

VITAL Allergen Risk Assessment



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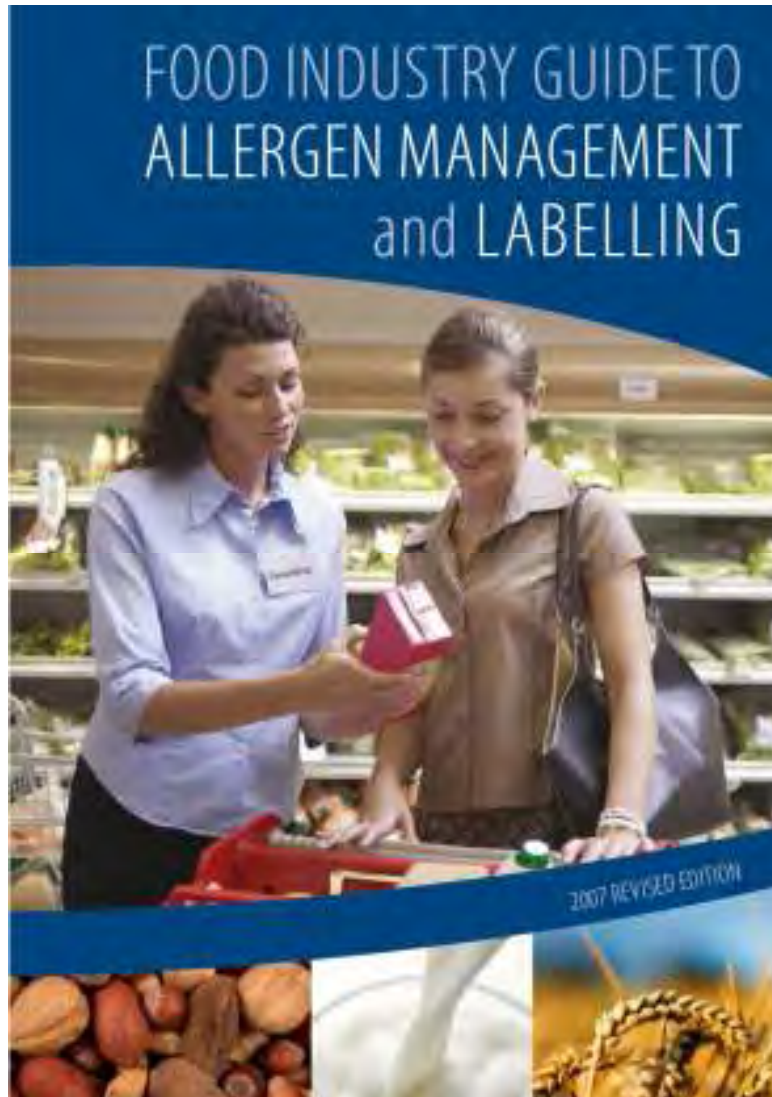
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VITAL – launched June 2007





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Voluntary Incidental Trace Allergen Labelling

www.allergenbureau.net

www.afgc.org.au



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What is Vital?

- ✓ An Industry solution
- ✓ A tool for industry intended to be used as part of a HACCP process when conducting the risk assessment for allergenic hazards
- ✓ 3 level grid to assist in determining if the presence of residual protein from allergenic substances requires a precautionary statement
- ✓ Intended to be used where cross contact is:
 - ✓ Documented using Vital; and
 - ✓ Unavoidable; and
 - ✓ sporadic
- ✓ A single consistent message to the allergic consumer “May be present: “
- ✓ **Reflects best evidence currently available**



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VITAL - Timeline

July 2004	Jul 2004 – Dec 04	Jan 2005 – Dec 2006	Feb 2006 – May 2006
Project Team formed	Review of current risk assessment protocols	Development of VITAL: <ul style="list-style-type: none">• literature review was conducted to develop the levels in the grid• Decision Tree and Procedure developed	Stakeholder consultations & refinement



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VITAL – Timeline (continued)

May 2006 – Dec 2006	Dec 2006 – Feb 2007	Jan 2007 – April 2007	May 2007	June 2007
VITAL Industry Pilots	Draft for inclusion into revised AFGC Guide	Targeted consultation on Action Level Grid	Finalise for AFGC Guide	Launch of AFGC Allergen Guide



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The Vital Process

- **assessment** of likely sources of cross contact allergenic substances from raw materials and the processing environment,
- **evaluation** of the amount present,
- **review** of the ability to reduce the allergenic material from all contributing sources,
- **decision** on precautionary labelling statement, and
- **ongoing monitoring and verification.**



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Microsoft Internet Explorer browser window showing the VITAL spreadsheet interface. The address bar displays the URL: http://www.allergenbureau.net/downloads/allergen-guide/VITAL/VITAL_Template_updated_19_May_08.xls.

