



# The VITAL<sup>®</sup> Guide

Allergen Bureau

VITAL 3.0 and Allergen Management Guidance  
Breakfast Seminars, 2020



*Informing the food industry*

Food Industry Guide to the  
Voluntary Incidental Trace Allergen  
Labelling (VITAL<sup>®</sup>) Program  
Version 3.0



October 2019



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

- Primary reference document for the implementation of the VITAL Program
- Updated from version 2.0 to version 3.0

## 2. THE VITAL PROCEDURE

### 2.1 Scope

The VITAL Procedure is applicable to allergens which are:

- homogeneously distributed or particulate cross contact allergens in food which is being prepared or manufactured; and
- listed in the VITAL Action Level Grid.

The VITAL Procedure is not applicable to:

- food specifically formulated for infants who often have heightened sensitivity to the presence of allergens and may require an alternative risk management approach; or
- food for special medical purposes.

#### Sulphites

Several legislations (including the Australia New Zealand Food Standards Code) require the declaration of added sulphites when they are present at 10 mg per kg or more in a finished product. Sulphites can be created or destroyed during production and the threshold for sulphite declaration is only applicable for added allergens and not those that are naturally occurring. It is suggested that foods are assessed on an individual basis to determine if the declaration of allergens is required. Analytical testing of finished product may be useful in this determination.

### 2.2 Pre-requisites

- It is not appropriate to apply the VITAL Program in the absence of a HACCP (Hazard Analysis Critical Control Point) based food safety program which includes allergens.
- The manufacturer must have documented and implemented an allergen management program.

#### Allergen Identification

### 2.3 Determination of relevant allergens

Determine the allergens to be included in the VITAL risk assessment. All allergens regulated for mandatory or precautionary allergen labelling should be considered, including both intentionally added and potential cross contact allergens.

Consider the relevant legislation for your product. For example, products sold in Australia and New Zealand markets should use, as a minimum, the allergens listed in Australia New Zealand Food Standard Code Standard 1.2.3-4. It is the responsibility of the user to ensure that all relevant allergens are included in the assessment.



### 2.4 Identification of intentionally added allergens

- Review the allergen information (e.g. product specification) from the supplier for each ingredient, raw material and processing aid, which must list the presence or absence of all relevant allergens.
- Intentionally added allergens that are present in the product being assessed should be listed in the ingredient listing on the label (for packaged product), or in customer information (for bulk product, if requested) as per regulatory requirements in the country of sale or the country of further manufacture.

### 2.5 Identification of unintentional (cross contact) allergens from materials or ingredients

- Review allergen information (e.g. product specification) from the supplier for each ingredient, raw material and processing aid to establish absence or the possible presence of cross contact allergens.
- For each identified cross contact allergen from raw materials, ingredients or processing aid determine the likelihood of its presence, and if present, whether it is in a readily dispersible or particulate form.
- For each identified cross contact allergen from materials or ingredients, investigate whether the cross contact allergen can be avoided, reduced, or eliminated without adversely impacting the safety or quality of the product.

# Voluntary Incidental Trace Allergen Labelling (VITAL) Procedure (As at 12 June 2007)

## Introduction

The Australia New Zealand Food Standards Code Standard 1.2.1 - Mandatory Warning and Advisory Statements and Declarations sets out mandatory advisory statements and declarations which must be made in relation to certain foods or foods containing certain substances. Clause 4 of this Standard requires the mandatory declaration of the presence in a food of any of the substances listed in the Table to Clause 4 (refer to Scope) when these are present as an ingredient, an ingredient of a compound ingredient, a food additive or component of a food additive, a processing aid or component of a processing aid.

In addition to named allergens present in a food due to direct, intentional addition as a component of one of these vehicles, allergens may also be present, even under conditions of Good Manufacturing Practice (GMP), due to cross contact with other materials in which they are present. This could occur at any point along the food chain from primary production, ingredients and through the manufacturing process.

Voluntary Incidental Trace Allergen Labelling (VITAL) has been developed to provide a risk based methodology for food producers to use in assessing the impact of allergen cross contact and provide appropriate precautionary allergen labelling. Application of this approach aims to avoid indiscriminate use of precautionary labelling and thereby preserve its value as a risk management tool. It will therefore contribute to minimise risk to allergic consumers.

VITAL should be used as part of a HACCP based food safety program.

VITAL uses a three level grid to assist in determining if the presence of residual protein from allergenic substances (as per the Scope) through unavoidable cross-contact, requires a precautionary labelling statement.

