

Allergen
Bureau

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The VITAL Journey

Sharing our Experience

VITAL Journey

- **Back to the beginning**
- **The Journey**
- **VITAL Flat Lining**
- **VITAL Revival**
- **VSEP**
- **VITAL Identity & Training**
- **Lessons Learnt**
- **The VITAL Future**



Inconsistent approach to food



Why we had to do Something!

- Initial development of risk hierarchy and associated statements
 - Made on the same line.....Made in the same factory/facility.....
- Proliferation of cross contact statements across the industry, survey of 350 products in 2005 revealed 42 creative statements!
- Allergic consumers were ignoring cross contact statements
- Some statements weren't about allergens at all!
 - May contain traces of **vitamins and water**
 - May contain traces of milk, egg and peanut, **Sorry**
- ***Action levels varied between manufacturers, no consistency***

Our Dream

Australia



New Zealand

Harmonised Action Levels

Imagine That!

Is it Possible?

What it would Mean

- Protection for all stakeholders
- Allergen labelling information would mean something to the allergic consumer, it had to be:
 - Relevant, ***consistent*** and easy to understand
 - Easily recognised by the allergic consumer
 - Cross contact statements would be based on the same action levels



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Our Journey



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What we Developed - VITAL Program

- Voluntary Incidental Trace Allergen Labelling
- VITAL is a risk based precautionary labelling system which uses action levels underpinned by scientific evidence
- VITAL is a:
 - a process, decision tree, grid (action levels) & calculator and;
 - promotes consistent labelling across industry by prescribing when a precautionary label statement is to be applied / avoided
 - one labelling approach 'May be present'
- VITAL was developed *BY* industry *FOR* industry and is adopted on a voluntary basis



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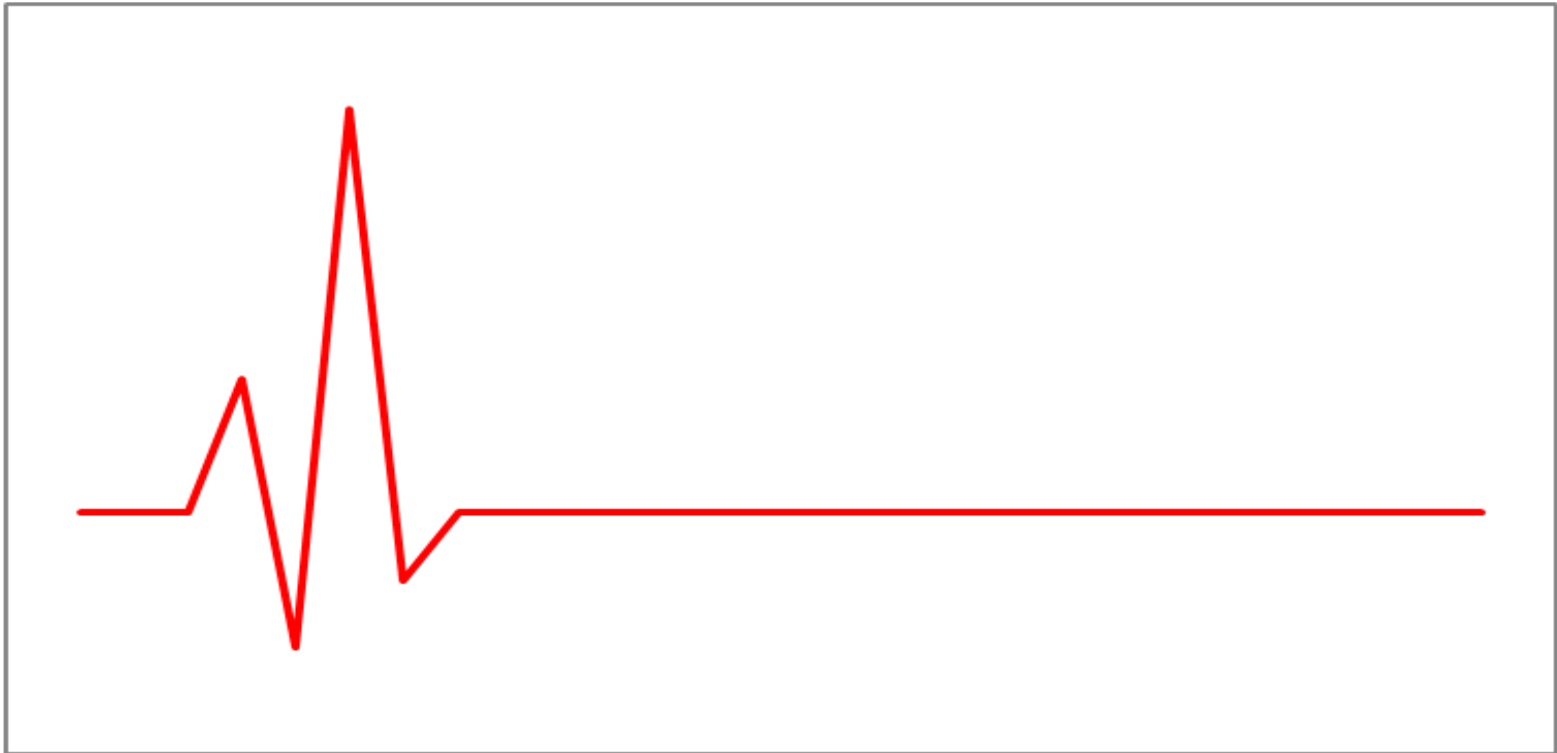
What we Developed – VITAL Grid

