

# **Voluntary Incidental Trace Allergen Labelling (VITAL) Procedure**

**(As at 12 June 2007)**

## **Introduction**

The Australia New Zealand Food Standards Code Standard 1.2.3 - 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.

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The VITAL Grid Action Levels do not extend to cover foods specifically formulated for infants who often have heightened sensitivity to the presence of allergens.

The process should be followed for each allergen that may be present in the final product due to cross contact via ingredients or processing. **VITAL is not applicable to ingredients which contain allergenic substances and have been intentionally formulated into the product.**

VITAL is applicable for allergen substances as per Standard 1.2.3, Table to Clause 4 (refer to box below).

Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively (not an allergen)

Crustacea and their products

Egg and egg products

Fish and fish products\*

Milk and milk products

Tree nuts and sesame seeds and their products

Peanuts and soybeans, and their products

Added Sulphites in concentrations of 10mg/kg or more #

# Sulphites have not been included within the scope of VITAL

\*Molluscs and Shellfish are not included

## Definitions

Allergen – any material which produces an allergic reaction in an individual. In VITAL the principal concern is with food proteins that can cause the production of IgE antibodies. For the purpose of VITAL, allergens are restricted to those substances listed in the Scope of this procedure.

Cross Contact – occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food.

Hang Up Point – point on the manufacturing line where material accumulates instead of flowing through freely.

LOAEL - Lowest Observed Adverse Effect Level.

Readily Dispersible Form - powder or liquid in homogenous form. For example – milk powder, soy flour.

Particulate – a separate and distinct particle of material. For example – sesame seeds, slithered nuts, grated cheese.

Total Protein – the protein content of a material as determined by an appropriate total protein assay.

Allergenic Protein – fraction of total protein that is responsible for allergic reactivity.

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Verification – activities (other than monitoring) that determine the adequacy of and compliance with the plan.

Validation – determination that the plan, when properly executed, will effectively control the significant hazards in the process.

Sporadic – intermittent presence of allergens appearing in isolated instances

Infants – person under the age of 12 months.

Children – person older than 12 months but under the age of 5 years

## **Components of VITAL:**

- VITAL Decision Tree
- VITAL Action Level Grid, including Explanatory Notes

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## Procedure

The numbering in this section of the procedure relates directly to the VITAL Decision Tree. It covers the review of ingredient and manufacturing process impact..

## Suitability Criteria

### Pre-Requisite for application of this procedure:

Appropriately HACCP trained food safety personnel should complete the assessment. The process requires an in depth knowledge of the manufacturing plant and processes.

VITAL should be followed for each allergen that may be present in the final product due to cross contact from ingredients or the process of manufacture. Any calculation made should be to an appropriate level compatible with the levels in the VITAL Grid.

VITAL is not applicable to ingredients intentionally formulated into the product.

## 1 Ingredient and Processing Impact

VITAL requires the assessment of likely sources of cross contact allergenic substances from raw materials and the processing environment.

## 2 Review the ingredient and processing allergen impacts

### 2.1 *Ingredient Impact - Assess allergen status of raw materials*

Assess the allergen status of the raw materials using the information from the Product Information Form (PIF). If an allergenic risk exists from cross contact, determine if the presence of the allergen is in particulate form or a readily dispersible form.

If the allergen is present in particulate form, review contributors with the supplier to prevent occurrence. If occurrence cannot be prevented, a precautionary allergen cross contact statement will be required.

If the allergen is present in a readily dispersible form determine with the supplier if it is feasible to reduce the level of allergen cross contact, for example:

- Can scheduling be changed to minimise the cross contact impact?
- Where is/are the allergen/s being introduced?
- Is the source of the cross contact through line/people/tools etc?
- Are there any hang-up points in the process? Can the line be re-engineered to remove hang up points?
- What cleaning or other control procedures are in place? Can they be changed?
- What is the carryover from one batch to the next batch?

Determine total protein of the allergenic ingredient i.e. protein of milk powder. Please refer to the Standard Protein Reference Table available on the Allergen Bureau website.

