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

Version 2.0



an initiative of the Allergen Bureau

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## PREFACE

Food regulations in many countries require the mandatory declaration of certain allergens in food. In addition to named allergens present in a food due to direct, intentional addition, allergens may also be present, even under conditions of Good Manufacturing Practice (GMP), due to cross contact with other materials. 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 minimising risk while communicating effectively to allergic consumers.

VITAL uses a two level Action Level grid to assist in determining if the presence of residual protein from allergenic substances through unavoidable cross contact requires a precautionary labelling statement.

### **i. Background Information**

The first version of VITAL was released in June 2007 in Australia and New Zealand to provide a risk-based assessment process to determine when a precautionary allergen labelling statement (May be present) is appropriate.

In 2010 the Allergen Bureau initiated a review of VITAL, building on a commitment to continue to invest in VITAL to ensure that it remains a relevant tool for industry.

The Allergen Bureau recognised a need to form a scientific expert panel, known as the VITAL Scientific Expert Panel (VSEP) to review the science underpinning the VITAL Action Level Grid. The scientific review was a critical body of work to ensure that the Action Levels protect the allergic consumer by enabling industry to make appropriate precautionary labelling decisions and provide clear and consistent consumer communication through the use (or not) of the “May be present” statement.

### **ii. The Regulatory Framework & VITAL**

VITAL has been developed against the Australian/New Zealand regulatory background. VITAL is applicable for allergen substances listed in the Australia New Zealand Food Standard Code Standard 1.2.3, Table to Clause 4. Additional allergens (lupin, mustard) have been added to the VITAL Action Level Grid and further allergens may be included when there is sufficient scientific data available to set a Reference Dose. It is the responsibility of the user to determine the cross contact allergens that may impact their product and to ensure the appropriateness of using VITAL in their market.

### **iii. The VITAL Program**

The VITAL Action Level Grid contains concentrations of cross contact allergens, called Action Levels, which determine when it is appropriate to use a precautionary allergen statement. The VITAL Action Level Grid is a key component of this program and is incorporated into the VITAL Calculator. The Action Level concentrations are determined using the Reference Dose information (set by the VITAL Scientific Expert Panel) in conjunction with the associated Reference Amount/Serving Size. The VITAL Action Levels Grid (incorporated into the VITAL Calculator) should be used in conjunction with this document.

Other tools, available from the Allergen Bureau website, which should be used to assist in the implementation of the VITAL 2.0 Program include:

- ➔ The VITAL Calculator: a tool to assist in recording information relevant to the VITAL program;
- ➔ VITAL Frequently Asked Questions (FAQs);
- ➔ Auditor's Guide to VITAL; and
- ➔ Other tools which will be released as required.

#### **iv. The VITAL Program Objective**

To ensure manufactured food is safe to consume 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 thus enabling allergic consumers and their carers to avoid purchasing foods that may present a personal risk.

#### **v. Use of VITAL**

- ➔ The purpose of this system is 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.
- ➔ 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 minute, levels of an allergen present through incidental cross contact, and this will not be labelled where the level is below a specified Action Level.
- ➔ VITAL relates to the allergen risks associated with those allergens listed in the VITAL Action Level Grid. 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.
- ➔ As with all general procedures, it will be necessary for the user to use their own skill, knowledge and experience in adapting VITAL to their specific circumstances. In using VITAL the user acknowledges that the Allergen Bureau and 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 Program.
- ➔ The VITAL Program and tools may be updated from time to time as scientific knowledge in relation to allergens increases. Please check to ensure the latest version is available prior to use.

