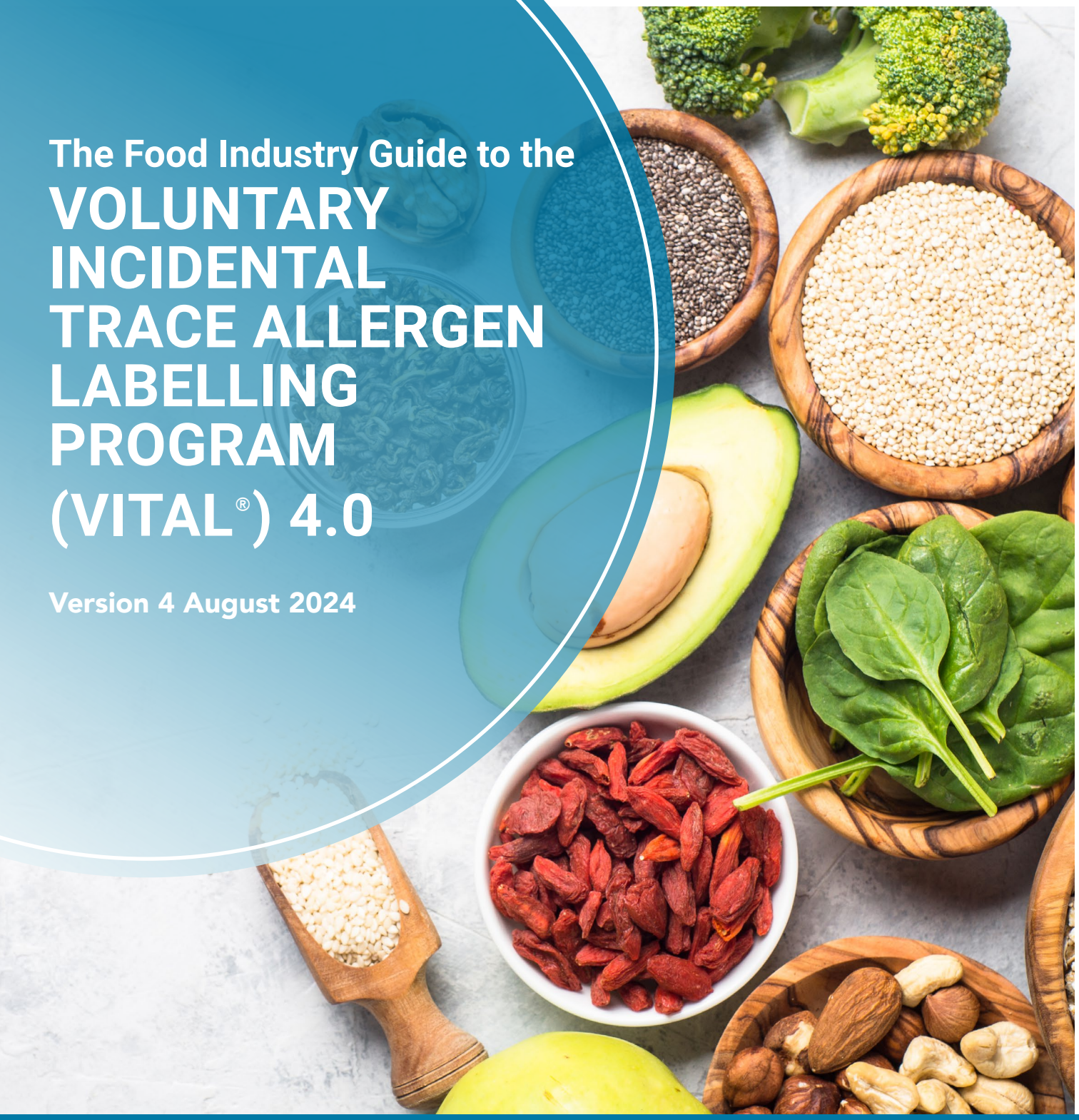
VITAL®

Allergen Bureau

The Food Industry Guide to the

VOLUNTARY INCIDENTAL TRACE ALLERGEN LABELLING PROGRAM (VITAL®) 4.0

Version 4 August 2024



Informing the food industry

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Allergen Bureau

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1. INTRODUCTION

Food regulations in many countries require the mandatory declaration of certain allergens in food. As well as 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, raw materials and ingredients and through the manufacturing process.

