

Allergen
Bureau

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VITAL

an initiative of the Allergen Bureau

VITAL 2.0

12th Annual Food Safety Summit
Auckland, March 2013



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VITAL 2.0

- **The Allergen Bureau**
- **Why was VITAL developed?**
 - **VITAL Review**
- **VITAL Scientific Expert Panel**
 - **Introducing VITAL 2.0**



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Allergen Bureau – Who we are

- Established in 2005 due to industry demand
- The food industry are our Members!
- We have 24 Members and 15 Associate Members
- The Members steer the resources & projects

Our reason for being

Share information & experience in the management of food allergens by developing tools to support industry with the needs of the allergic consumer at the forefront

Allergen Labelling – Australia/New Zealand

- In 2002 it became a requirement for **mandatory** labelling of certain allergens (gluten, crustacea, egg, fish, milk, tree nuts, sesame seeds, peanuts and soybeans) in the Australia New Zealand Food Standards Code. This covers **intentionally added** allergens only.
- Allergens which may be present **unintentionally** are covered by precautionary labels, such as “May Contain”. These are voluntary declarations.

Precautionary Allergen Statements = “May contain” labels, allergen advisory statements or “trace” statements



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Allergen Labelling – Australia/New Zealand

- Food regulations are silent on the labelling of cross contact allergens
- Industry did not have a uniform process for determining when to use precautionary labelling
- Allergic consumers confused and may take risks – Clinicians were advising allergic consumers to ignore “May Contain...” statements



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Voluntary Incidental Trace Allergen Labelling (VITAL)

VITAL Objectives:

to provide a risk-based methodology for food producers to use in assessing the impact of allergen cross contact & provide appropriate allergen labelling.

to avoid the indiscriminate use of precautionary labelling and thereby preserve its value as a risk management tool.



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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 & 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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Getting to the Heart of VITAL!

- Knowledge of all parts of the supply chain
 - From raw materials, storage, manufacturing & distribution
 - Harnessing the value of physical risk review and analysis to validate management decisions and assumptions
 - Communicating accurately and consistently to the allergic consumer



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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)



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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



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VITAL losing its Way 2010

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



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The Mistakes & Learnings

- Did not anticipate the impact of International organisations
- 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
- 3 Action Levels added complexity & went too far
- Process for evaluation of risks & the role of analysis not clear
- Limited support tools and industry engagement



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Getting Back on Track

- VITAL Review initiated in 2010
- Scientific review of the data
- Government Feedback & Support
 - FSANZ / Review of Labelling Law & Policy
- VITAL Program overhaul
- VITAL - Training project to drive engagement



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VITAL Scientific Expert Panel (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)
- Initial meeting (2011) focus, Action Levels in the VITAL Grid
 - Underpinning science



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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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Philosophy behind the VSEP

What we needed to facilitate consistency in process !

- Transparent approach to drive credibility
- Established parameters to be shared far and wide
- Penetration into the market
- We needed to access best science and we recognised that the only way was through collaborative partners
- We needed to not only maintain but grow our connection with the food allergic community



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VITAL Scientific Review

- Established 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



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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



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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 flour derivatives 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 2.0

New Identity



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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) (VSEP Reference Dose)
- 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 at www.allergenbureau.net



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Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program

Version 2.0



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23 April 2012



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New VITAL Calculator

- New version more detailed and follows new procedure
- PDF report
- Point and Click
- PC compatible only
- Summary page for customers
- Long term plan to move to web-based application

A screenshot of a software application window titled "VITAL Calculator". The window has a light blue header bar with the title and a close button. Below the header is a white area containing the VITAL logo (a green checkmark inside a circle) and the text "VITAL an initiative of the Allergen Bureau". The main content area has a dark blue background with the heading "Enter Product Information" in white. There are three input fields: "Product Name" with the text "Choc chip biscuits", "Product Reference" with "BB22", and "Date of Calculation" with "11-Mar-2013". At the bottom, there is a vertical stack of three buttons: "Main Menu", "Save", and "Save As". To the right of these are two larger buttons: "Back" and "Next".



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VITAL Action Level Grid ?

Reference Amount / Serving Size ?