| | VITAL GRID | | | | | | | | |
|----------------------|----------------|--------|----------|----------|----------|------------|--------------|------------|----------|
| | Allergen Milk* | Egg* | Soy*^ | Fish* | Peanuts* | Tree Nuts* | Sesame Seed* | Crustacea* | Gluten# |
| Action Level 1 (ppm) | <5 | <2 | <10 | <20 | <2 | <2 | <2 | <2 | <20 |
| Action Level 2 (ppm) | 5 - 50 | 2 - 20 | 10 - 100 | 20 - 200 | 2 - 20 | 2 - 20 | 2 - 20 | 2 - 20 | 20 - 100 |
| Action level 3 (ppm) | >50 | >20 | >100 | >200 | >20 | >20 | >20 | >20 | >100 |

* 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

- Total protein basis
- Expressed as a concentration in food (5g)
- 3 Action Levels, **Green** no label, **Yellow** - may be present, **Red**– contains

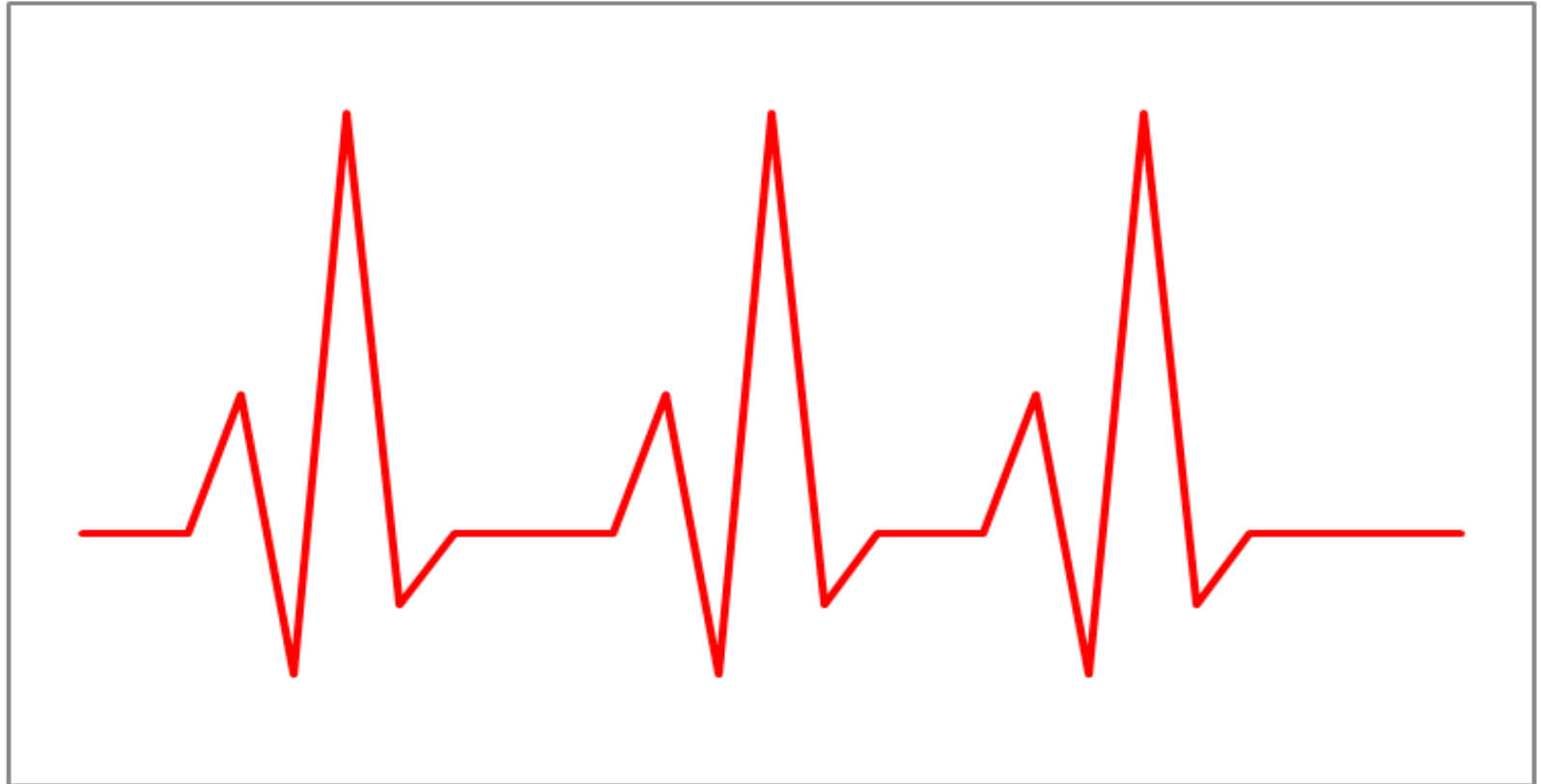
VITAL Flat lining



VITAL Flat Lining in 2010

- Limited uptake across the industry
- Numerous barriers to implementation
 - large /small organisation impacts
- Clinicians created an environment of zero tolerance
- Many companies still not getting the fundamentals right
- There was so much more science to consider to underpin the grid cross contact levels

VITAL Revival



VITAL Revival

- VITAL Review initiated in 2010 – International interest
- A Scientific Expert Panel was convened to review the science underpinning the action levels in the grid
- Government Feedback & Support
 - FSA NZ / Review of Labelling Law & Policy
- Complete VITAL Program review
- VITAL - Training project



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VSEP

The Science

VSEP - Collaboration

- Significant collaboration
 - The Allergen Bureau;
 - FARRP (Food Allergy Research and Resource Program (University of Nebraska) and;
 - TNO (The Netherlands Organisation for Applied Scientific Research)