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 to provide appropriate precautionary allergen labelling (PAL). Application of this approach aims to avoid the 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 consumers with food allergy.

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 allergen labelling statement. The VITAL Action Level grid can be accessed via VITAL Online – a web-based calculator, developed by the Allergen Bureau, which also supports the application of the VITAL Program.

The first version of the VITAL Program was released in June 2007 in Australia and New Zealand. VITAL 4.0 marks the third update since that date.

During this time the VITAL Program has been supported by some of the world's leading scientific experts the VITAL Scientific Expert Panel (VSEP) who systematically reviewed the science ensuring it reflects the latest data and risk management practices.

VITAL 4.0 follows a wider global review of the science underpinning quantitative risk assessment more broadly, for Codex. This global review was completed by a FAO/WHO Ad Hoc Joint Expert Committee, that included many members of the VSEP.

1.1 VITAL science

The data set endorsed by the FAO/WHO Expert Committee was that from the publications of Remington et al., (2020)[1] and Houben et al., (2020)[2]. This is the current data set that underpinned VITAL 3.0, which was slightly expanded, to consider additional new publications on sesame seed and cow's milk.

For full details on the number of data sets and other considerations please refer to the FAO and WHO 2002 Report Risk Assessment of Food Allergens Part 2: Review and Establish Threshold Levels in Foods for Priority Allergens, Chapter 6.

The data is analysed by applying a Stacked Model Averaging program[3] (Wheeler et al, 2019) for each allergenic food. The Stacked Model Averaging program produces a single curve for each allergen from which Eliciting Doses (ED) may be derived. The FAO/WHO Expert Committee identified the ED_{05} based reference doses (which is the dose of the total allergenic protein, in milligrams, that is predicted to produce objective symptoms in 5% of the allergic population) as suitable and these have been adopted as the Reference Doses for VITAL 4.0. Further information about VITAL Science is available at the VITAL Online website and in the supporting document VITAL 4.0 Summary and FAQ's.

1.2 The Regulatory Framework & the VITAL Program

The VITAL Program has been developed against the Australian and New Zealand regulatory background and is also applicable in many international jurisdictions. 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 the VITAL Program and any labelling outcomes in their market.

1.3 The VITAL Program

The objective of the VITAL Program is to ensure manufactured food is safe to consume for the vast majority of consumers with food allergy by providing consistent food labels that declare the presence of allergens, due to documented, unavoidable and sporadic cross contact thus enabling consumers with food allergy and their carers to avoid purchasing foods that may present a personal risk.

The VITAL Action Level Grid contains concentrations of cross contact allergen proteins, called Action Levels, which determine when it is appropriate to use a precautionary allergen labelling statement. The Action Level concentrations are determined using the Reference Dose information in conjunction with the associated Reference Amount. The VITAL Action Level Grid should be used in conjunction with this document.

1.4 Use of the VITAL Program

- 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. Zero risk (for allergen management) is not possible. The use of the VITAL Program must be supported by robust allergen management to minimise risk.
- This risk assessment tool was developed to assist where the labelling of incidental trace allergens is not mandated in regulation. The VITAL Program is based on the premise that some products may have foreseeable levels of an allergen present through incidental cross contact, and this will not be labelled where the level is below a specified Action Level.
- This program 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 and foods for special medical purposes. Foods intended for these purposes may need a different risk management approach.
- The Action Level concept has not been developed to address the appropriateness of a "free from" claim (e.g. "free from gluten" or "free from peanut"). It is likely that a higher level of validation is required to substantiate such a claim.
- As with all risk management procedures, it will be necessary for the user to apply their own skill, knowledge and experience in adapting the VITAL Program to their specific circumstances. In using the VITAL Program the user acknowledges that the Allergen Bureau, its employees, committees 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 use of Reference Doses associated with previous VITAL 1.0 and VITAL 2.0 versions, are no longer considered valid to support best practice quantitative risk assessments for precautionary allergen labelling.

2. THE VITAL PROCEDURE

2.1 Scope

The VITAL Procedure is applicable to allergens which are:

- homogenously 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.

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.