## APPLICATION OF VITAL (THE VITAL PROCEDURE)

### i. Definitions

Term	Definition
<b>Action Levels</b>	Action Levels are the concentrations which define the labelling outcomes for each concentration of cross contact allergen. They are determined using the Reference Dose and the Reference Amount/Serving Size.
<b>Allergen</b>	refers to any substance that causes an allergic reaction. In the VITAL program the principal concern is with foods that are listed in the Australia New Zealand Food Standard Code Standard 1.2.3, Table to Clause 4.
<b>Cross Contact Allergen</b>	<p>a residue or other trace amount of an allergenic food that is unintentionally incorporated into another food. For the purpose of VITAL, cross contact sources can be from Raw Materials or Processing.</p> <p>Cross contact from <b>Raw Materials</b> refers to allergens which may be incorporated during the supply chain of ingredients (eg. shared harvesting/storage/packing and processing of the ingredient) prior to the addition of the raw material to the product to be assessed.</p> <p>Cross contact due to <b>Processing</b> is the unintentional incorporation of allergens during production of the product to be assessed due to shared manufacturing lines, equipment, tools and/or people.</p>
<b>HACCP</b>	Hazard Analysis Critical Control Point is a food safety system that uses a preventative approach to controlling hazards (such as chemical, physical, biological and allergen) in food production.
<b>Hang Up Point</b>	a point on a manufacturing line where material may accumulate instead of flowing through freely.
<b>Infant</b>	person under the age of 12 months.
<b>Intentionally Added Allergen</b>	intrinsic part of the ingredient materials and includes all allergens which are required for mandatory declaration in the ingredient list or ingredient statement.
<b>Particulate</b>	<p>a separate and distinct particle of material (eg. sesame seeds, slivered nuts, grated cheese). For the purpose of VITAL, a particulate refers to an entity of food which either</p> <ul style="list-style-type: none"> <li>➤ Does not mix homogeneously with other parts of the food; or</li> <li>➤ May consist of, or are likely to aggregate into an entity which contains a level equal to or greater than the relevant Reference Dose.</li> </ul> <p>(see also <b>Readily Dispersible Form</b>)</p>
<b>ppm</b>	parts per million – a measure of concentration equivalent to mg/kg.
<b>Precautionary Allergen Statement</b>	a statement about the possible presence of cross contact allergens in a product. The only precautionary statement recommended for use with VITAL is “May be present:...”.
<b>Product Information Form (PIF)</b>	standard specification form developed by the Australian Food and Grocery Council.
<b>Readily Dispersible Form</b>	a powder or liquid in homogeneous form eg. milk powder, soy flour. A readily dispersible cross contact allergen which is considered homogeneously distributed in the final product. (see also <b>Particulate</b> )

Term	Definition
<b>Reference Amount / Serving Size</b>	<p>the maximum amount of a food eaten in a typical eating occasion. This may be the same as the “serving size” on the nutrition information panel or it may be appropriate that the reference amount is considered to be the whole product as presented to the consumer. The determination of the reference amount or serving size is a business decision. It is recommended that where serving size is used that the AFGC serving size principles (listed below) should be applied.</p> <p><b>SERVING SIZE PRINCIPLES</b> (sourced from AFGC Code of Practice for Food Labelling and Promotion)</p> <p>It is the manufacturer’s responsibility to determine the serving or portion size for a food or beverage product, but they must reflect the agreed industry serving size principles.</p> <ul style="list-style-type: none"> <li>➤ Single serve items should be appropriate sizes for the target market.</li> <li>➤ The serving portion should be realistic (at both the lower and upper levels).</li> <li>➤ If a product is packed such that it can be reasonably expected to be consumed by the target consumer in one serving then the pack should be the serving size, and the energy and nutrient content of the whole pack should be clearly indicated.</li> <li>➤ Multiple serve items should consist of appropriate serving sizes in relation to single serve packs.</li> <li>➤ Serving sizes must not be used inappropriately to manipulate energy or nutrient content per serving.</li> </ul>
<b>Reference Dose</b>	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.
<b>Sporadic distribution</b>	the intermittent presence of allergens appearing in isolated instances.
<b>Total Protein</b>	the protein content of a material as determined by an appropriate total protein assay. Information about the total protein in a food product may be sourced from food tables, nutrition information panels or other reliable sources.
<b>Total Protein Concentration (TPC)</b>	the measure used in the VITAL Action Level Grid. To convert the presence of cross contact allergen to TPC, determine the amount of protein present in the cross contact allergen and then its concentration in the final product.
<b>Validation</b>	determination that the food safety plan, when properly executed, will effectively control the significant hazards in the process.
<b>Verification</b>	activities (other than monitoring) that determine the adequacy of and compliance with the Allergen Management Plan.
<b>VITAL Action Level Grid</b>	<p>The VITAL Action Level Grid is composed of two Action Levels for each allergen of interest which relate to labelling recommendations. The VITAL Grid is based on clinical oral challenge threshold data to which statistical models are applied to determine an eliciting dose of the allergen (ED<sub>p</sub>) at which a proportion (p) of the allergic population would be likely to react. (see also <b>Action Level</b>)</p> <p>NB. The onus is on the user to ensure that they are using the most recent VITAL Action Level Grid.</p>
<b>VITAL Calculator</b>	a tool which can assist in implementing VITAL by storing information and performing calculations outlined in this procedure. The VITAL Calculator can be downloaded from the Allergen Bureau website.