50 g

Update

	Action Level 1	Action Level 2
Almond	<2 ppm	≥2 ppm
Brazil nut	<2 ppm	≥2 ppm
Cashew	<2 ppm	≥2 ppm
Hazelnuts	<2 ppm	≥2 ppm
Macadamia nut	<2 ppm	≥2 ppm
Pecan	<2 ppm	≥2 ppm
Pine nut	<2 ppm	≥2 ppm
Pistachio nut	<2 ppm	≥2 ppm
Walnut	<2 ppm	≥2 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	<0.6 ppm	≥0.6 ppm
Crustacea	<200 ppm	≥200 ppm
Fish	<2 ppm	≥2 ppm
Milk	<2 ppm	≥2 ppm
Peanut	<4 ppm	≥4 ppm
Sesame seed	<4 ppm	≥4 ppm
Soy	<20 ppm	≥20 ppm
Lupin	<80 ppm	≥80 ppm
Mustard	<1 ppm	≥1 ppm

Developed by



Back

Print

Finish



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Table 1 Summary of Labelling outcomes

Substances	Reference Dose (mg)	Action Level (ppm) where Reference Amount / Serving Size is 50g		Cross Contact Amount		Labelling Outcome	
		Action Level 1	Action Level 2	Particulate	Readily Dispersible (ppm)		
Tree Nuts (Total)	0.1	<2 ppm	≥2 ppm				
Almond							
Brazil nut							
Cashew							
Hazelnuts							
Macadamia nut							
Pecan							
Pine nut							
Pistachio nut							
Walnut							
Gluten-containing cereals (total)	1	<20 ppm	≥20 ppm			Intentionally Added	
Wheat							Intentionally Added
Rye							
Barley							
Oats							
Spelt							
Egg	0.03	<0.6 ppm	≥0.6 ppm			Intentionally Added	
Crustacea	1	<20 ppm	≥20 ppm		0	Action Level 1	
Fish	0.1	<2 ppm	≥2 ppm		160	Action Level 2	
Milk	0.1	<2 ppm	≥2 ppm			Intentionally Added	
Peanut	0.2	<4 ppm	≥4 ppm		0.1	Action Level 1	
Sesame seed	0.2	<4 ppm	≥4 ppm	YES	8.8	Action Level 2	
Soy	1	<20 ppm	≥20 ppm		0.5	Action Level 1	
Lupin	Not assessed						
Mustard	Not assessed						

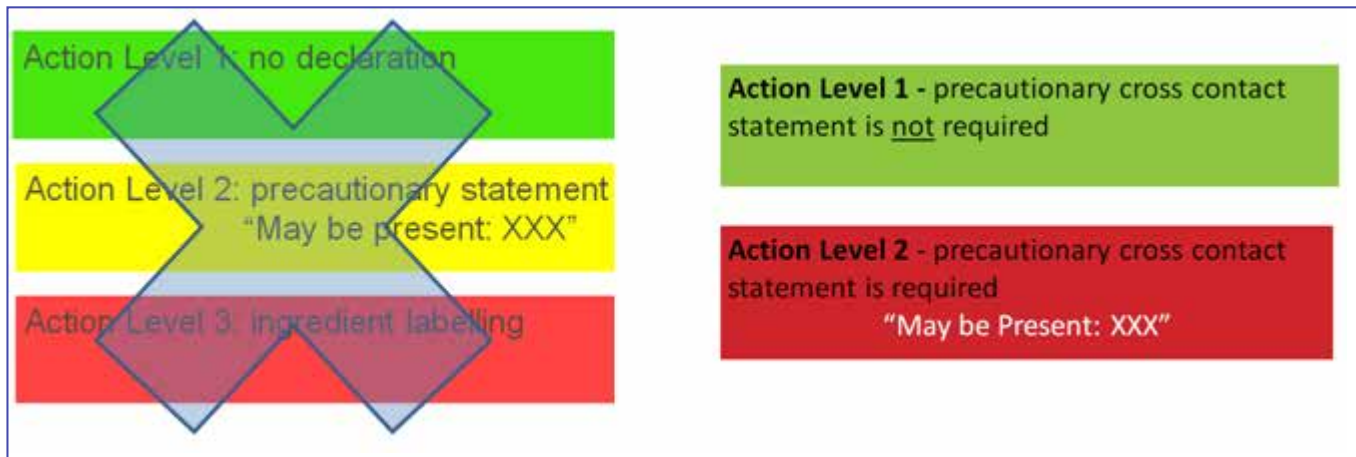
New Allergens to VITAL Action Level Grid

- New allergens added to VITAL Action Level Grid
- Lupin
- Mustard



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





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Action Level 1 - precautionary cross contact statement is not required

Action Level 1 - precautionary cross contact statement is required

“May be Present: XXX”



