

**Allergen**  
Bureau

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## VITAL 2.0 – What you need to know

April 2012

Allergen Bureau Information Session



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# Agenda

1. Introducing VITAL 2.0
2. What can be recycled from VITAL Version 1
3. What is new



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## Introducing VITAL 2.0

- NEW Action Levels
- NEW Concepts
  - Reference Dose
  - Reference Amount/Serving Size
- NEW Definitions
  - Fish
  - Tree nuts
  - Particulates



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## Introducing VITAL 2.0

- VITAL (Version 1) was launched in 2007
- VITAL has been reviewed including:
  - recommendations from VITAL Scientific Expert Panel, and
  - feedback from VITAL users
- VITAL 2.0 is the updated version of VITAL and will supersede VITAL (Version 1)



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## Introducing VITAL 2.0

- New procedure (Guidance document)
- New VITAL Calculator
- New VITAL Action Level Grid (incorporated in the VITAL Calculator)
- New FAQ's



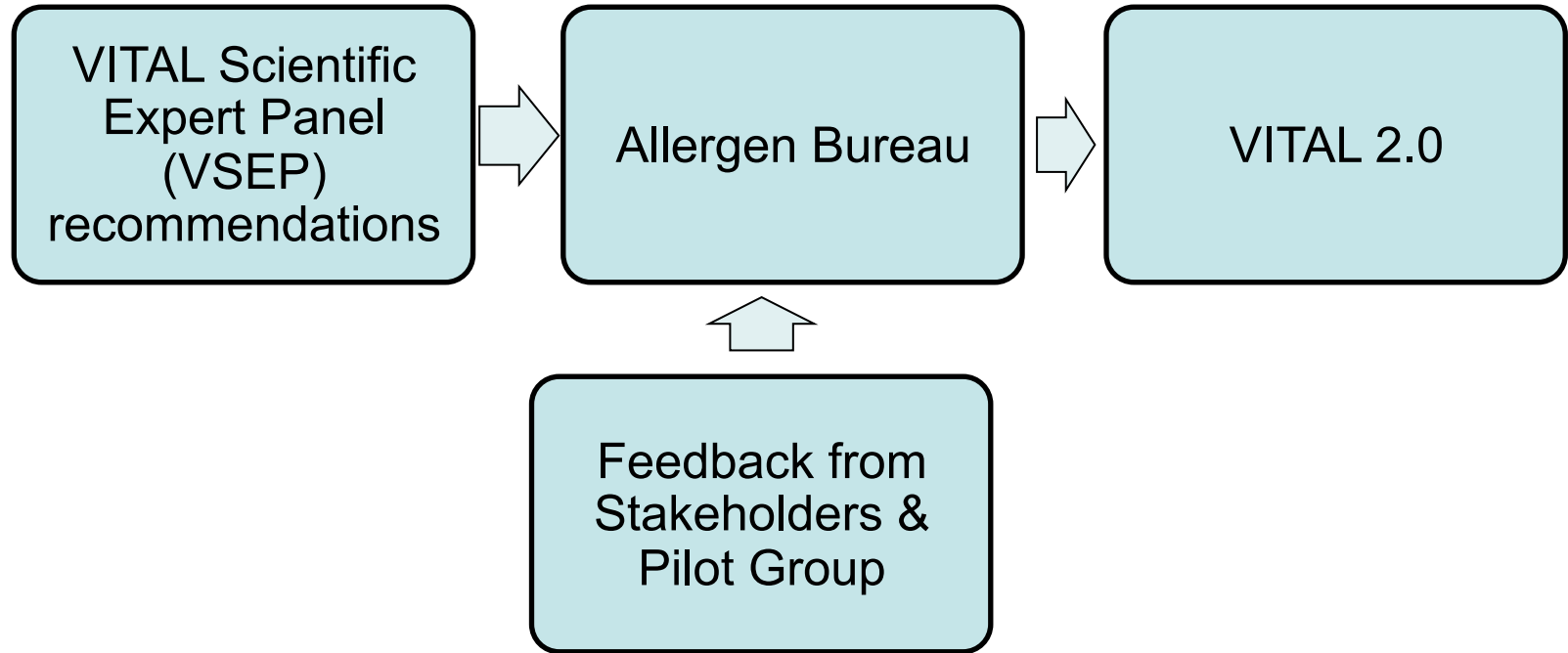
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# Introducing VITAL 2.0 – New Identity!