## ii. Scope

The VITAL Procedure is applicable to particulate and homogeneously distributed cross contact allergens in food which is being prepared or manufactured.

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 rigorous risk approach.

VITAL is applicable only to the substances listed in the **VITAL Action Level Grid**.

## iii. Pre-requisites

- ➔ VITAL should be used as part of a HACCP (Hazard Analysis Critical Control Point) based food safety program.
- ➔ Appropriately HACCP trained food safety personnel should complete the risk assessment. The process requires an in depth knowledge of the manufacturing plant and processes and ingredients.

## iv. Determination of relevant allergens

Determine the allergens that will be considered in the risk assessment. For example, for products sold in Australian/New Zealand markets, the Allergen Bureau recommends that only those allergens listed in Australia New Zealand Food Standard Code Standard 1.2.3, Table to Clause 4 should be considered<sup>1</sup>. The choice of allergens will be impacted by local regulations as well as the regulations of the export market, if appropriate.

## v. Identification of intentionally added allergens

- ➔ Review allergen information from supplier for each ingredient (e.g. Product Information Form (PIF), specification or other information). Ensure information is obtained about the absence/presence of all relevant allergens. Determine allergens which are intentionally present in each ingredient.
- ➔ Where intentionally added allergens have been identified, these are required to be declared in the ingredient list or ingredient statement on the product label<sup>2</sup>.

## vi. Identification and quantification of cross contact allergens due to ingredients

- ➔ Review the Product Information Form (PIF), specification or other information from the supplier for each ingredient. Ensure information is obtained about the possible unintentional incorporation of all relevant allergens (cross contact allergens) for each ingredient.
- ➔ For each cross contact allergen, determine if it is present in the final product in a Readily Dispersible or Particulate form.
- ➔ For Particulate Allergens: declare the allergen in the precautionary labelling statement (as per Action Level 2).

<sup>1</sup> Sulphites are included in the Table to Clause 4 however they should be treated differently to other allergens. Sulphites can be created or destroyed during the manufacture of food. Products which are likely to contain sulphites should be assessed by analysis of the final product instead of using calculated values.

<sup>2</sup> The Allergen Bureau recommends the labelling guidance in the AFGC Food Industry Guide to Allergen Management and Labelling.

- ➔ For Readily Dispersible cross contact allergens: determine the Total Protein Concentration from the allergen source in the ingredient. Use this information to calculate the concentration of the total protein from the cross contact allergen in the ingoing formulation of the product being assessed.

Total protein concentration from cross contact allergen in formulation (ppm) = concentration of cross contact protein in ingredient (ppm) x amount of ingredient in formulation (%)

For example: A supplier advises the concentration of cross contact soy protein in butter is 50ppm. The butter is used at 40% in the ingoing formulation of biscuits.

Soy protein concentration in ingoing formulation of biscuits = 50 x 40% = 20ppm

## vii. Identification and quantification of cross contact allergens due to processing

- ➔ Review the manufacturing line and environment to determine if there are (cross contact) allergens which may become incorporated in the product during the manufacturing process. Consider all areas of the production line e.g. mixing bowl, conveyor belts, baking tins etc and possible incorporation due to shared tools and people. 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.