2.3 Allergen identification

2.3.1 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 the allergens listed in Australia New Zealand Food Standards Code table to section S9-3 in Schedule 9. It is the responsibility of the user to ensure that all relevant allergens are included in the assessment.

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 sulphites is required. Analytical testing of finished product may be useful in this determination.

2.3.2 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.

2.3.3 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.

2.3.4 Identification of unintentional (cross contact) allergens due to processing

- Establish the possible presence of cross contact allergens in the product being assessed due to storage conditions, manufacturing processes, or the design and layout of the premises. Consideration should be given to all areas of the manufacturing facility and all stages of manufacturing and storage from receipt to despatch. NB. Any cross contact allergens identified should be reflected in the HACCP plan.
- For each identified cross contact allergen that cannot be avoided, determine the likelihood of its presence in the final product, and if present, whether it will be in a readily dispersible or particulate form.
- For each identified cross contact allergen due to processing, investigate whether the cross contact allergen can be avoided, reduced, or eliminated without adversely impacting the safety or quality of the finished product.
- Refer to the Allergen Risk Review website info.allergenbureau.net for further information that may assist with identifying cross contact allergens due to processing.
- See Table 1: Tips for determining cross contact due to processing.

Table 1: Tips for determining cross contact due to processing	
Production errors	Production errors are not examples of cross contact and should not be included as possible sources of cross contact allergens. Production errors should be addressed using the HACCP plan and appropriate procedures. Cross contact during the manufacturing process should include all possible instances of incorporation of unintended allergens where processing occurs in compliance with procedures.
Hang up points	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 product on or in the lines. Some facilities, 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.
Form a cross-functional team to perform the risk assessment	An initial risk assessment should include a cross-functional team, which includes the quality assurance staff and key staff that are familiar with scheduling, cleaning and the engineering of the facility. All allergen containing ingredients should be identified, equipment exposure identified, and opportunities for cross contact identified. Each opportunity for cross contact should be eliminated or reduced wherever possible.
Quantifying the cross contact allergen	Quantifying the cross contact allergens 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 hang up cannot be reached, it may be necessary to estimate based on the volume of the pipe or other factors.

2.4 Quantification of cross contact allergens

2.4.1 Particulate cross contact allergens

- Particulate cross contact allergens are separate and discrete particles of material of localised concentration which do not mix homogenously with other parts of the food, and consist of, or are likely to aggregate into, an entity which contains a level of protein equal to or greater than the relevant Reference Dose. They may be identified in ingredients, raw materials, or production processes.
- Where particulate cross contact allergens cannot be eliminated, the allergen is determined to be Action Level 2 (based on the definition above) in the VITAL Program. Action Level 2 allergens should be declared on the label (for packaged product), or in consumer information (for non-packaged product) in a precautionary allergen labelling statement.

2.4.2 Readily dispersible cross contact allergens from materials or ingredients

- Where readily dispersible cross contact allergens from materials or ingredients cannot be eliminated, determine the total protein concentration from the allergen source in the ingredient and from this information, calculate the concentration of the total protein from the cross contact allergen in the finished product.

Total protein concentration from cross contact allergen in formulation (ppm)

=

concentration of cross contact protein in ingredient (ppm) x amount of ingredient in formulation (%)

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 = 50ppm x 40% = 20ppm

- The total concentration of a particular allergenic protein due to raw materials or ingredients in the finished product is determined by summing the cross contact concentrations for the allergen from each source.

2.4.3 Readily dispersible cross contact allergens due to processing

- Where readily dispersible cross contact allergens due to processing cannot be eliminated, calculate the maximum amount of total protein from each cross contact allergen present in the final product.
- Determine the total protein concentration from each cross contact allergen, and the minimum amount of product into which this allergen will become incorporated (e.g. the total batch size). The total protein concentration of the cross contact allergen in the product formulation can then be calculated.

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.

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.

For example: A biscuit manufacturer identifies that a maximum of 500g of previously run product can hang up and become homogenously mixed into the following 800kg 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

Divide this result by the batch size to determine the concentration in the product.

Concentration of egg cross contact in butter biscuit formulation (ppm) = 3250/800 = 4ppm

2.4.4 Calculation of total cross contact allergen in finished product

- For each cross contact allergen, sum the concentration of allergen protein from raw materials, ingredients and processing aids and those from processing.
- It may be necessary to apply a dehydration or hydration factor to consider 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). However, the maximum possible concentration should be used as this will provide the most conservative result.