The spreadsheet content includes:

- VITAL** logo
- Allergen Bureau** logo and tagline: *informing the food industry*
- VOLUNTARY INCIDENTAL TRACE ALLERGEN LABELLING (VITAL)**
- © Australian Food and Grocery Council 2007. All rights reserved
- INDEX**
- Last Updated on:** 19-May-08
- VITAL Grid, Notes, Decision Tree, Procedure**: Table showing the Allergen Advisory Action Levels. Links to Explanatory Notes, Decision Tree & Procedure on how use the Allergen Advisory Action levels.
- Guidelines**: Guidelines, Instructions and Assumptions about using this worksheet for calculations.
- Assumptions**: Worksheet to document any key assumptions when running this calculation.
- 1. Raw Material Impact**: Worksheet to calculate the allergen impact of the raw materials in the product.
- 2. Raw Material Cross Contact**: Worksheet to calculate the potential cross contact allergen impact of the raw materials in the product.

The spreadsheet interface shows a navigation bar at the bottom with tabs: Index, VITAL, Guidelines, Assumptions, 1. RM Impact, 2. RM Cross Contact, 3. Processing Impact, 4. Summary, and Chan.

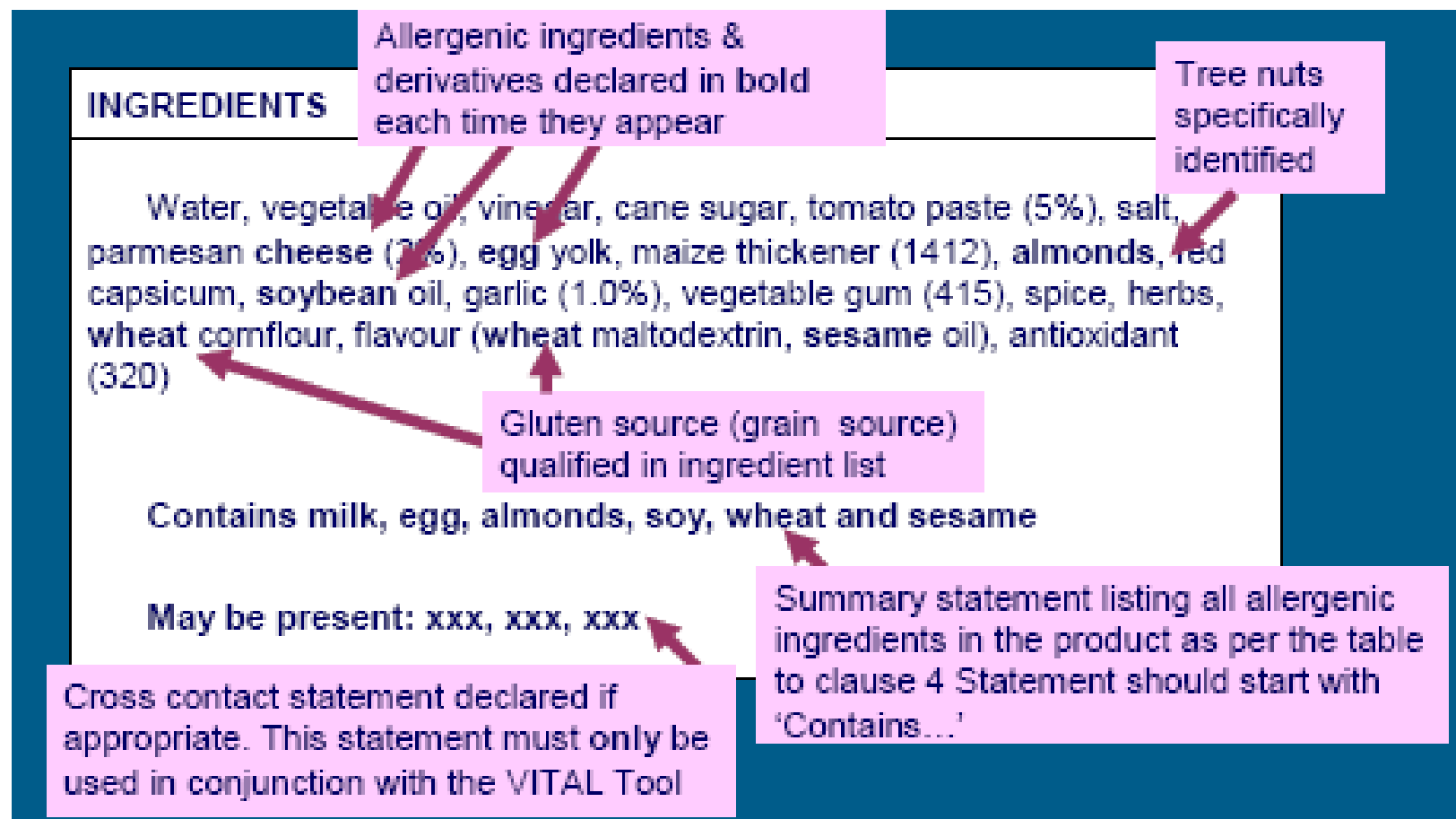


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The Vital Action Level Grid

	VITAL GRID								
	as at 02 July 2007								
	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									

Recommended Allergen Labelling





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Products in the market