### Tips for determining cross contact due to processing

<b>Production Errors</b>	Cross contact during the manufacturing process should include all possible instances of incorporation of unintended allergens where processing occurs in compliance with procedures. Production errors should not be included as possible sources of cross contact allergens – where such an issue occurs the HACCP plan should be used to resolve the issue.
<b>Hang up points</b>	It is important to correctly identify hang up points in your manufacturing facility. Some manufacturing facilities may be able to completely eliminate cross contact due to processing by having cleaning programs which have been validated to eliminate any product on the lines. Some plants, such as chocolate or dry-blend plants, face more significant challenges with regard to eliminating cross contact allergens. All manufacturers should commit to reducing or eliminating cross contact allergens.
<b>Form a cross-functional team to perform the risk assessment</b>	An initial risk assessment should include a cross-functional team such as quality assurance staff and those that are familiar with scheduling, cleaning and the engineering of the facility. All allergen containing ingredients should be identified and opportunities for cross contact identified. Where each opportunity for cross contact is identified, it should be eliminated or reduced wherever possible.
<b>Quantifying the cross contact allergen</b>	Quantifying the cross contact allergen will depend on the nature of the manufacturing facility. If the hang up point is inside a pump, pipe or other area which is difficult to access, an engineer may be able to assist with estimating the amount of product that may be left in the line and become incorporated into a subsequent product. If there is a powder residue, it may be able to be swept up and weighed. If the hangup cannot be reached, it may be necessary to use some estimation based on the volume of the pipe or other factors.

- ➔ Where the possibility of cross contact is identified, investigate if it can be reduced or eliminated.
- ➔ For each cross contact allergen which cannot be avoided, determine if it is present in the final product in 'Readily Dispersible' or 'Particulate' form.
- ➔ For Particulate cross contact allergens: declare the allergen in the precautionary statement (as per Action Level 2).

For Readily Dispersible cross contact allergens: determine the maximum amount of total protein from each cross contact allergen. Determine the amount of product into which this allergen will become incorporated (eg the total batch size). Convert the total protein to a concentration of the cross contact allergen in the product formulation.

Amount of cross contact protein from hang up point (mg) = amount of hang up (g) x amount of allergen ingredient in formulation of product in hang up (%) x protein level of cross contact allergen (%) x 1000.

To calculate the total concentration (ppm) of the cross contact allergen in the product formulation, divide the answer above by the amount of product into which this cross contact can become incorporated.

For example: A biscuit manufacturer identifies that a maximum of 500g of previously run product can hang up and become homogeneously mixed into the following 1000kg batch of butter biscuits. The hang up may consist of egg containing biscuits. Egg has a protein level of 13% and they are used in the egg biscuit formulation at 5%.

Amount of cross contact egg from hang up point (mg) = 500 x 5% x 13% x 1000 = 3250mg

Concentration of egg cross contact in butter biscuit formulation (ppm) = 3250/1000 = 3.25ppm

### viii. Calculation of total cross contact allergen in finished product

- ➔ For each allergen, sum the concentration of cross contact allergen protein from raw ingredients and processing.
- ➔ It may be appropriate to apply a dehydration or hydration factor to take into account the effect of losing water through the cooking process (e.g. baking bread) or adding water (a concentrated gravy or soup premix which will be diluted prior to consumption).  
NB. The maximum possible concentration should be used as this will provide the most conservative result.

Concentration of cross contact after **hydration** (mg) = concentration of cross contact allergen / (% dilution + 100%) (where % dilution = water added (kg) x weight original product (kg) x 100%)

Concentration of cross contact after **dehydration** (mg) = concentration of cross contact allergen / (% concentration)

For example: Butter biscuits, containing 20ppm soy and 3.25ppm egg cross contact allergens are baked and lose 25% of their weight.

Concentration of soy after baking (mg) = 20 / (100-25%) = 27ppm

Concentration of egg after baking (mg) = 3.25 / (100-25%) = 4.3ppm

## ix. Determination of Action Levels

**N.B.** If the product being assessed is an ingredient which is intended for further processing, the Reference Amount/ Serving Size will not be relevant and this step can be skipped. Supply your customer(s) with the following:

- The presence of any particulate cross contact allergen
- The concentration of any Readily Dispersible allergen

- ➔ Determine the appropriate Reference Amount / Serving Size for the finished product.
- ➔ Enter the Reference Amount / Serving Size into the interactive VITAL Action Levels Grid (incorporated in the VITAL Calculator) to determine the appropriate Action Levels.

The example below shows how Action Levels can be calculated manually. It is recommended that Action Levels are calculated using the VITAL Calculator. Reference Doses can be downloaded from the Allergen Bureau website.