Where the product is **hydrated**:
Concentration of cross contact after hydration (mg) = concentration of cross contact allergen ÷ (% dilution + 100%), where % dilution = [water added (kg) ÷ weight original product (kg)] x 100%

Where the product is **dehydrated**:
Concentration of cross contact after dehydration (mg) = concentration of cross contact allergen ÷ % concentration, where % concentration = 100% - ([water lost (kg) ÷ weight original product (kg)] x 100%)

Hydration Example: Ham roll, containing 50ppm egg cross contact is steam injected. The original 150kg batch gains 30kg during cooking.

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

Concentration of egg after cooking (mg) = 50 ÷ ([30 ÷ 150] x 100%) + 100%) = 50 ÷ 120% = 42 ppm

Dehydration Example: Butter biscuits containing 20ppm soy cross contact allergen are baked. The original 100kg batch loses 25kg of water during cooking.

Concentration of cross contact after **dehydration** (mg) = concentration of cross contact allergen ÷ % concentration, where % concentration = 100% – ([water lost (kg) ÷ weight original product (kg)] x 100%)

Concentration of soy after baking (mg) = 20 ÷ (100% - ([25÷100]) x 100%) = 20 ÷ 75% = 27ppm

2.5 Determination of Action Levels

2.5.1 Ingredients intended for further processing (e.g. bulk ingredients)

- Action Level calculations, which may result in the application of PAL, are only relevant for products which are intended for presentation to consumers. Action Level calculations cannot be made for bulk products (i.e. products intended for food service or further processing prior to presentation to a consumer) because a Reference Amount cannot be accurately determined for such products.
- For bulk products, supply your customer with the following information about cross contact allergens:
  -the presence of any particulate cross contact allergen
  -the total concentration (in parts per million (ppm)) of any readily dispersible cross contact allergens.

2.5.2 Determination of Reference Amounts for packaged products

- The Reference Amount is the maximum amount of food eaten in a typical eating occasion. This may or may not be the same as the nominal or declared serving size but it will not be an amount less than the declared serving size.
- The determination of the Reference Amount is a business decision. It is recommended that where the serving size is used that the AFGC serving size principles (listed below) should be considered.
- The FAO/WHO Expert Committee have recommended the use of a consumption amount of P50 - 50th percentile value from the general population distribution of the single-eating occasion intake of a food.[4]
- Some countries have established or recommend standardised reference amounts based on consumption data. Where these are available, their use should be considered.

Serving size principles:
(sourced from AFGC Code of Practice for Food Labelling and Promotion)

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.

- Single serve items should be appropriate sizes for the target market
- The serving portion should be realistic (at both the lower and upper levels)
- 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
- Multiple serve items should consist of appropriate serving sizes in relation to single serve packs
- Serving sizes must not be used inappropriately to manipulate energy or nutrient content per serving

2.5.3 Determination of Reference Doses for packaged products

- A Reference Dose is the protein level (total protein in milligrams from an allergenic food) below which only the most sensitive individuals (5%) of the allergic population are likely to experience an objective reaction.
- Select the relevant Reference Dose for each readily dispersible cross contact allergen.
- Reference Doses can be accessed within VITAL Online allergenbureau.net or via theVITAL 4.0 Summary and FAQ's document.

2.5.4 Establish Action Levels for each identified cross contact allergen in a packaged products

- Action Levels are the concentrations of protein which define the labelling outcomes for each concentration of cross contact allergen in a VITAL risk assessment. For packaged products, they are determined using the Reference Dose and the Reference Amount.

Action Level 1: Low concentration of the relevant allergen under evaluation, low chance of adverse reaction and no precautionary allergen labelling statement is required

Action Level 2: Significant concentration of relevant allergen under evaluation, significant chance of adverse reaction and a precautionary allergen labelling statement is required (if legally permitted in the country of sale or the country of further manufacture)

- Determine the Action Levels for each identified cross contact allergen in every packaged product. For accuracy and simplicity, it is recommended to use the interactive VITAL Action Level Grid, which is incorporated into VITAL Online. Action Levels can also be calculated manually using the formula below:

The Action Level transition point *(ppm)

=

Reference Dose (mg) x (1000/Reference Amount (g))

(*except cereals containing gluten[a] where formula above is applicable or 20ppm, whichever is lower)

Example:

The Reference Amount for a biscuit is 40g.