- Meeting focus & objective was to review and discuss Action Levels in the VITAL Grid
 - Underpinning science

VITAL Scientific Expert Panel (VSEP)

- Scientific Expert Panel

Panel Members are:

- Dr Steve Taylor (FARRP)
- Dr Joseph Baumert (FARRP) , supported by Mr Benjamin Remington (FARRP),
- Dr Geert Houben (Program Manager Food Safety, TNO. NL)
- Dr Rene Crevel (Allergy & Immunology, Unilever)
- Dr Katie Allen (Paediatric Gastroenterologist/Allergist , Royal Childrens Hospital, University of Melbourne), supported by Ms Jennifer Koplin
- Dr Simon Brooke Taylor (Food Safety & Risk Analysis Consultant, Allergen Bureau)
- The VSEP received significant support from Astrid Kruizinga (TNO), Ellen Dutman (TNO) & Harrie Buist (TNO)



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VITAL Scientific Review

- Established that the Level of acceptable risk, protection for vast majority
 - Reiterated that exquisitely allergic consumers are not accounted for in VITAL, continue to assume they do not eat processed foods
- Established principles to be used in selecting 'Action Levels' that are;
 - Scientifically & clinically sound, defensible and transparent
- Set 'Action Levels' with the highest degree of safety
 - The more data the more confidence in the model
 - Lack of data drives research

VITAL Scientific Review

- Established the importance of Portion/Serving Size
 - Allergen protein expressed as mg of protein as well as a concentration in reference quantities or serving size
- Determined that the current 'Action Levels' in VITAL were:
 - appropriate based on available science at that time
- Science underpinning the 'Action Levels' needs to be subject to ongoing review to remain relevant