A MARS® BAR CONTAINS MILK CHOCOLATE 40%, NOUGAT 33% AND CARAMEL 27%. **INGREDIENTS:** SUGAR, GLUCOSE SYRUP (SOURCES INCLUDE WHEAT), MILK SOLIDS, VEGETABLE FAT, COCOA BUTTER, COCOA MASS, BARLEY MALT EXTRACT, COCOA POWDER, EMULSIFIER (SOY LECITHIN), SALT, EGG WHITE, NATURAL VANILLA EXTRACT. MILK CHOCOLATE CONTAINS A MINIMUM OF 25% COCOA SOLIDS AND 22% MILK SOLIDS. **MAY BE PRESENT: PEANUTS AND TREENUTS.**

MALTESERS® CONTAINS 75% MILK CHOCOLATE AND 7.5% MALT EXTRACT. **INGREDIENTS:** SUGAR, MILK SOLIDS, COCOA BUTTER, COCOA MASS, GLUCOSE SYRUP (SOURCES INCLUDE WHEAT), BARLEY MALT EXTRACT, VEGETABLE FAT, EMULSIFIER (SOY LECITHIN), WHEAT GLUTEN, RAISING AGENTS (500, 501), SALT, PECTIN, NATURAL VANILLA EXTRACT. MILK CHOCOLATE CONTAINS A MINIMUM OF 25% COCOA SOLIDS AND 22% MILK SOLIDS. **MAY BE PRESENT: PEANUTS.**

Let's cook

- Preheat oven to 180°C (350°F) and place the oven rack in the middle.
- Place the dough on a parchment-lined baking sheet and brush with egg wash.
- Cook for 15 minutes, or until the crust is golden brown.
- Allow to cool for 5 minutes before serving.

COOKING TEMPERATURES AND TIMES ARE PROVIDED AS A GUIDE. COOKS WILL VARY BETWEEN BATCHES.

ALLERGY ADVICE

CONTAINS GLUTEN, WHEAT, SEAM AND SOY.
MAY BE PRESENT: EGG AND CRUSTEES.

Nutrition Information

	Per 100g (3.5oz)	Per 100g (3.5oz)
Energy	1400kJ (335kcal)	1400kJ (335kcal)
Protein	11.0g	11.0g
Fat, total	18.0g	18.0g
Carbohydrate	49.7g	49.7g
Sodium	1.2g	1.2g

Ingredients

Meat Sauce (45%), Battered Tuna (15%), Pasta (32%), Pappardelle Sauce.