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Two Action Levels

- Action Level 3 has been removed – no requirement for ingredient labelling
- Cross contact allergens above the action levels in VITAL 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



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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



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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



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VITAL Grid

Peanut Reference Dose = 0.2 mg protein

Example (**5g** Reference Amount/Serving Size):

Action Level 1 : < **40ppm** (Transition = $0.2 \times 1000/5 = 40\text{ppm}$)

Action Level 2 : \geq **40ppm**

Example (**50g** Reference Amount/Serving Size):

Action Level 1 : < **4 ppm** (Transition = $0.2 \times 1000/50 = 4\text{ppm}$)

Action Level 2 : \geq **4 ppm**



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Summary of changes for VITAL 2.0

- 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

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.



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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 of 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

PRODUCT FORMULATION:			%		Milk	Egg	Gluten
1	Glucose (wheat)		20.0000%		No	No	No
2	sugar		20.0000%		No	No	N
3	butter		40.0000%		Yes	No	N
4	water		20.0000%		No	No	N

Allergen content
Does this raw material contain this allergen?

What can be retained from existing VITAL assessments to help with implementing VITAL 2.0?



Scope /
Pre-requisites



Risk
assessment



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

Units	Milk	Egg	Soy	Fish	Peanut	Tree Nut	Sesame
ppm	0.0	0.0	221.7	0.0	0.0	0.0	0.0
Labelling	<i>Must label</i>	<i>No Label</i>	<i>Must Label</i>	<i>No Label</i>	<i>No Label</i>	<i>No Label</i>	<i>No Label</i>

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



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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



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After the launch of VITAL 2.0

- VITAL 2.0 has been well accepted
- Feedback from industry has helped to make the calculator run more smoothly
- The food industry is beginning to train in VITAL 2.0 & transition to VITAL
- The Allergen Bureau will continue to provide resources & support the industry through the transition stage



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Training

Engagement



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VITAL 2.0 – Consistency in Training

- Risk based program
- Critical to long term success
- Development of facilitator's guide
- Recognition of training providers
- Industry engagement & connection



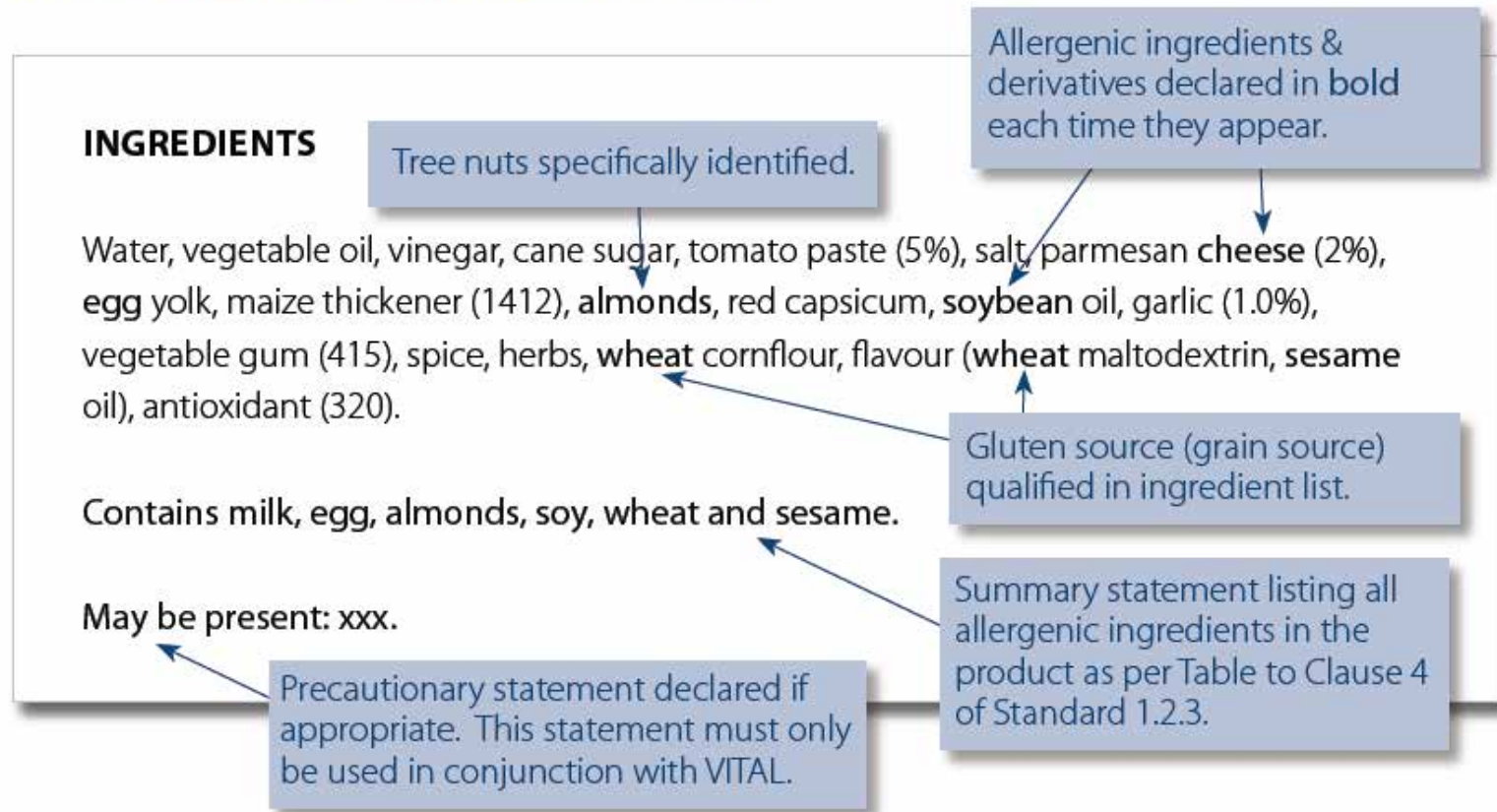
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What continues to go well