Original VITAL Scientific Approach

- Key information taken from the FDA Threshold Working Group Report of 2006
- Used LOAELs from FDA table
- Applied an uncertainty factor (UF) to action levels set
- Expressed 'Action Levels' in concentration (ppm) rather than amount of protein(mg); based on 5 g serving size (**teaspoon/mouthful**)
- Most VITAL min levels set at = <2 ppm (exceptions fish, milk, soy, gluten)

The VSEP Overarching Scientific Approach

Quantitative Risk Assessment

- Statistically based risk assessment provides the ideal approach to the establishment of a population thresholds for allergenic foods
 - This type of risk assessment requires *individual threshold doses* from a sufficiently *large* number of allergic individuals
- The threshold /reference dose needs to be *predictive* for the *entire population*
 - Representative population weighted to include individuals who react to very low amts & their counterparts who require large amts
- Analysis of the clinical literature was conducted to determine if the **quantity** and **quality** of published and unpublished data was sufficient,
 - to apply RA modelling & prediction of population based thresholds

Data Collection & Screening

- Reviewing data
 - Screening for *NOAEL and or LOAEL* on individual allergic subjects
 - *Raw data on individual thresholds*, taken from FARRP and TNO publications
 - *Unpublished* clinical data were also used from Dutch clinics and FARRP studies
- Publications looked for *DBPCFC* starting at low doses that potentially allowed identification of NOAELS and LOAELS for individual patients
- NOAELS & LOAELS were expressed in terms of doses of either whole food or food protein eliciting *subjective or objective* symptoms
 - Focus was *objective* symptoms as basis for the LOAEL
 - Objective symptoms, discernible to clinical observer, vomiting, Urticaria

The Tools Applied

- Applied Interval Censoring Survival Analysis (ICSA) approach
 - Considered appropriate when the exact dose that provoked a reaction is not known, but known to fall into a particular interval (NOAEL & LOAEL)
 - Determined NOAELs and LOAELs to estimate thresholds
- Used statistical dose-distribution modelling and applied 3 different probability models: log-normal, log-logistic, and Weibull to all data sets
 - Looking for the model that provides data best fit
 - Given that the principle application lay in low dose estimations, goodness of fit in that part of the dose range is important
- From dose distribution models the eliciting dose is decided (dose predicted to provide reactions in 1, 5 and 10% of the allergic population respectively)
 - ED01, ED05, ED10, ED50, and 95% confidence intervals



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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 |
| Celery | NA |
| Fish | NA (VITAL – original VITAL value applied) |



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VITAL & Risk

- VITAL approach used all of the existing published data plus some unpublished data - **Unpublished data needs to be published**
- VITAL grid levels will protect 95-99% of allergic consumers (99% is desirable when sufficient data exists to allow statistically sound estimates at this level)
- Exquisitely sensitive allergic consumers may not be fully protected by the VITAL grid levels (assume do not consume packaged foods)
- No additional uncertainty factors needed because of use of ED01 or lower 95% confidence interval of ED05
- Risk of mild, transitory objective reactions typically requiring no pharmacological intervention
- Allergic populations studied appear to be representative or skewed toward more highly sensitive (referral clinics, immunotherapy studies)

VSEP - What does Success look like?

- *Standardised methodology* to determine allergen reference dose
- *A reference dose* determined for each of the top food allergens
- *Research data gaps* continue to be addressed
- That the importance of the *Reference Amount or Serving Size* to determine Action Levels is understood and there is clarity around actual *consumption data*
- Wide food industry adoption of a sound *allergen risk assessment process*
- *Consistent application globally* that drives safe food choices, protection for the allergic consumer means protection for our industry'
- *International recognition* by the scientific community



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VITAL 2.0

New Identity



VITAL

an initiative of the Allergen Bureau



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Introducing VITAL 2.0

- New procedure (Guidance document) & decision tree
- New VITAL Calculator
- New VITAL Action Level Grid (incorporated in the VITAL Calculator)
- New FAQ's and support documentation



