a sensitive issue !

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VITAL (Voluntary Incidental Trace Allergen Labelling)

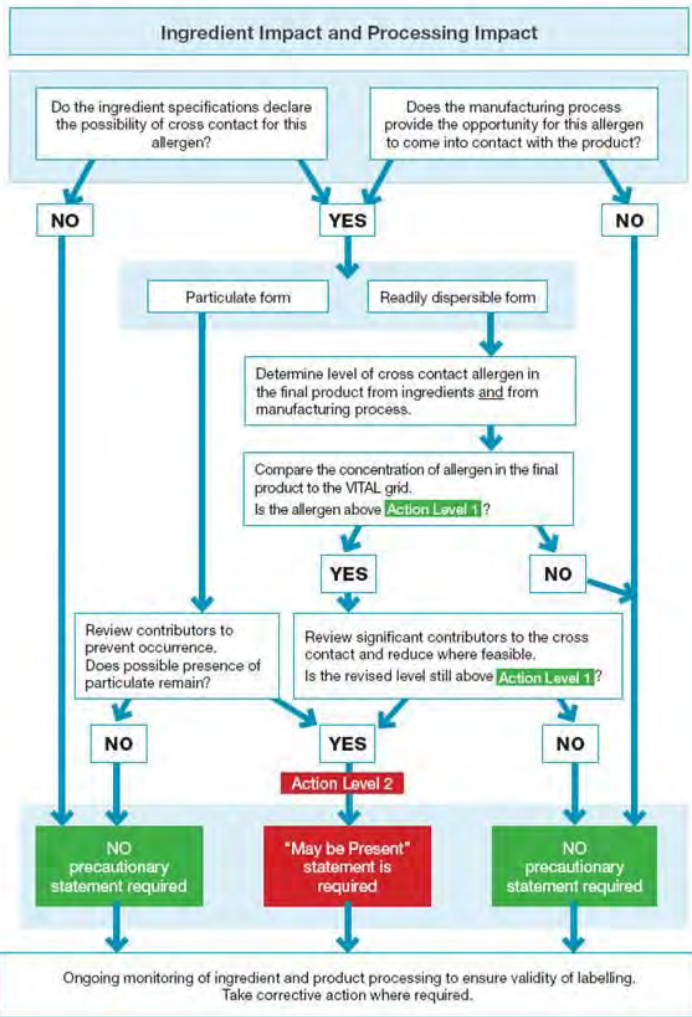
- Developed in conjunction with industry, regulatory and consumer stakeholders in Australia and New Zealand.
- A risk assessment tool supported and maintained by the Allergen Bureau
- Shaped by a regulatory background where the labelling of incidental cross contact allergens is not mandated.

A Risk Assessment Tool



- Used to assess the impact of allergen cross contact
- Stipulates a consistent precautionary allergen labelling statement.
- Uses an action level grid to determine if the presence of residual protein from allergenic substances through cross contact requires precautionary labelling

ii.  Decision Tree for Cross Contact Allergens



VSEP and VITAL 2.0

- VITAL launched in 2007 but the Allergen Bureau recognised a need to form a VITAL Scientific Expert Panel (VSEP) to review the underpinning science around the food allergen thresholds used in VITAL.
- Review began in January 2011 and the initial findings were released in November 2011 .
- The VSEP convened to develop a consistent criteria for assessment of published data .
- Critical piece of work to ensure that the action levels set protect the allergic consumer and provide consistent consumer communication through the use of a defined precautionary labelling statement .
- Outcome was a revised interactive grid based on new action levels.

Action Levels

- Concept is consistent across the VITAL programs
 - Action levels are the concentrations which define how cross contact allergens should be labelled
 - Action Level One = a low concentration of cross contact allergen protein and a low chance of adverse reaction.
 - **No precautionary statement is required.**
 - Action Level Two = a significant concentration of cross contact allergen protein and a significant chance of adverse reaction.
 - **A precautionary statement is required.**
- **Based on Reference Dose and Serving Size or Reference Amount**

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

Allergen	Peanut	Milk	Egg	Tree nuts	Soy	Wheat	Mustard	Lupin	Sesame	Crustacea (Shrimp)	Fish
Reference Dose (mg)	0.2	0.1	0.03	0.1	1	1	0.05	4	0.2	10	NA

VSEP Recommendations – Reference Doses

Allergen

Protein Level (mg)