Action Level transition point for egg (40g Reference Amount) = 2 x (1000/40) = 50ppm

For cross contact egg in the biscuit, where the Reference Amount is 40g, Action Level 1 is < 50ppm and Action Level 2 is ≥ 50ppm.

Action Level transition point for soy (40g Reference Amount) = 10 x (1000/40) = 250ppm

For cross contact soy in the biscuit, where the Reference Amount is 40g, Action Level 1 is <250ppm and Action Level 2 is ≥250ppm.

2.5.5 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. Analytical results should not be considered in isolation, however, they may be useful to support VITAL assumptions and product verification.
- If analytical allergen testing is conducted, consult a skilled analyst to ensure that the correct methodologies are used and that the units of measure are appropriate to use with the VITAL Action Level Grid. Refer to the VITAL Program and Allergen Analysis on page 14 for further information.
- Where the concentration of allergens identified by analytical testing is greater than found during the VITAL risk assessment, consider reviewing the risk assessment . Businesses are encouraged initially to review cross contact risks associated with ingredients, along with hang up assumptions to ensure all risks have been identified in the initial assessment. Where no gaps are determined, further consultation may be required with a skilled analyst to review the analytical outcome.

a). The Action Level threshold for cereals containing gluten is locked at a maximum of 20ppm to reflect the level for gluten established by Codex Alimentarius as a safe level for individuals with coeliac disease (20ppm of gluten)." Food Chem Toxicol 2020 May;139:111259.

2.6 Determination of Labelling Outcomes

2.6.1 Precautionary Allergen Labelling

- Where cross contact allergens cannot be eliminated, packaged products should be labelled according to the determined Action Levels.
- Packaged products where cross contact allergens are determined to be Action Level 1, do not require a precautionary allergen labelling statement.
- Packaged products where cross contact allergens are determined to be Action Level 2 should be labelled with an appropriate precautionary allergen labelling statement if legally permitted in the country of sale.

> The recommended precautionary allergen labelling statement to be used in conjunction with the VITAL Program is :
>
> "**May be present: allergen x, allergen y.**"

- Intentionally added allergens must be declared on the product label (e.g. in the ingredient list).

N.B. Precautionary allergen labeling statements should only be used after a thorough assessment of the risk and 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.

2.7 Recording Assumptions & Ongoing Monitoring

2.7.1 Recording of assumptions

The assumptions for a product assessed using the VITAL Program should include any relevant details used to inform your VITAL risk assessment. This information may be recorded using VITAL Online and/or with your food safety/quality plan.

When any of the assumptions for the VITAL assessment change, this should trigger a review of the VITAL assessment.

These may include:

- the relevant allergens to be assessed
- considerations for setting the Reference Amount
- source for Reference Doses (not required where VITAL Online is used to perform the risk assessment)
- source of information for allergen status of ingredients (e.g. Specification version/reference)
- source of information for cross contact allergens due to processing including reference to the Allergen Management Plan
- reference to other Food Safety/Quality Documentation such as Approved Supplier Program and production procedures.

2.7.2 Ongoing monitoring

Examples of when VITAL risk assessment should be reviewed include:

- changes to any assumptions of the VITAL risk assessment
- changes to ingredients or suppliers
- changes to equipment or manufacturing processes
- changes to cleaning procedures
- receival of consumer complaints regarding allergic reactions
- new knowledge, insights and industry learnings OR
- every 12 months, whichever occurs sooner.

3. 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 Action Level Grid which can be used to create a VITAL Action Level Summary report.

VITAL Online is available at vital.allergenbureau.net

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. Access the Allergen Risk Review website at info.allergenbureau.net.

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. This guide was developed for products sold in Australia and New Zealand, however, it contains information that may be useful for other jurisdictions.

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 VITAL Online 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 VITAL Online website.

3.6 Other resources

The Allergen Bureau frequently updates and releases new information and guidance material.

Refer to vital.allergenbureau.net for supporting resources for VITAL Online and the VITAL Program including scientific rationale for the VITAL Program and Helpful Hints for users of VITAL Online.