Action Level transition point \*(ppm) = Reference Dose (mg) x (1000/Reference Amount (g))

(\*except gluten where formula above is applicable or 20ppm, whichever is lower)

For example: A biscuit manufacturer uses 40g Reference Amount/Serving Size.

Action Level transition for egg (40g Reference Amount) =  $0.03 \times (1000/40) = 0.75\text{ppm}$

Action Level transition for soy (40g Reference Amount) =  $1 \times (1000/40) = 25\text{ppm}$

Where cross contact soy is 27ppm, this is greater than the transition point, and will be Action Level 2.

Where cross contact egg is 4.3ppm, this is greater than the transition point and will be Action Level 2.

- ➔ Use the VITAL Action Level Grid to determine the appropriate Action Level for each cross contact allergen.

## x. Review of labelling recommendations and of sources of cross contact

- ➔ Intentionally added allergens must be declared on the product label (eg. in the ingredient list).
- ➔ Review cross contact allergens for opportunities to reduce or eliminate from the product.
- ➔ Where they cannot be eliminated, cross contact allergens should be labelled as specified by the appropriate Action Level:
  - **Action Level 1** – precautionary cross contact statement is not required for the relevant allergen under evaluation
  - **Action Level 2** – precautionary cross contact labelling statement is required for the relevant allergen using the standard VITAL statement.

**N.B.** 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.

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

## xi. Recording of Assumptions

Record the relevant details of your VITAL risk assessment. This information may be recorded in the VITAL Calculator and/or with your food safety/quality plan.

These may include (but are not limited to):

- ➔ Version and supplier details for PIFs or other source information;
- ➔ Allergen scheduling rules;
- ➔ Reference to other Food Safety/Quality Documentation such as Approved Supplier Program and production procedures;
- ➔ Processing assumptions made to assist with determining cross contact impact; and
- ➔ Manufacturing or processing cleaning schedules.

Tips for writing assumptions	
Any change in assumptions should trigger a review of the VITAL Assessment. Therefore, it is important to include all items which affect the allergen status of a product. This may include:	
<b>Ingredients</b>	sourcing details or any changes to the allergen status of raw ingredients
<b>Processing environment</b>	changes to any additional allergens introduced to the processing site and/or processing line, changes the equipment or procedures which could change hang-ups in the product, changes to the cleaning procedure, changes to the product schedule.

## xii. Validation of VITAL Assessment

- ➔ The concentration of cross contact allergens in a final product may be validated using analytical testing. It should be noted that this is not a mandatory part of this procedure, but that it may be useful in some circumstances.
- ➔ Consult a skilled analyst to ensure that the correct methodologies are used and to ensure that the units of measure are appropriate to use with the VITAL Action Levels Grid.  
NB. Cross contact allergens are sporadically distributed so even rigorous testing may not include all cross contact allergens or the maximum concentrations of each allergen.
- ➔ Where the concentration of allergens identified by analytical testing is greater than found during the VITAL risk assessment, consider reviewing the risk assessment for other factors. Where there is a discrepancy in the testing and risk assessment concentrations of cross contact allergens, the greater of the two values should be used.

Further information on VITAL and Allergen Analysis is available on page 12-14 of this document.

### **xiii. Ongoing Monitoring**

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

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

- ➔ Any assumptions of the VITAL risk assessment are changed;
- ➔ Ingredients or suppliers are changed;
- ➔ Equipment or manufacturing processes are changed;
- ➔ Cleaning procedures are changed; and
- ➔ Consumer complaints are received regarding allergic reactions.

OR

- ➔ Every 12 months, whichever occurs sooner.

#### **a. Ingredients**

This could be done in the following ways:

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

An assessment of the presence of inadvertent (cross contact) allergen(s) 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.

#### **b. Processing Environment**

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

- ➔ analytical 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).

Testing should be used for validation purposes 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.

## ADDITIONAL INFORMATION FOR VITAL PROGRAM USERS

### VITAL and Allergen Analysis

This information is intended to provide guidance on how allergen testing can be used in conjunction with the VITAL process and highlight some of the key issues to consider when choosing an allergen analysis technique.

Allergen analysis is the testing of a material to identify and/or quantify the presence of an allergen. Analytical test results are a useful tool for allergen management in food processing and may be used to enhance both an allergen management plan and the implementation of the VITAL tool.