Meat Sauce (45%): Beef, Beef Stock, Tomato, Onion, Garlic, Worcestershire Sauce, Salt, Pepper, Paprika, Bay Leaf, Red Wine, Olive Oil.

Battered Tuna (15%): Tuna, Egg, Flour, Breadcrumbs, Salt, Pepper.

Pasta (32%): Durum Wheat Semolina.

Pappardelle Sauce: Olive Oil, Garlic, Tomato, Salt, Pepper.



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Question 1

- *What manufacturing circumstances prompt manufacturers to place advisory statements on a food label?*

Where cross contact is:

- ✓ Documented using Vital; and
- ✓ Unavoidable; and
- ✓ Sporadic

Vital Risk assessment determines that the allergen is present at Action Level 2 or 3

- *What manufacturing circumstances do not prompt manufacturers to include an advisory statement? Why?*

Vital Risk assessment determines that:

- the allergen is present at Action Level 1 or
- that there is no potential for cross contact
- Allergen not present.



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Question 2

- *If we decide to develop guidance for using advisory labeling, should we incorporate any of the guidelines from the Food Allergy Issues Alliance or the principles of the VITAL system? If so, why?*

Vital:

- ✓ International harmonisation – we are operating in an increasingly global market place
- ✓ Outcome based, practical solution
- ✓ Don't reinvent the wheel



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Question 3

- *Are there circumstances under which there is no possibility of cross-contact with a food allergen? If so, what are they?*

The allergen is not present either via ingredients or processing

Very controlled environment with validated control measures



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Question 4

- ***When manufacturers declare an allergenic ingredient in the ingredient list or in the "Contains" statement, do they also use an advisory statement indicating the presence of that ingredient? If so, why?***
 - *Contains statement is a summary of the allergens present as ingredients in the product.*
 - *Advisory statement is determined using Vital. The same allergen would not be labelled twice.*
 - *Regulatory issues under ANZ Trade practices law*
- ***What do allergic consumers think of such labeling?***
 - *We do not yet have data in ANZ on consumers attitude to this form of labelling. Anecdotal evidence would suggest that they are looking for one simple, consistent statement.*
- ***Do consumers consume the food product if they are allergic to the allergen referred to in the advisory statement?***
 - *We do not know definitively – there is anecdotal evidence to suggest that there is some consumers who are taking risks*
 - *Vital Consumer education program will have a clear message not to consume the product if you are allergic to the allergen in the advisory statement.*
- ***Is the presence of both an advisory statement and a "Contains" statement that include the same allergen on the same food label confusing? Why or why not?***
 - *Yes which is why Vital does not work this way*



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Question 5

- *What criteria and considerations does a small firm rely on when determining whether to use advisory labeling? Are these the same criteria and considerations that a large firm relies on?*
 - *Vital criteria apply equally regardless of the food, manufacturing circumstances or the size of an organisation to ensure consistency across the industry for consumers.*
- *How frequently does a small firm use advisory labeling compared to a large firm?*
 - *In some cases overuse of use of statement as it is seen as a way to protect the business without understanding the implications to the allergic consumer.*
- *If we decide to develop guidance for using advisory labeling, what options should we investigate to consider the circumstances of small firms?*
 - *All food products should be treated the same irrespective of the size of the manufacturer – need to have a consistent system for allergic consumers.*
 - *Need to provide resources and training for smaller companies to enable them to be able to implement advisory labeling.*



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Question 6

- *How do manufacturers decide whether to label their finished products with advisory labeling when their incoming ingredients are labeled with advisory statements?*
 - *Currently there is a large degree of inconsistency around this - use of the Vital tool is the way ANZ industry is seeking to address this.*
 - *Use of the Vital calculator enables consideration of contribution of cross contact allergens from ingredients as well as the process.*



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Question 7

- *Consumer research suggests that different advisory statements convey different degrees of potential for the inadvertent presence of an allergen in a food. What message do manufacturers want to convey by an advisory statement generally?*
 - *Australian and NZ manufacturers want to convey a consistent message to allergic consumers -*
 - *If you are allergic to this material, do not consume this product*
 - *We have taken responsible action to determine the risk using best available information.*
 - *This product has been assessed and we have determined that there is a risk that the allergen may be present in the product at a level that could pose a risk to the allergic consumer*

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