Refer to allergenbureau.net/resources for access to allergen management and labelling guidance.

3.7 The VITAL program and allergen analysis

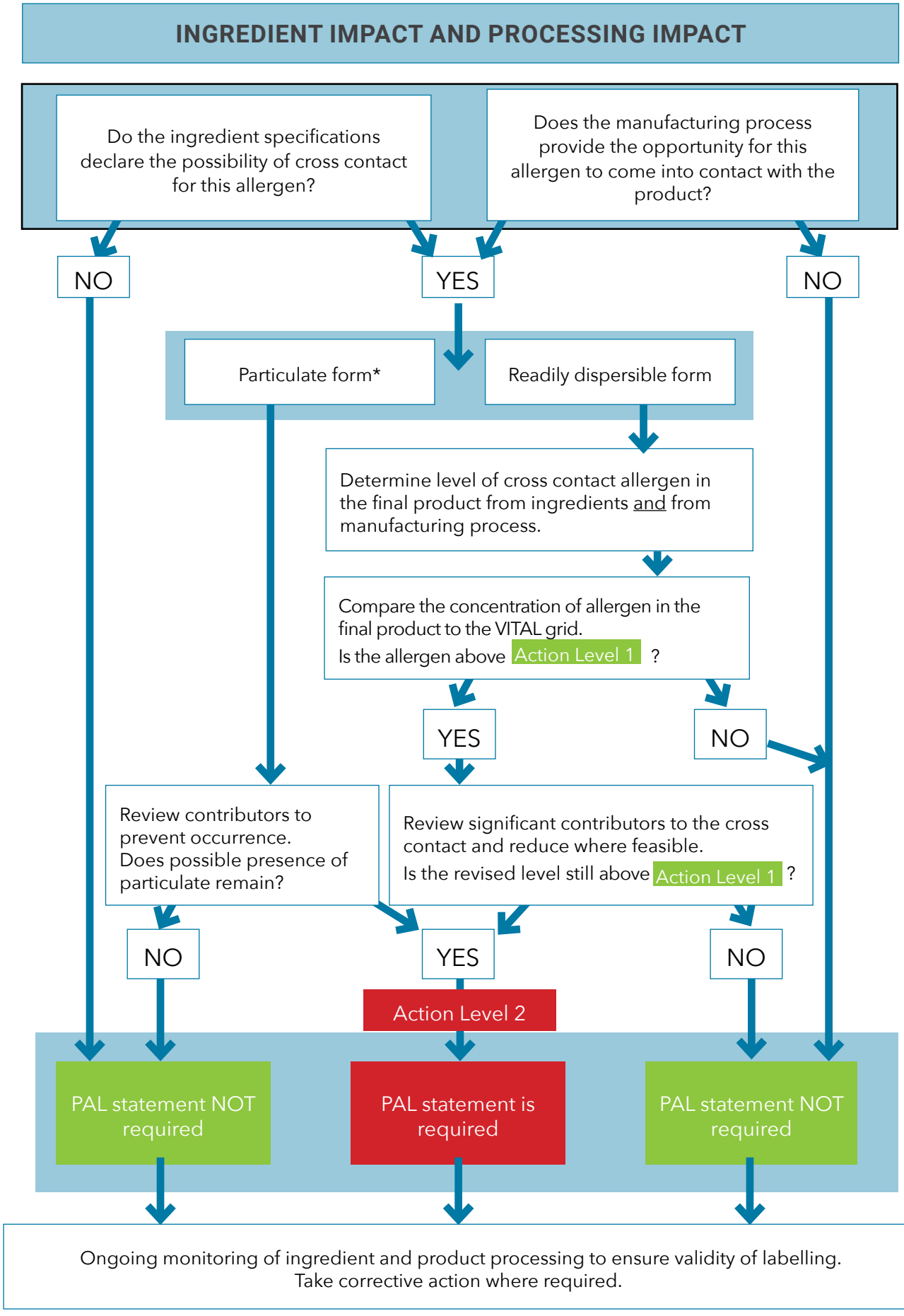
The preferred method to identify and quantify cross contact allergens in a VITAL risk assessment is to sum the cross contact, which is identified by the supplier in each raw material, with cross contact allergens identified during a physical audit of the production environment. However, there is a significant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

- 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)
- monitoring the effect of critical changes.