There are different allergen analysis techniques and each may be relevant to different scenarios. It is important to understand the requirements of allergen testing so that the correct test can be used. The incorrect choice of an analysis test may result in a false negative result which means that the allergen is present but the test is not capable of identifying the allergen. The Allergen Bureau recommends the use of a skilled analyst with experience in allergen management to assist in choosing the correct methodology.

#### Role of Allergen Analysis in the VITAL process:

The preferred method to identify and quantify cross contact allergens in a VITAL risk assessment is to sum the cross contact which is identified by the supplier in each raw material with cross contact allergens identified during a physical audit of the production environment. However, there is a significant role for allergen analysis in:

- ➔ validation of the VITAL risk assessment;
- ➔ verifying ingredient allergen statements and potential raw material cross contact;
- ➔ targeted analysis of problem pieces of processing equipment;
- ➔ confirming assumptions made during the implementation of VITAL (such as validation of cleaning);
- ➔ testing allergen status of the final product to compare with calculated results from VITAL assessment (this may be especially relevant to high risk environments); and,
- ➔ monitoring the effect of critical changes.

#### Choosing Method of Analysis:

- ➔ When choosing a method of allergen analysis, it is critical that there is a clear understanding of the analytical outcomes and the appropriate application of laboratory results for each allergen detection scenario. There are many factors that can affect the accuracy of analytical testing – a skilled analyst will be able to check and control for these possibilities.
- ➔ Identify required outcome: an understanding of the required outcome will help to choose the correct method of analysis. Some methods provide quick results and may be useful for production scenarios such as to check if a production line has been sufficiently cleaned. However, often tests which can be performed rapidly do not provide quantitative results. Scenarios where quantitative results may be required, such as finished product testing to verify a VITAL risk assessment, may be required to be performed under laboratory conditions and be more time-consuming. Further to this, the costs of testing may be an important consideration.