- 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
- Standardised allergen labelling format across industry (**bolding**)
- Training material developed and training providers sourced
- Retailer support is powerful
- Government feedback positive no regulatory outcome

VITAL Labelling

RECOMMENDED LABELLING FORMAT EXAMPLE.

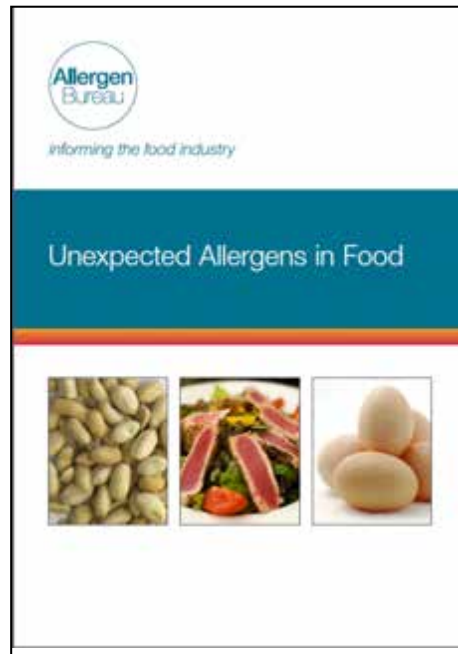




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What Now

- Partner Organisations & Training providers to facilitate uptake
- VITAL calculator Project
 - Seeking Government Funding & Potential Partners
- E-Commerce & Extended Labelling, connecting with the allergic consumer (Launch of GoScan in Australia end March 2013)
- How does the consumer know if VITAL has been used if the product carries no precautionary label?
 - Project work being proposed to investigate the scope of potentially moving towards certification, logo perhaps? Project for 2013



Fatty Acids (mono and di-glycerides)	What are they derived from (e.g. soy)?
Flavour Enhancers (620, 621, 622, 623, 624, 625, 627, 631, 635)*	What are they derived from? (e.g. meat, sardines (fish) , wheat , soy , maize). If microbial synthesis, what is the source of the nitrogen and carbohydrate (e.g. wheat , soy , maize etc)?
Flavours	<p>Do they contain any bases, carriers, free flowing agents (e.g. maltodextrin [refer to section on Maltodextrin], casein, oleoresins [refer to section on Oleoresins], emulsifiers [refer to section on Emulsifiers], oils [refer to section on Fat/Oil]. If yes, what are they derived from (e.g. wheat, maize, soy, egg, peanut)?</p> <p>Do they contain hydrolysed protein? (refer to sections on Hydrolysed Proteins)</p> <p>Do they contain fatty acids eg mono-, di- or tri-glycerides (refer to section on Fatty Acids)?</p> <p>Have they been encapsulated with fish gelatine?</p>



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Thank you

Allergen Bureau Management Committee

Robin Sherlock - FACTa
Julie Newlands – Unilever
Neil Smith - Kraft
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