- Peanut •0.2
- Milk •0.1
- Egg •0.03
- Hazelnut •0.1 (VITAL – Level used as generic tree nut value)
- Soy •1.0 (VITAL – Soy protein isolates not soy milk)
- Wheat •1.0 (VITAL – GCC (Coeliac & wheat allergic population))
- Cashew •2.0 *(VITAL - Hazelnut as generic tree nuts value)
- Mustard •0.05
- Lupin •4.0
- Sesame •0.2
- Shrimp •10.0 (VITAL – initially 1ppm)
- Celery •NA
- Fish •NA (VITAL – original VITAL 0.1 mg value applied)

Simply Speaking

- Action Levels guide labelling recommendations
- VITAL 2.0 has only 2 Action Levels and a new interactive VITAL Action Level Grid



VITAL Action Level Grid

- Embedded in the Calculator
- Specific to each product
- Based on Reference Dose and appropriate Reference Amount/Serving Size

VITAL Action Level Grid

Reference Amount / Serving Size g

	Action Level 1	Action Level 2
Almond	<20 ppm	≥20 ppm
Brazil nut	<20 ppm	≥20 ppm
Cashew	<20 ppm	≥20 ppm
Hazelnuts	<20 ppm	≥20 ppm
Macadamia nut	<20 ppm	≥20 ppm
Pecan	<20 ppm	≥20 ppm
Pine nut	<20 ppm	≥20 ppm
Pistachio nut	<20 ppm	≥20 ppm
Walnut	<20 ppm	≥20 ppm
Wheat	<20 ppm	≥20 ppm
Rye	<20 ppm	≥20 ppm
Barley	<20 ppm	≥20 ppm
Oats	<20 ppm	≥20 ppm
Spelt	<20 ppm	≥20 ppm
Egg	<6 ppm	≥6 ppm
Crustacea	<200 ppm	≥200 ppm
Fish	<20 ppm	≥20 ppm
Milk	<20 ppm	≥20 ppm
Peanut	<40 ppm	≥40 ppm
Sesame seed	<40 ppm	≥40 ppm
Soy	<200 ppm	≥200 ppm
Sulphites	<10 ppm	≥10 ppm
Lupin	<800 ppm	≥800 ppm
Mustard	<10 ppm	≥10 ppm

Two Possible Applications

- Raw material
 - option for no serving size . Recommendation based on reference dose
- Prepared and Finished Product
 - Serving size is critical
 - Peanut Reference Dose = 0.2 mg protein
 - 5g Reference Amount/Serving Size:
 - » Action Level 1 : $< 40\text{ppm}$ (Transition = $0.2 \times 1000/5 = 40\text{ppm}$)
 - » Action Level 2 : $\geq 40\text{ppm}$
 - 50g Reference Amount/Serving Size
 - » Action Level 1 : $< 4\text{ ppm}$ (Transition = $0.2 \times 1000/50 = 4\text{ppm}$)
 - » Action Level 2 : $\geq 4\text{ ppm}$

Impact - Snap Shot Serving Size Survey

- 36 products
- Range of product types

- Cereals

Biscuits

Chocolates

- Frozen meals

Bread

- Serving sizes range from 9-375 gms

- Egg

0.08 - 3.3 ppm Egg Protein

- Peanut

0.53 -22.22 ppm Peanut Protein

- Milk

0.42 -11.11 ppm Milk Protein

FROZEN MEALS

Frozen Meal	Serving Size (g)	Egg ppm protein	Egg ppm commodity	Peanut ppm protein	Peanut ppm commodity	Milk ppm protein	Milk ppm commodity
A	320	0.42	0.91	0.62	2.48	0.31	0.89
B	370	0.08	0.17	0.54	2.16	0.27	0.77
C	375	0.08	0.17	0.53	2.12	0.27	0.77
D	100	0.3	0.65	2	8.00	1	2.86
E	250	0.12	0.26	0.8	3.20	0.4	1.14
F	284	0.11	0.24	0.7	2.80	0.35	1.00
G	300	0.1	0.22	0.67	2.68	0.33	0.94
H	71	0.42	0.91	2.82	11.28	1.41	4.03
I	370	0.08	0.17	0.54	2.16	0.27	0.77
J	300	0.1	0.22	0.67	2.68	0.33	0.94

LOQ Peanut: 1ppm Peanut Protein Kit A

2.5 ppm whole peanut Kit B

LOQ for Egg: 0.46ppm total egg protein Kit A

Sensitivity is a sensitive issue

- Some commodities more exposed to risk by the expectation related to serving size
- Serving size will be critical to risk communication
- Large serving size
 - Drive the methods
 - Guidelines around serving size (AFGC)
 - Consumption data research gaps to inform company decisions