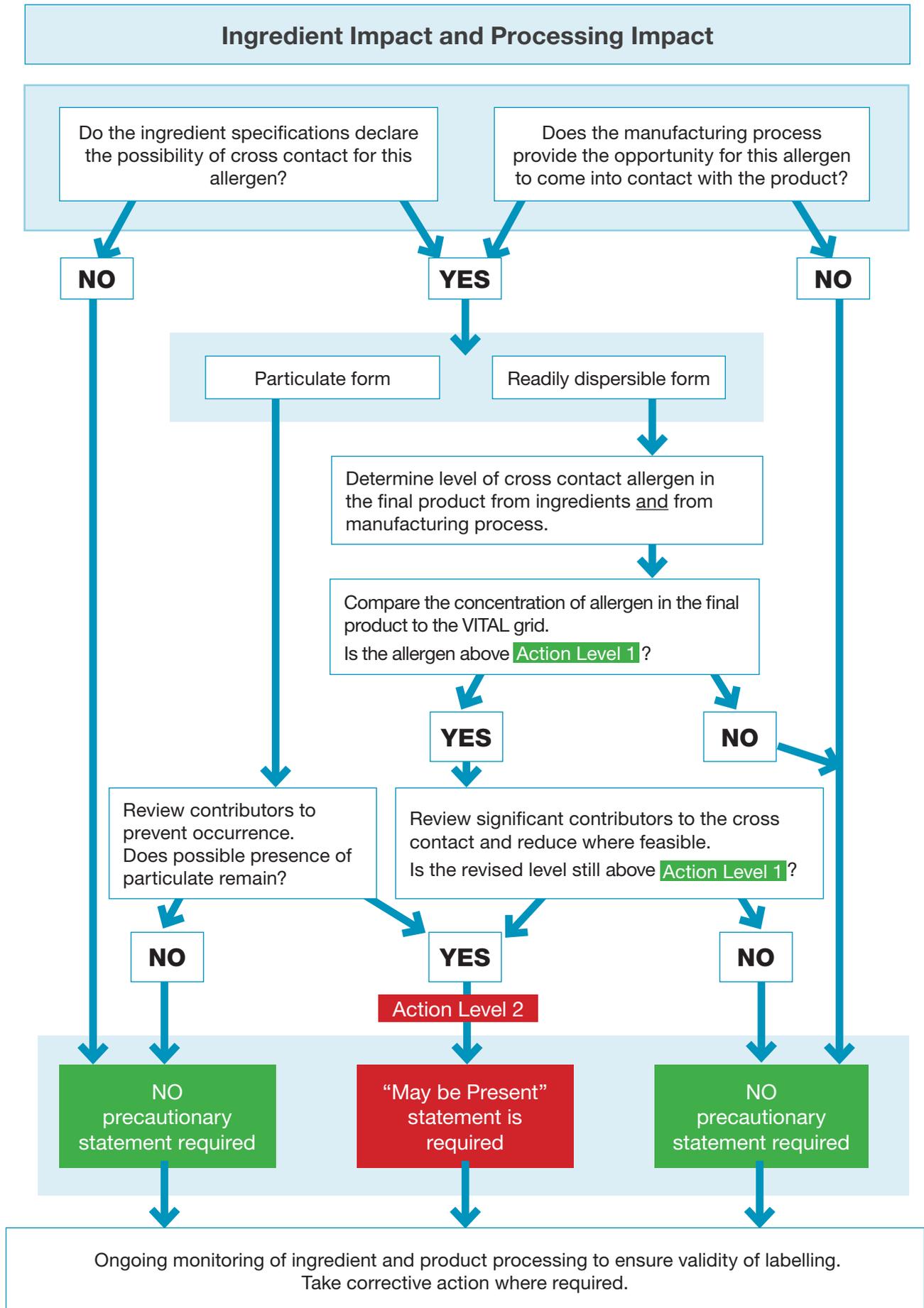
- ➔ Specificity of test: Care should be taken to choose a test kit which is looking for the correct target. Allergen testing may be highly specific for a particular target and it is important to establish which marker the test is looking for and whether it will be in the product being tested. For example, ELISA Beta Lactoglobulin Kits, commonly used to detect the presence of milk, are specific to the beta lactoglobulin fraction of milk. If the cross contact allergen comes from the casein fraction of milk (which does not contain beta lactoglobulin) then a Beta Lactoglobulin kit would provide a false negative result for milk.
- ➔ Affect of Matrices: Different matrices will affect the validity of allergen testing. Some matrices inconsistently and reluctantly liberate target proteins for identification by test kits. Also, some matrices, such as cleaning or flush solutions, may destroy target proteins and give a negative result which does not accurately reflect the allergen status of the product or flush.
- ➔ Affect of Processing: The target protein can be adversely affected by processing, with high temperatures and/or hydrolysis possibly altering the structure of the proteins and making it more difficult to detect. Whilst these changes generally reduce the detectability of the allergen, they may in fact enhance allergenicity. For example, trypsin is a target used by some soy allergen test kits. If the product that you are testing contains hydrolysed soy, which does not contain trypsin, then the presence of soy will not be detected in this kit and would show a false negative result. Cleaning products may hydrolyse allergenic proteins so it is particularly important that this is taken into account when testing after a clean.
- ➔ Sampling Plan: Quantitative assessment of cross contact allergens using analytical testing should take into account the sporadic nature of cross contact allergens by using a comprehensive testing regime, covering different batches across different production runs and different time points within a particular batch.

### **Interpreting Results from Allergen Testing:**

Finished product testing may be used to verify results from cross contact allergens identified in a VITAL risk assessment. When comparing analytical test results with concentrations calculated from the VITAL risk assessment, it is important to ensure that the units of measure are comparable. The VITAL Action Levels Grid uses concentration (parts per million [ppm]) of total protein. Analytical results use a range of units of measure. Check with the analyst as some kits provide conversion factors to assist in standardising units of measure.

Where there is an apparent discrepancy between analytical and calculated results, consideration should be given to the type of analysis, nature and form of the allergen. It is important to consider the nature of food processing as some processes may reduce the amount of detectable allergen. Further to this, where quantitative measure is done by both analytical and physical measures, in order to consider the situation of greater risk, the greater of the two should be taken. Where analytical results are significantly higher than would be expected based on calculation, consideration should be given to other possible contributing factors.

ii.  **VITAL Decision Tree for Cross Contact Allergens**





*informing the food industry*

Toll Free **1800 263 829** (Australia) Toll Free **0800 263 829** (New Zealand)  
Email **info@allergenbureau.net** website **www.allergenbureau.net**

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