## Food Safety Objective

To ensure safer manufactured food for the vast majority of food allergic consumers by providing consistent food labels that declare the presence of allergens, due to documented, unavoidable and sporadic cross contact, to enable allergic consumers to avoid purchasing foods that may present a personal risk. Precautionary labelling, used to warn about the occasional inadvertent presence of small amounts of allergen, has become increasingly devalued and disregarded among food allergic individuals owing to its inconsistent application. Zero risk is theoretically and practically unattainable given the extreme reactivity of some allergic individuals.

## Purpose

The Procedure sets out how VITAL is to be applied and describes the steps required to be followed to determine if a precautionary allergen cross contact statement is required.

## Scope

VITAL is only applicable in situations where food is being prepared or manufactured for consumption by consumers.

## Procedure

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## Procedure

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## Procedure

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## Procedure

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Voluntary Incidental Trace Allergen Labelling (VITAL) has been developed to provide a risk based methodology for food producers to use in assessing the impact of allergen cross contact and provide appropriate precautionary allergen labelling. Application of this approach aims to avoid indiscriminate use of precautionary labelling and thereby preserve its value as a risk management tool. It will therefore contribute to minimise risk to allergic consumers.

The Voluntary Incidental Trace Allergen Labelling (VITAL) Program has been developed to provide a risk based methodology for food manufacturers to use in assessing the impact of allergen cross contact and provide appropriate precautionary allergen labelling (PAL). Application of this approach aims to avoid indiscriminate use of precautionary allergen labelling and thereby preserve its value as a risk management tool. It aims to minimise risk while communicating effectively to allergic consumers.





# New to the VITAL Guide

- Aligns with new VITAL Standard
- Incorporates 2019 VSEP recommendations
- Directs to new VITAL resources
  - Allergen Risk Review website
  - VITAL Best Practice Labelling Guide
  - VITAL Standard
  - Allergen Risk Review Anomaly for dark chocolate

## 3. SUPPORTING INFORMATION

### 3.1 VITAL Online (including the interactive VITAL Action Level Grid)

VITAL Online is a user-friendly, web-based VITAL calculator. It was developed to assist with and record the implementation of the VITAL Program for food products. VITAL Online provides a useful format to store the allergen status of ingredients and processing profiles and to record the assumptions used for the VITAL risk assessment. VITAL Online includes the interactive VITAL Grid which can be used to create a VITAL Action Level Summary report.

VITAL Online is available at [www.vital.allergenbureau.net](http://www.vital.allergenbureau.net)

Please also see [www.allergenbureau.net/vital/vital-online](http://www.allergenbureau.net/vital/vital-online) for further information about VITAL Online, including "Helpful Hints".

### 3.2 Allergen Risk Review website

The Allergen Bureau's Allergen Risk Review website is a freely available interactive guide designed to assist the food industry with understanding the allergen status of its products. This resource was developed to assist food manufacturers to prepare for implementation of the VITAL Procedure. For example, the Allergen Risk Review website contains information about how to determine the allergen status of ingredients and how to quantify hang up. Access the Allergen Risk Review website at [www.allergenbureau.net/risk-review](http://www.allergenbureau.net/risk-review).

### 3.3 VITAL Best Practice Labelling Guide

The VITAL Best Practice Labelling Guide contains worked examples of the application of the VITAL Program to food products. It was developed by members of the food industry and intended to provide the food industry with guidance for declaring allergens on a label. This guide was developed for products sold in Australia and New Zealand, however, it contains information that may be useful for other jurisdictions. The VITAL Best Practice Labelling Guide is available at the Allergen Bureau website.

### 3.4 The VITAL Standard

The VITAL Program is available as the VITAL Standard, a supplementary certification program for food manufacturers that are already certified to GFSI recognised food safety management standards that include allergen management. The VITAL Standard is certified by Certification Bodies

accredited to ISO/IEC 17065:2012 (or subsequent version) and audited by auditors trained in the VITAL Standard and registered with The Allergen Bureau Ltd. Manufacturers that achieve VITAL certification may use the VITAL mark on the products within their scope of certification.

Further information about the VITAL Standard is available at the Allergen Bureau website.

### 3.5 VITAL Training

Training in the VITAL Program and VITAL Online is available from Allergen Bureau-endorsed Training Providers. The register of training providers, listed by country, is available at the Allergen Bureau website.

### 3.6 Allergen Risk Review Anomaly for Dark Chocolate

An allergen risk review anomaly, in relation to dark chocolate, and inconsistent labelling practices were identified by the confectionary industry. This occurs where dark chocolate is manufactured following production of milk chocolate, i.e. milk remains in the dark chocolate at variable levels, often above the VITAL Program Action Level 2 where precautionary allergen labelling would be recommended. This is also above the allergic consumer and their carers' expectation of 'trace' or 'minimal' (cow's) milk levels.