Before performing analysis, consideration should be given to the suitability of the method, the detectability of the allergen, the form of the allergen, along with the sampling plan employed to determine the presence, prevalence and concentration of allergen in the food produced.

Further information about food allergen analysis is available on the Allergen Bureau website and on the Allergen Risk Review website.

3.8 Decision tree for cross contact allergens



*Please refer to the definition of a particulate in the glossary below.

4. GLOSSARY

Term	Definition
Action Levels	Action Levels are the concentrations (of protein) which define the labelling outcomes for each concentration of cross contact allergen in a VITAL risk assessment. They are determined using the Reference Dose and the Reference Amount. • *Action Level 1:* Low concentration of the relevant allergen under evaluation, low chance of adverse reaction and no precautionary allergen labelling statement required. • *Action Level 2*: Significant concentration of relevant allergen under evaluation, significant chance of adverse reaction and a precautionary allergen labelling statement is required.
Allergen	A substance within a food product that has been identified as an allergen for consideration within a VITAL risk assessment. The choice of allergens will be impacted by local regulations as well as the regulations of the export market, if appropriate.
Bulk products	Includes product intended for food service or further processing, where the Reference Amount cannot be calculated.
Cross Contact Allergen	A residue or other trace amount of a food allergen that is unintentionally incorporated into another food. Cross contact sources can be from ingredients, raw materials, personnel, inadequate cleaning of equipment, or concurrent and/or co-located plants.
HACCP Plans	Food hazard analysis and risk mitigation plans developed according to the HACCP principles and steps outlined in the *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application,* published by the Codex Alimentarius Commission/RCP-1 (1969), Rev.6 (2022)
Hang Up Point	A point on a manufacturing line where material may accumulate instead of flowing through freely.
Infant	A person under the age of 12 months.
Intentionally Added Allergen	Any ingredient (or intrinsic part of the ingredient) of the recipe/formulation which contains an allergen, and includes all allergens which require mandatory declaration in the country of sale.
Packaged Product	Packaged product includes products that are packaged ready for sale to the consumer where the Reference Amount can be calculated.
Particulate	Separate and discrete particles of material of localised concentration which do not mix homogenously with other parts of the food, and consist of, or are likely to aggregate into, an entity which contains a level of protein equal to or greater than the relevant Reference Dose. They may be identified in ingredients, raw materials, or production processes. When selecting particulate, record your assumptions. This may include recording the level of protein present in the particulate(s). (Also see also **Readily Dispersible**)
ppm	Parts per million – a measure of concentration equivalent to milligrams per kilogram (mg/kg).

Term	Definition
Precautionary Allergen Labelling (PAL) Statement	A voluntary statement listing all allergens that are present because of cross contact at Action Level 2 as per the VITAL Procedure. The precautionary allergen labelling statement recommended for use with the VITAL Program is "**May be present: allergen x, allergen y.**"
Product Information Form (PIF)	Standard specification form developed by the Australian Food and Grocery Council.
Readily Dispersible Form	A powder or liquid in homogenous form that is easily distributed throughout a food product eg. milk powder, soy flour. A readily dispersible cross contact allergen is considered homogenously distributed in the final product. (see also Particulate)
Reference Amount	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.
Reference Dose	The milligram protein level (total protein from an allergenic food) below which only the most sensitive (5%) of individuals in the allergic population are likely to experience an objective allergic reaction.
Sporadic distribution	The intermittent presence of allergens appearing in isolated instances.
Total Protein	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.
Validation	Determination that the food safety plan, when properly executed, will effectively control the significant hazards in the process.
Verification	Activities (other than monitoring) that determine the adequacy of and compliance with the Allergen Management Plan.
VITAL Action Level Grid	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 (EDp) at which a proportion (p) of the allergic population would be likely to react. (see also Action Level) NB. The onus is on the user to ensure that they are using the most recent VITAL Action Level Grid.
VITAL Online	An on-line tool available at vital.allergenbureau.net to assist manufacturers with the calculations for the VITAL Program.
VITAL Risk Assessment	The process developed for quantifying the amount of residual cross-contact allergen present from raw materials, ingredients, processing aids and/or other production processes that may be present in a typical eating occasion.

5. REFERENCES

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