

VITAL 2.0 – What you need to know

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Allergen Bureau Seminar

Sydney, Australia



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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

- 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



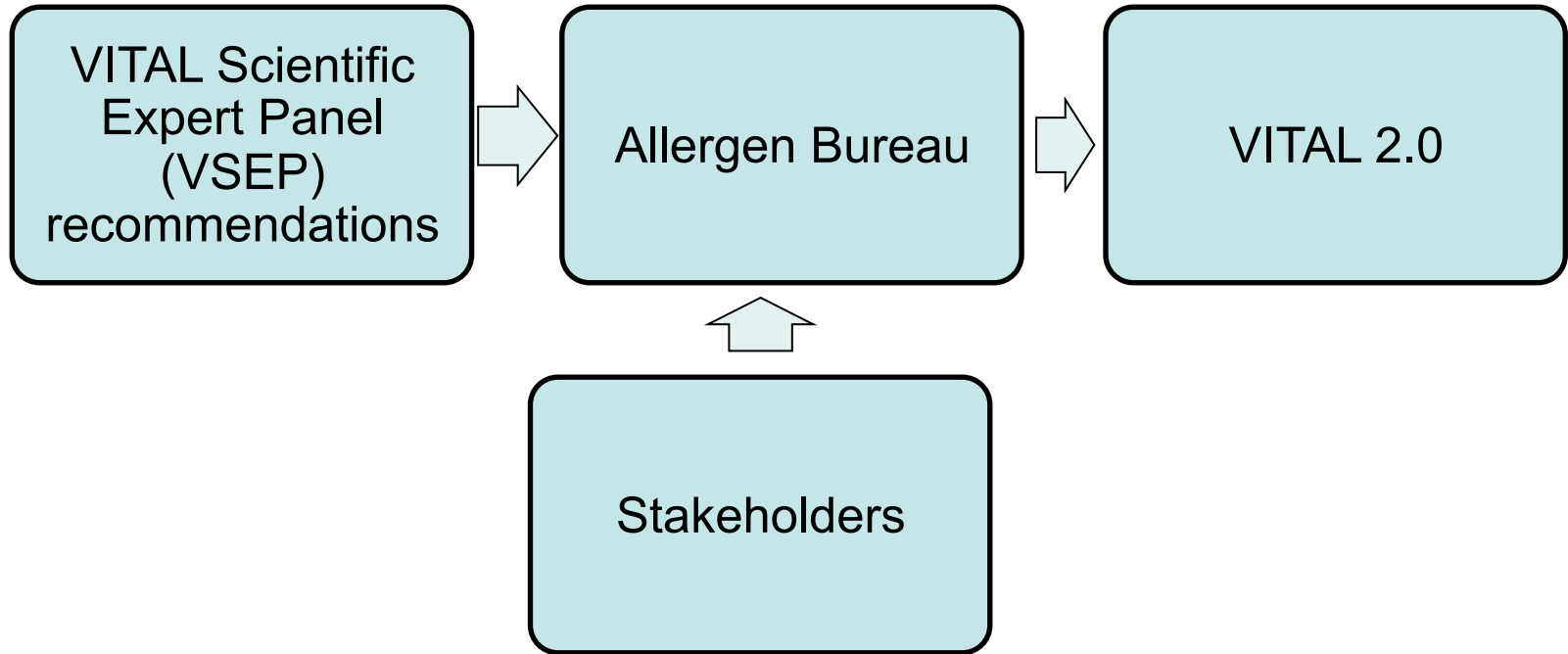
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Introducing VITAL 2.0 – New Identity!

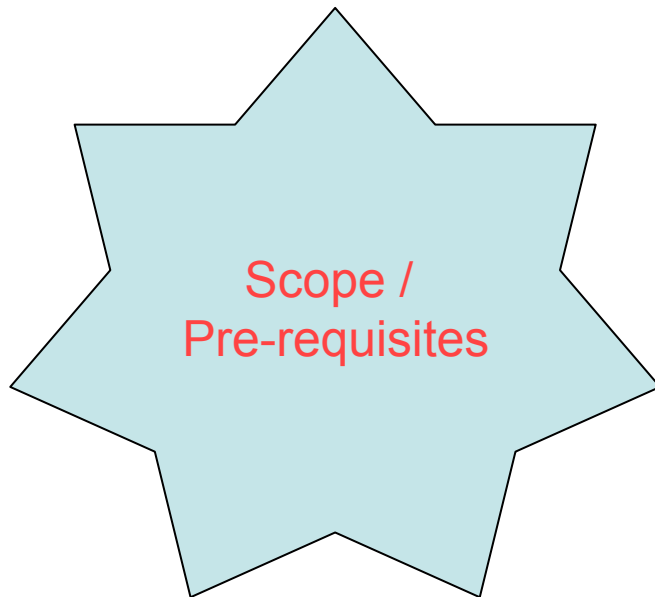


VITAL

an initiative of the Allergen Bureau



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



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



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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

What is new in VITAL 2.0?

New
Allergens

Only 2
Action
Levels +
New Action
Levels

Reference
Dose
+
Reference
Amount

New VITAL
Calculator

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 ?

	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**

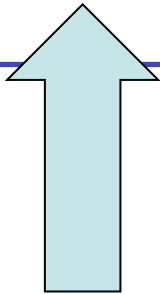
Transition between Action Levels*

= Reference dose x (1000 / Reference amount (g))

***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 (g))



Set by VSEP

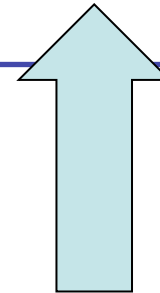
Reference Dose

- 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

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	1	0.1

Transition between Action Levels

= Reference dose x (1000 / **Reference amount (g)**)



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 : $\geq 4 \text{ ppm}$

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?

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.

Tree nuts

- **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.



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Fish

FSANZ definition of fish = Fin fish + Molluscs

VITAL 2.0: Fish = Fin fish



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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
- Currently DRAFT format only – we welcome your comments!



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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

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