The Australian Industry Group (Ai Group) Technical Committee established a working group with the Allergen Bureau and, in consultation with the Australian Food & Grocery Council (AFGC), worked together to consider industry guidance in relation to this allergen risk review anomaly and food labelling for the Australian and New Zealand food industry. This advice is available at the Allergen Bureau website.



# Recommended PAL Statement

The **ONLY** precautionary statement to be used in conjunction with VITAL is:  
**May be present: XXX**



The **recommended** precautionary allergen labelling statement to be used in conjunction with the VITAL Program is :

**"May be present: allergen x, allergen y."**



# Reference Dose Definition

the milligram protein level (total protein from an allergenic food) below which only the most sensitive individuals (between 1% and 5% depending on the quality of the data set available) in the allergic population are likely to experience an adverse reaction.



the milligram protein level (total protein from an allergenic food) below which only the most sensitive (1%) of individuals in the allergic population are likely to experience an adverse reaction. If reactions to unlabelled allergens do occur from exposure below the Reference Dose they will be mild and transient, requiring no emergency medical intervention.



# 2019 VSEP Recommendations

- Released in October 2019
- Includes the changes from 2018 & 2019 meetings of the VSEP
- Methodology moved to model averaging (robust science is the key for all stakeholders)
- Reference Dose recommendations based on  $ED_{01}$  (1 in 100 allergic consumers reacting)



*Informing the food industry*

Summary of the 2019  
VITAL Scientific Expert Panel  
Recommendations







# Clinical Trial Data

- Recommendations for Reference Doses are based on clinical trials of allergic individuals
- Increased from >1800 (2011) to >3400 (2019)
- e.g. peanut clinical trial data 744 (2011) to 1306 (2019) & cashew clinical trial data 31 (2011) to 245 (2019)

Allergen	Number of available individual challenge studies	
	2011	2019
Egg	206	431
Hazelnut	200	411
Lupin	24	25
Milk	344	450
Mustard	33	33
Peanut	744	1306
Sesame	21	40
Shrimp	48	75
Soy (milk + flour)	51	87
Wheat	40	99
Cashew	31	245
Celery	39	82
Fish	19	82
Walnut	~15	74



# The VSEP impacts for VITAL<sup>®</sup>

Allergen	No. of individuals	VITAL 2.0 Ref Dose (mg protein)	2019 VSEP Ref Dose (mg protein) [ED <sub>01</sub> ]	Change
Egg	431	0.03	0.2	↑
Hazelnut	411	0.1	0.1	✓
Lupin	25	4.0	2.6	↓
Milk	450	0.1	0.2	↑
Mustard	33	0.05	0.05	✓
Peanut	1306	0.2	0.2	✓
Sesame	40	0.2	0.1	↓
Shrimp	75	10.0	25	↑
Soy (milk + flour)	87	1.0 (soy flour)	0.5	↓
Wheat	99	1.0	0.7	↓
Cashew	245		0.05	+
Celery	82		0.05	+
Fish (finfish)	82		1.3	+
Walnut	74		0.03	+

- Some Reference Dose levels have changed
- New Reference Doses added
- Consistent approach across all Reference Doses

↑	Reference Dose increased
✓	Reference Dose unchanged
↓	Reference Dose decreased
+	New Reference Dose



# Impacts for VITAL - what we need to consider

- Tree Nuts
  - New Reference doses for Walnut, and Cashew and their relatives
  - Default reference dose for 'all other tree nuts'
- Soy Flour & Soymilk
  - Combined data
- New Reference Doses
  - Supports other country regulations – Celery & Mustard
- Reference Dose levels that are changing
  - Transition plan is key – Help in VITAL Online - 2.0 vs 3.0





# Transition

- Allergen management due diligence should include an assessment of any impacts to your products from the changes to Reference Doses
- Case-by-case review to determine the appropriate action
- Some changes may be significant (that is, changing from Action Level 1 to Action Level 2) and may trigger the requirement to update product labelling
- VITAL is a voluntary program **there is no timeline imposed** by the Allergen Bureau for labelling changes

On Monday 28 October 2019 VITAL Online will be updated to v3.0.0

[Email not showing correctly? View in your browser](#)



## Allergen Bureau eAlert

### Release of VITAL Online Version 3.0.0

On Monday 28 October 2019 at 3:00pm Australian Eastern Daylight Time (4:00am same day UTC), VITAL



Online will be updated from v2.3.30 (previous version) to v3.0.0 (updated version) with the following key changes and additions.

- an updated set of Reference Doses
- the addition of a Reference Dose for celery in the European Union legislation
- updated tree nut groupings
- update functionality



# The VITAL<sup>®</sup> Guide

<http://allergenbureau.net/vital/>



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