Determine the maximum amount of total protein from the allergenic raw materials and express in parts per million (ppm) or mg/kg of protein in the final product taking into account the amount present in the product.

This process should be applied for each allergen in the material under consideration.

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## **2.2 *Manufacturing Process Impact - Review the production line used to manufacture the product***

Determine if there are allergens present on the production line, through cross contact of ingredients or product that are not formulated into the product. Consider all areas of the production line e.g mixing bowl, conveyor belts, baking tins etc.

Determine if there are any hang-up points in the process that may cause accumulation of residues or particulate material which may result in significant variations in the quantity of cross-contact allergens present in the product.

If the allergen is present in a readily dispersible form determine with the supplier if it is feasible to reduce the level of allergen cross contact, for example:

- Can scheduling be changed to minimise the impact of cross contact?
- What cleaning or other control procedures are in place? Can they be changed?
- What is the carryover from one batch to the next batch?
- Can the line be re-engineered to remove hang up points?

Determine the maximum amount of total protein from the allergen due to manufacturing cross contact and calculate in ppm or mg/kg of protein in the product.

## **3 *Form of Allergenic Material***

### **3.1 *Particulate***

Particulate materials such as pieces of tree nut or peanut or flakes of wheat or soy may not be evenly dispersed through the "cross contacted" product which will lead to a much higher level of allergenic protein in a smaller proportion of the final product.

### **3.2 *Readily Dispersible***

Substances that are readily dispersible would be considered to be evenly distributed throughout the product and therefore of a uniform concentration.

## **4 *Determine the amount of Cross Contact Allergen Protein in the Finished Product***

Determine the level of cross contact allergen protein in the product from both ingredients and the manufacturing process. This can be done via a manual calculation process or by using the VITAL calculation tool.

### **4.1 *Manual Calculation***

Determine the total level of protein from allergenic sources in the finished product in mg of total protein by combining the amount of cross contact total protein from allergenic ingredients and the manufacturing processes.

### **4.2 *VITAL calculation tool***

The VITAL calculation tool is an Excel spreadsheet which has been specifically designed to guide the user through the VITAL process and removes the need for manual calculations.

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## 4.3 *The Role of Allergen Testing*

Testing should be used for validation purposes only as part of a HACCP based food safety program. It is not expected that testing be used in 'real-time' as a quality control step. Only validated test kits should be used for testing. Please refer to the Allergen Residue Detection Table for guidelines on test kits and methodology.

## 5 **The VITAL grid.**

Compare the concentration of the allergen in the final product to the VITAL Grid.

In summary the VITAL Action Levels indicated are:

- **Action Level 1 – Green Zone** - precautionary cross contact statement is not required for the relevant allergen under evaluation.
- **Action Level 2 – Yellow Zone** - precautionary cross contact statement is required for the relevant allergen using the standard VITAL statement.
- **Action Level 3 – Red Zone** – significant levels of the allergen are likely to be present. Labelling of the relevant allergen as an ingredient in the ingredient list is required.

The VITAL cross contact statement is "May be present: XXX"

Precautionary labelling should only be used after a thorough assessment of the risk. Precautionary cross contact statements must **NEVER** be used as a substitute for good manufacturing practice (GMP) or as a generic disclaimer. Every attempt must be made to eliminate or minimise cross contact by adhering to GMP.

## 6 **Review Significant Contributors and Reduce Cross Contact**

Allergen management should be reviewed regularly. A precautionary statement would not necessarily be instituted after a first iteration of the assessment process. Rather that first assessment would indicate whether a more refined evaluation was required and highlight areas of concern which should be addressed.

### 6.1 *Ingredient Impact - Assess allergen status of raw materials*

Determine if it is possible to purchase from an alternative supplier to avoid the allergen completely. If not possible, determine with the supplier if it is feasible to reduce the level of allergen cross contact by assessing the allergen management program, process design, cleaning schedules and product handling. Implement changes with supplier if appropriate and reassess the contribution to the cross contact allergen level.