VITAL

an initiative of the Allergen Bureau



# What is new in VITAL 2.0?

New  
Allergens

New Action  
Levels

Reference  
Dose  
+  
Reference  
Amount/  
Serving Size

New VITAL  
Calculator



## Action Levels

- Action Levels are the concentrations which define how cross contact allergens should be labelled
- Cross contact allergens are those which are unintentionally incorporated
- Action Level One = low concentration of allergens, low chance of adverse reaction & no precautionary statement required
- Action Level Two = significant concentration of allergen protein, significant chance of adverse reaction and a precautionary statement is required

## 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



## Two Action Levels

- Action Level 3 has been removed – no requirement for ingredient labelling
- High levels of cross contact allergen 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

# VITAL Action Level Grid

**Action Level 1** - precautionary cross contact statement is not required

**Action Level 2** - precautionary cross contact statement is required

“May be Present: XXX”

# VITAL Action Level Grid

- Interactive
- Specific to each product
- Based on Reference Dose and appropriate Reference Amount/ Serving Size

**VITAL Action Level Grid**

Reference Amount / Serving Size ?  Update

	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



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## Action Levels

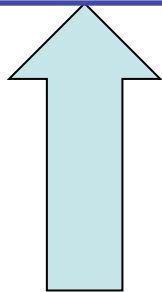
- Action Levels are found in the interactive VITAL Action Levels Grid
- Calculated from **Reference Dose** and **Reference Amount/Serving Size**

### **Transition between Action Levels\***

**= Reference Dose x (1000 / Reference Amount/  
Serving Size)**

**\*with the exception of gluten containing cereals where it is either this formula or 20ppm, whichever is smaller**

**Transition between Action Levels =**  
**Reference Dose** x (1000 / Reference Amount/Serving size )



**Set by VSEP**

## 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

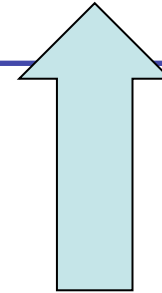
<b>Allergen</b>	Peanut	Milk	Egg	Tree nuts	Soy	Wheat	Mustard	Lupin	Sesame	Crustacea (Shrimp)	Fish
<b>Reference Dose (mg)</b>	0.2	0.1	0.03	0.1	1	1	0.05	4	0.2	1	0.1





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**Transition between Action Levels =  
Reference Dose x (1000 / Reference Amount/Serving Size)**



**Set by User**

## 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 :  $\geq 40\text{ppm}$**

Example (50g Reference Amount/Serving Size):

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

**Action Level 2 :  $\geq 4\text{ ppm}$**

## New Allergens to VITAL Action Level Grid

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



## 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

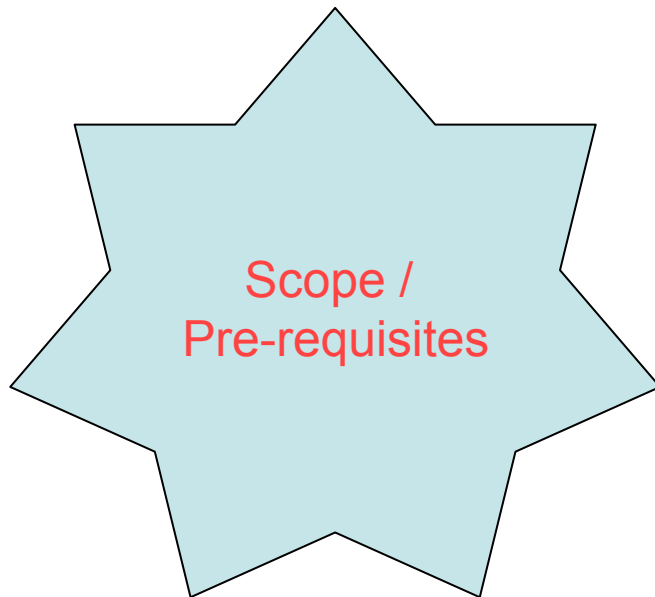
# Gluten Representation

- 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?





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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

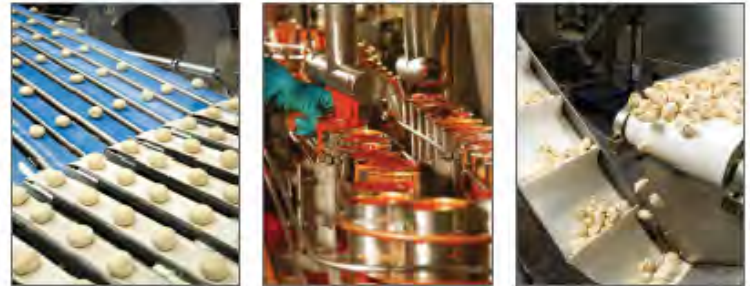
## Risk Assessment

- 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

## 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
- Currently DRAFT format only – we welcome your comments!

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





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## New VITAL Calculator

- New version more detailed and follows new procedure
- Point and Click
- Summary page for customers
- Current DRAFT format only – we welcome your comments!



## Summary of changes:

- 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



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# Thank you

VITAL Co-ordinator  
[vital@allergenbureau.net](mailto:vital@allergenbureau.net)

Allergen Bureau Management  
[management@allergenbureau.net](mailto:management@allergenbureau.net)

Information  
[info@allergenbureau.net](mailto:info@allergenbureau.net)