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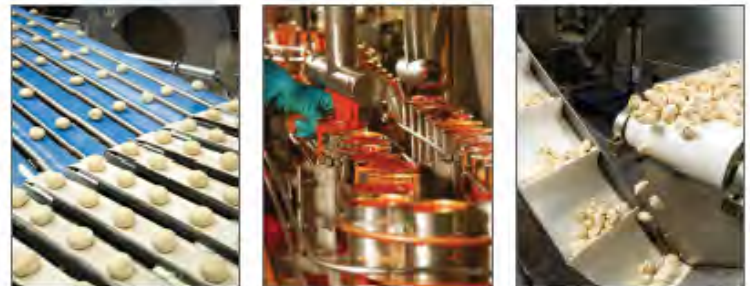
New VITAL Procedure

- Now called Guidance Document – more detailed
- New definitions and expanded explanations
- Attempts to avoid common mistakes
- Includes detailed information about allergen analysis
- Available on our website



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Food Industry Guide to the
Voluntary Incidental Trace Allergen
Labelling (VITAL) Program
Version 2.0 (14 November 2011)



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





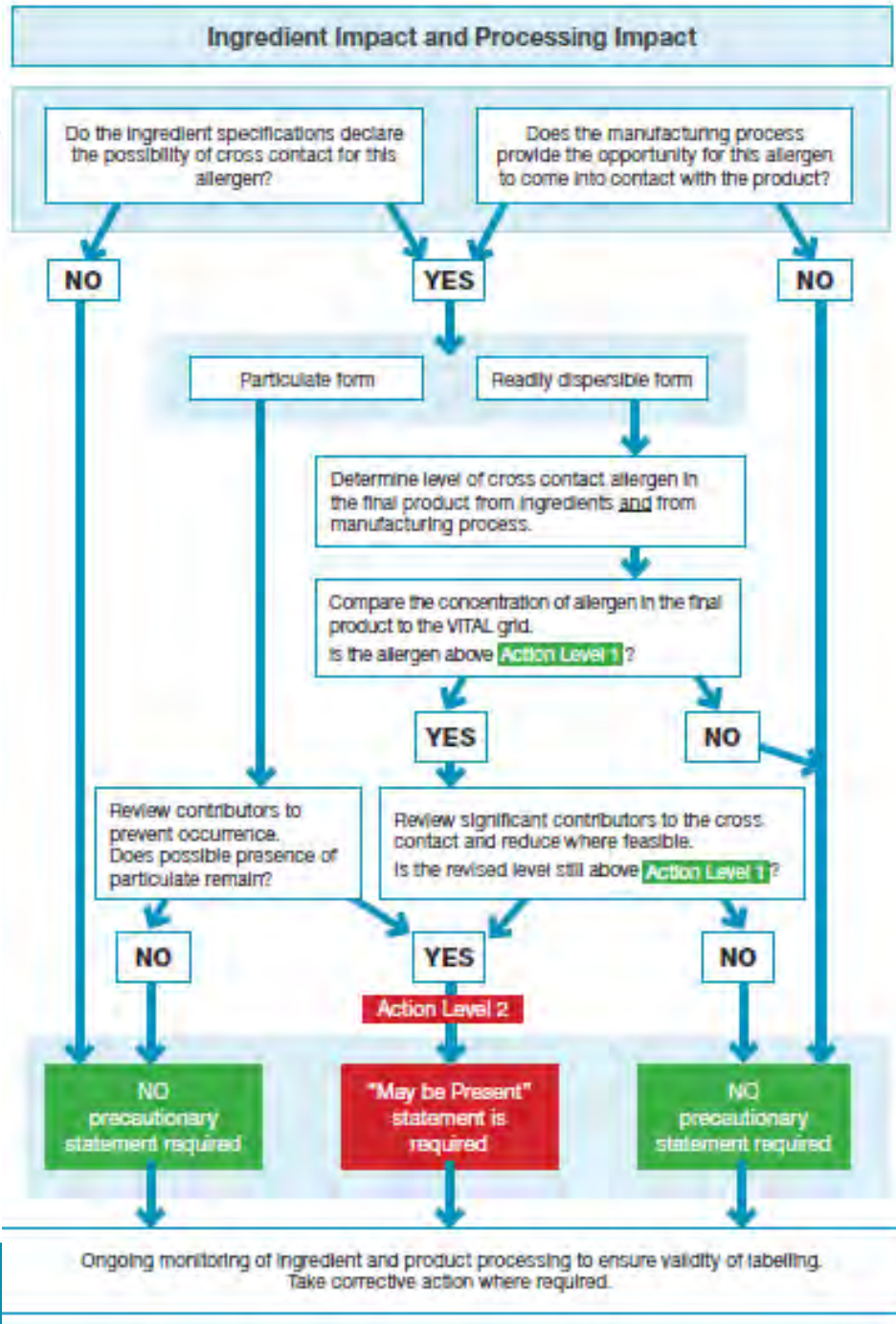
VITAL Action Level Grid

Reference Amount / Serving Size **?** g

| | Action Level 1 | Action Level 2 |
|---------------|----------------|----------------|
| Almond | <2.5 ppm | ≥2.5 ppm |
| Brazil nut | <2.5 ppm | ≥2.5 ppm |
| Cashew | <2.5 ppm | ≥2.5 ppm |
| Hazelnuts | <2.5 ppm | ≥2.5 ppm |
| Macadamia nut | <2.5 ppm | ≥2.5 ppm |
| Pecan | <2.5 ppm | ≥2.5 ppm |
| Pine nut | <2.5 ppm | ≥2.5 ppm |
| Pistachio nut | <2.5 ppm | ≥2.5 ppm |
| Walnut | <2.5 ppm | ≥2.5 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 | <0.75 ppm | ≥0.75 ppm |
| Crustacea | <25 ppm | ≥25 ppm |
| Fish | <2.5 ppm | ≥2.5 ppm |
| Milk | <2.5 ppm | ≥2.5 ppm |
| Peanut | <5 ppm | ≥5 ppm |
| Sesame seed | <5 ppm | ≥5 ppm |
| Soy | <25 ppm | ≥25 ppm |
| Lupin | <100 ppm | ≥100 ppm |
| Mustard | <1.25 ppm | ≥1.25 ppm |



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Communication



VITAL 2.0 Communication Strategy

- Industry communication, what has changed, what it means, impacts at grocery level – Pilot phase
- Working with Anaphylaxis Australia & Allergy New Zealand to develop a communication plan targeted at the allergic consumer, current advice:
 - “Don’t eat products which have a precautionary statement with an allergen to which you are sensitive”
- HCP stakeholder communication and management program
- Communication Strategy aligned with launch of VITAL 2.0 to drive industry implementation



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Training Consistency

VITAL 2.0 – Consistency in Training

- Risk assessment tool
- Critical to long term success
- Development of facilitator' s guide
- Recognition of training providers



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VITAL 2.0 - Training

- Phase out the original version of VITAL over next 7 mths
 - Support offered for the original VITAL until end
October 2012
- All training from today should be VITAL 2.0
- Global presence ? Next Steps for the Allergen Bureau