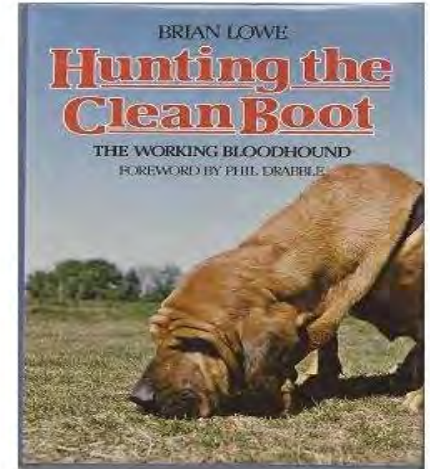


More than Sensitivity

- ELISA
- PCR
- Mass Spec
- LC-MS.MS

Lets talk about numbers

- The danger if industry is hunting the numbers alone
- Need to consider
 - Sensitivity
 - Suitability i.e Fit for purpose
 - Matrix effect
 - Extraction efficiency
 - Additive suppression action
 - Differing calibrators



Sensitivity isn't everything

- Method harmonisation
- Decreased detectability has implication for application to VITAL levels .
- Matrix interference and cooking impacts mean analysis alone is inappropriate
- Method variability or MOU
 - Impact of MOU – labelling based on interpretation of levels and requires informed response around uncertainty issues

Sampling Plans



- A critical element of the analytical picture

Type of health hazard	Hazard is unchanged	Examples
No hazard	n=0	Products produced in a mixed environment where the allergen is declared as an ingredient
Low hazard	Case A1 n=5, c=0	<ul style="list-style-type: none"> ▪ where an allergen is declared as a justified “may contain claim “ (testing is to ensure claims are correct and control measures in place) ▪ in an “Excluded “ facility where allergen is not handled on facility but no specific labeling claim is made
Moderate hazard	Case A2 2 class n=10, c=0	Products manufactured in allergen excluded premises, with no specific allergen free claims. (not specifically targeting sensitive population .
Severe hazard	Case A3 2 class n=30, c=0	<ul style="list-style-type: none"> ■ A product produced and labeled as ALLERGEN FREE would be expected to comply with the label claim and is actively targeting a sensitized population.

Draft Plan Stringency (Case) in relation to degree of health hazard and conditions of use. Modified for Food borne allergen testing.

Reference: Stuttard, E.J. Jenson, I. and Best, J. Sampling for Microbiological Analysis, in Foodborne Microorganisms of Public Health Significance, 5th Ed AIFST, 1997.

Gaps

- Balance the issues around analysis with confidence in the results
- As an analyst, know your target
- Know your end point user
- The answer they want versus they answer they can have



VITAL

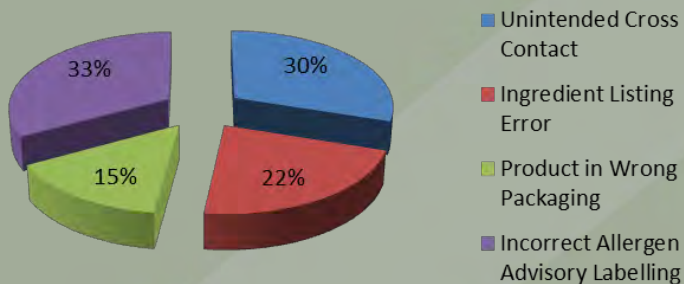
- Always more than the grid
- Numbers alone can be misleading
- Recommended use of analysis
 - Confirmation of assumptions
 - Assessment of allergen profile of raw materials
 - Validation of cleaning and critical control points
 - Monitoring of change impact

VITAL Difference

- Not a regulatory response
- Supported but not endorsed by government
- Allows rapid response to changing science
- Recognise that not all bodies and organisations will follow the same approach

Learnings

- VITAL itself does not convey safety
- VITAL must be part of a total allergen management package
- VITAL requires a robust risk assessment process and risk management strategies



Source :Uk FSA Allergen Allergy Alerts Jan -Jun 2011

70 % of all allergy recalls due to incorrect labelling

Unintended Cross Contact 30%

Product in Wrong Packaging 15%

Incorrect Allergen Advisory Labelling 33%

Ingredient Listing Error 22%

Andrew Sheard
Campbells



Cow named Daisy makes reduced-allergy milk

Daisy the transgenic cow makes reduced-allergy milk. Genetically modified to produce Beta free milk !!!

Thank you

DTS FACTA colleagues

Allergen Bureau Management Committee

Neil Smith - Kraft

Kirsten Grinter – Nestle

David Henning – Campbell Arnotts

Robin Sherlock - DTS FACTA

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Appropriate Serving Size !!!!



WELL THAT ALL DEPENDS