### 6.2 *Manufacturing Process Impact - Review the production line used to manufacture the product*

Determine if it is feasible to reduce the level of allergen cross contact on the production line by rescheduling to minimise the cross contact impact, changing cleaning procedures, re-engineering to remove hang up points and changing handling procedures. Implement changes if appropriate and reassess the contribution to the cross contact allergen level.

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## 6.3 *Particulates*

If the allergenic protein is present in particulate form, review contributors to prevent occurrence. If this is not possible an allergen cross contact statement will be required.

## 7 **Allergen Labelling Statement**

If it is determined that a cross contact statement is required (Action Level 2), the following statement is required to be used.

‘May be present: XXX’

No other cross contact statements are to be used.

**The VITAL cross contact statement should only be used where cross contact is:**

- documented using VITAL, **and**
- unavoidable, **and**
- sporadic.

## 8 **Ongoing Monitoring**

Ongoing monitoring of the raw materials and the manufacturing processing environment as part of the HACCP validation and verification program is required to ensure compliance to VITAL.

The VITAL process should be reviewed when (but not limited to):

- Ingredient or suppliers are changed,
- Equipment or manufacturing processes are changed,
- Cleaning procedures are changed,
- Consumer complaints are received regarding allergic reactions

OR

Every six to 12 months

whichever occurs sooner.

### 8.1 *Ingredients*

This could be done in the following ways:

- testing by the supplier and notification of changes via the PIF; OR
- testing by the manufacturer.

An assessment of the presence of inadvertent (cross-contact) allergen in raw materials and its implications for the products in which it will be used (for instance, the presence of a small amount of cross-contact allergen would be of minor significance in an ingredient used at low concentrations, but could present a serious risk in one which is a major component of a formulated product). This assessment may include testing, where appropriate.

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## **8.2 Processing Environment**

This could be done in one or more of the following ways:

- testing by the manufacturer (raw materials, manufacturing equipment, flush materials, as appropriate);
- process audits;
- environmental testing; and
- post cleaning equipment swabs (consider that swab results only provide a present/absent answer with regards to the allergen).

## **9 Review of Procedure**

Procedure to be reviewed no later than February 2008 and then periodically.

## **10 Use of the Voluntary Incidental Trace Allergen Labelling (VITAL) Procedure**

[1] The purpose of this system is more consistent risk communication. It is not designed to deliver total safety in relation to food allergen risks. It does not guarantee that a consumer eating the food will not suffer any allergic response. A total approach to allergen risk management is outside the scope of this procedure, and would involve a range of issues from supplier selection through to factory design and production management.

[2] This risk assessment tool has been developed against a regulatory background where the labelling of incidental trace allergens is not mandated. VITAL is based on the premise that some products may have foreseeable, but microscopic, levels of an allergen present through incidental cross-contact, and this will not be labelled where the level is below a specified action level.

[3] VITAL relates to the allergen risks associated with peanuts, cereals containing gluten, fish, milk, soybeans, tree nuts and sesame seeds and crustacea. It does not address the risks associated with products such as royal jelly or propolis for which mandatory labelling exists. It also does not extend to cover infants who often have heightened sensitivity to the presence of allergens. Foods aimed at infants may need a more rigorous risk approach.

[4] As with all general procedures, it will be necessary for the user to use his or her own skill, knowledge and experience in adapting VITAL to the specific circumstances. In using VITAL the user acknowledges that the Australian Food and Grocery Council, its employees, committee and working group members and agents, are not responsible and will accept no liability (including as a result of negligence) for any loss, injury or death that may result from the consumption of a product labelling using the VITAL system.

[5] The VITAL Procedure may be updated from time to time as scientific knowledge in relation to allergens and reactions increases. Please check to ensure the latest version is available prior to use.

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## **REFERENCED DOCUMENTS**

- 1 VITAL Decision Tree
- 2 VITAL Action Level Grid
- 3 VITAL Calculation Tool
- 4 Allergen Residue Detection Table
- 5 Standard Protein Reference Table