Lessons Learnt





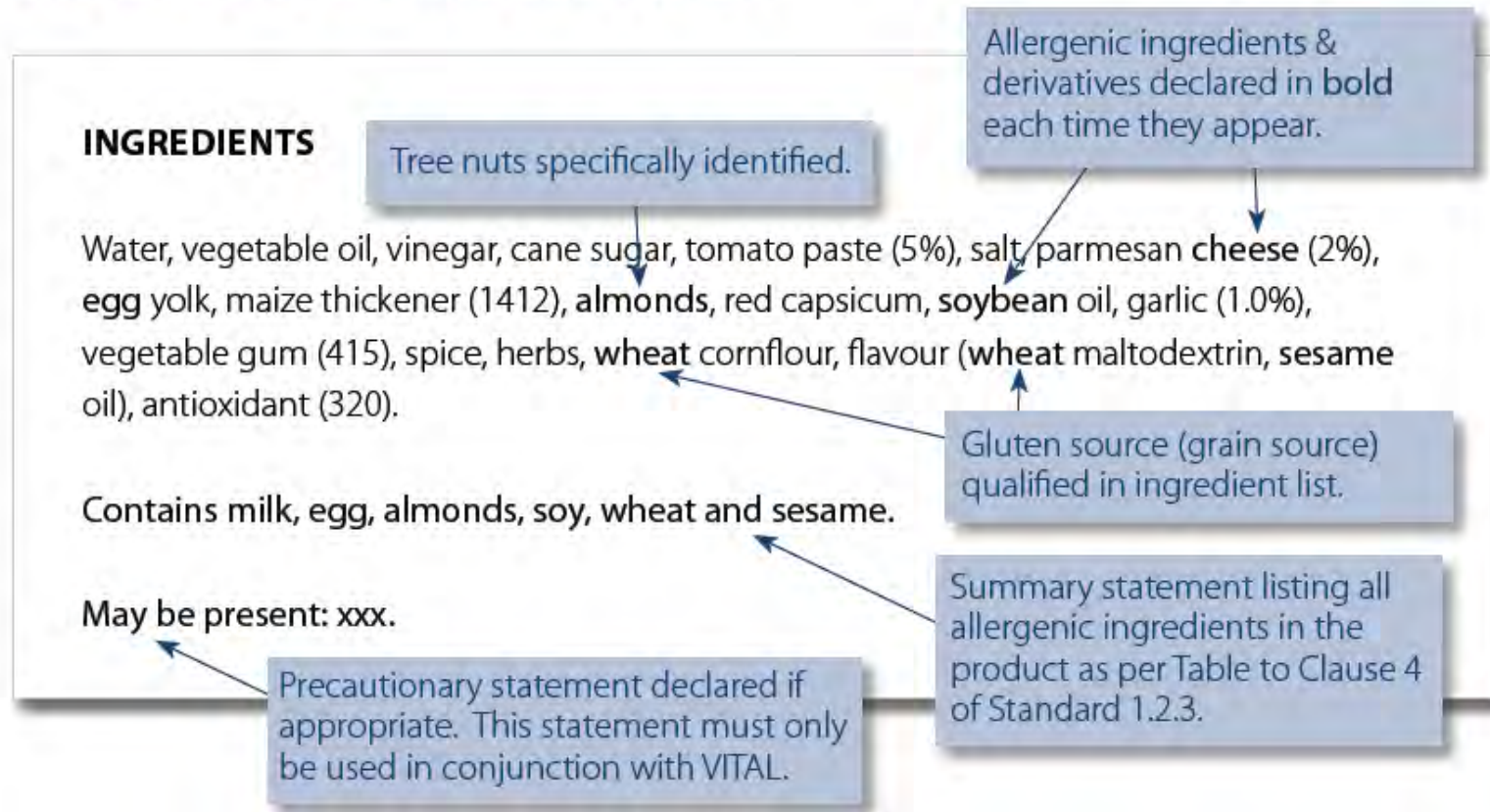
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What went well

- All tools and information will be available for entire industry
- Dedicated VITAL support, single point of contact
- Consumer group collaboration was key – AAI, & Coeliac Society
- VITAL was developed at the same time that the allergen labelling format was developed with the AFGC (**bolding**)
- Training material developed and training providers sourced
- Penetration of the PIF, support provided to industry
- Government feedback positive no regulatory outcome

VITAL Labelling

RECOMMENDED LABELLING FORMAT EXAMPLE.



The Mistakes and Learning's

- How does the consumer know if VITAL has been used if the product carries no precautionary label?
- Initial scientific review used only publicly available allergen data to determine Action Levels for the grid
 - Difficult to leverage wider support at the time
 - Where to obtain information & expertise?
 - Potential financial burden
- Grid stipulating 3 levels, added complexity & went too far
- Did not anticipate the impact of International organisations
- Process for evaluation of risks & the role of analysis not clear



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A VITAL Future – Continuing the Journey

- VITAL 2.0 Launch
 - VITAL calculator, Guidance document, FAQ's, examples and other supporting information
- VITAL Training project, increase training consistency, providers & international presence
- VITAL calculator - ongoing
 - We have launched with the updated excel based tool
 - Longer term project , working with GS1 to produce a sustainable tool that is web based, easy to use with a global footprint
- E-Commerce & Extended Labelling, connecting with the allergic consumer



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Summary

- VITAL was developed to ensure a consistent approach to precautionary labelling across industry
- It has been a successful and positive collaboration between industry and consumer groups and we continue to collaborate
- VITAL flat lining, where we lost our way!
- VITAL Revival encompasses, Procedure & Decision Tree, Action Level Grid – Scientific Review, VITAL calculator
- The scientific expert panel work has been instrumental
 - it underpins the credibility of the system and ensures there is a VITAL future
- VITAL journey will continue!



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The VITAL Dream

2005

- Industry in Australia & New Zealand would use same process and information to drive precautionary labelling

2008 - 2010

- External forces impacted heavily, Corporate drivers began to impact our dream, sustainability in question

2011

- Drive toward Industry globally using the same process and information to drive precautionary labelling



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Dream becoming a Reality



**Global Harmonised Action Levels
Within Our Reach
Imagine That!**



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Thank you

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