VITAL®

Allergen Bureau

VITAL® STANDARD

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Informing the food industry

allergenbureau.net

Contents

Introduction

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, Raw materials and Ingredients, packing, and through the manufacturing process.

The Voluntary Incidental Trace Allergen Labelling (VITAL®) Program was 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 through effective communication to consumers with food allergy.

The VITAL Program contains Reference Doses for Allergens commonly listed as substances for mandatory declaration in different jurisdictions. The current Allergens and their Reference Doses are maintained in VITAL Online. Additional Allergens may be included when there is sufficient scientific data available to set a Reference Dose. However, 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.

The VITAL Standard is a supplementary certification for Manufacturers that are already certified to Global Food Safety Initiative (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 versions). It is audited as an addendum to existing standards i.e. GFSI benchmarked scheme or a retailer standard, etc. by auditors trained in the VITAL Standard and registered with The Allergen Bureau Ltd.

Manufacturers that achieve VITAL Certification may use or agree to the use of the VITAL Certification Mark on Products and associated communication Materials within the scope of their certification.

There is no fee for use of the VITAL Certification Mark. Any Product that will bear the VITAL Certification Mark shall be outlined in a Product Licencing Agreement (PLA) between the Brand Owner and the Allergen Bureau.

Whilst the PLA is Product specific, Product certification may be achieved based on the audit outcome for Products grouped by Allergen profile and risk. For example, a range of Products that have shared Ingredients with common Allergen status, produced on a line with the same Processing profile may be audited collectively. The rationale of such a grouping shall be agreed to via the contract of agreement with the Certification Body.

This document provides guidance for businesses seeking certification to the VITAL Standard.

It contains

- the Scheme Rules for management of the VITAL Standard (Part A)
- the auditable standard (Part B).

Definitions used in the VITAL Program are listed in Attachment 1: Glossary.

Objective

The objective of the VITAL Certification scheme is to help consumers and carers of those susceptible to allergic reactions, to have greater assurance as to the suitability of a Product they intend to consume. Application of the VITAL Program and compliance with the VITAL Scheme Requirements, (as documented in the VITAL Standard), aids in accurate communication of food allergen risks via **appropriate** use of Precautionary Allergen Labelling (PAL) statements. Appropriate use of PAL is identifiable to consumers by use of the VITAL Certification Mark.

Use of the VITAL Certification Mark indicates that the presence or absence of a PAL, has been derived through appropriate application of the VITAL Program. Products marked with a Precautionary Allergen Label (PAL) such as "Maybe present [Allergen…] and the VITAL Certification Mark, indicate a risk of allergic reaction to consumers with that allergy. Products without a PAL statement, bearing the VITAL Certification Mark, indicate they have been risk assessed as unlikely to contain a level of allergen that will result in a reaction with appreciable health risks, and can be consumed by the allergic consumer. Products without a VITAL Certification Mark may or may not have been risk assessed appropriately. Therefore the consumer may have more confidence in understanding the risk of a Product bearing the VITAL Certification Mark.

Disclaimer

Material included in this publication is made available on the understanding that the Allergen Bureau is not providing professional advice, that the VITAL Standard is intended as a risk management tool which may assist in a total approach to Allergen risk management, and that using the VITAL Program does not guarantee that a consumer will not suffer an allergic reaction.

If you intend to use information provided in this publication, you must exercise your own skill, care, and judgement, evaluate the accuracy, completeness and relevance of any information or recommendation for your purposes, and obtain your own professional advice.

The Allergen Bureau provides no warranty and does not guarantee the accuracy or completeness of the material contained in this publication, or in any recommendation obtained from it, including regarding compliance with food labelling laws and regulations or the management of the risk of Product liability and personal injury.

The Allergen Bureau disclaims all liability to any person in respect of any loss or liability suffered in connection with the reliance, whether wholly or partly, on any information contained in this publication.

1. Pre-requisites

1.1 VITAL® certification applies on a site-by-site basis. The applicant for certification to the VITAL Standard must be an individual food manufacturing site involved in the manufacture of Packaged Product, Bulk Product, or a combination thereof.

1.2 Food corporations with multiple sites cannot be collectively certified.

1.3 To be considered for certification to the VITAL Standard, the manufacturing site shall be certified to a recognised Food Safety Management Standard (FSMS), by a Certification Body that is accredited to ISO/IEC 17065:2012 or ISO/IEC 17021:2015, (or subsequent versions). This includes only food safety management schemes that are recognised by the Global Food Safety Initiative (GFSI), (refer *Part B, 2.1.1*).

1.4 Irrespective of the requirements of the certified standard, the manufacturing site shall have documented and implemented a HACCP based Allergen Management Program, (refer *Part B 2.2.1*, and *Part B, 2.2.2*).

2. Scope

2.1 VITAL Certification is site and Product specific. Only Products that are included in the scope of FSMS certification can be considered for certification to the VITAL Standard. Products (refer *Attachment 1: Glossary*) can include Packaged Product, Bulk Product, or a combination of packaged and Bulk Products.

2.2 Any agreed exemptions from FSMS certification shall also be exempted from VITAL Certification and the scope of VITAL Certification shall not be extended or changed from FSMS certification.

2.3 Exempted Products shall not be promoted as being covered by VITAL Certification. Instances where promotion of exempted Products are identified and substantiated (either by regular audit or by other means) shall result in immediate withdrawal of the VITAL certificate.

2.4 The scope of certification shall be agreed between the Certification Body and the Manufacturer before the VITAL Certification or recertification audit. It cannot be changed during the VITAL audit.

Requests for changes to scope must be made in writing to the Certification Body prior to a certification audit or recertification audit.

3. The Certification and Product Licencing Process

3.1 The Manufacturer is responsible for

- applying for certification (by completing the VITAL Standard Application Form);
- entering into the contract agreement with the Certification Body for auditing and recertification services;
- ensuring the site is ready and available for audit;
- ensuring that any corrective actions are completed in the agreed time frames;
- ensuring the re-certification process is followed;
- notifying the Brand Owner, should the scope of certification change.

3.2 In the case where the Manufacturer is not the Brand Owner, the Manufacturer is responsible for liaising with the Brand Owner to inform them of the status of the certification.

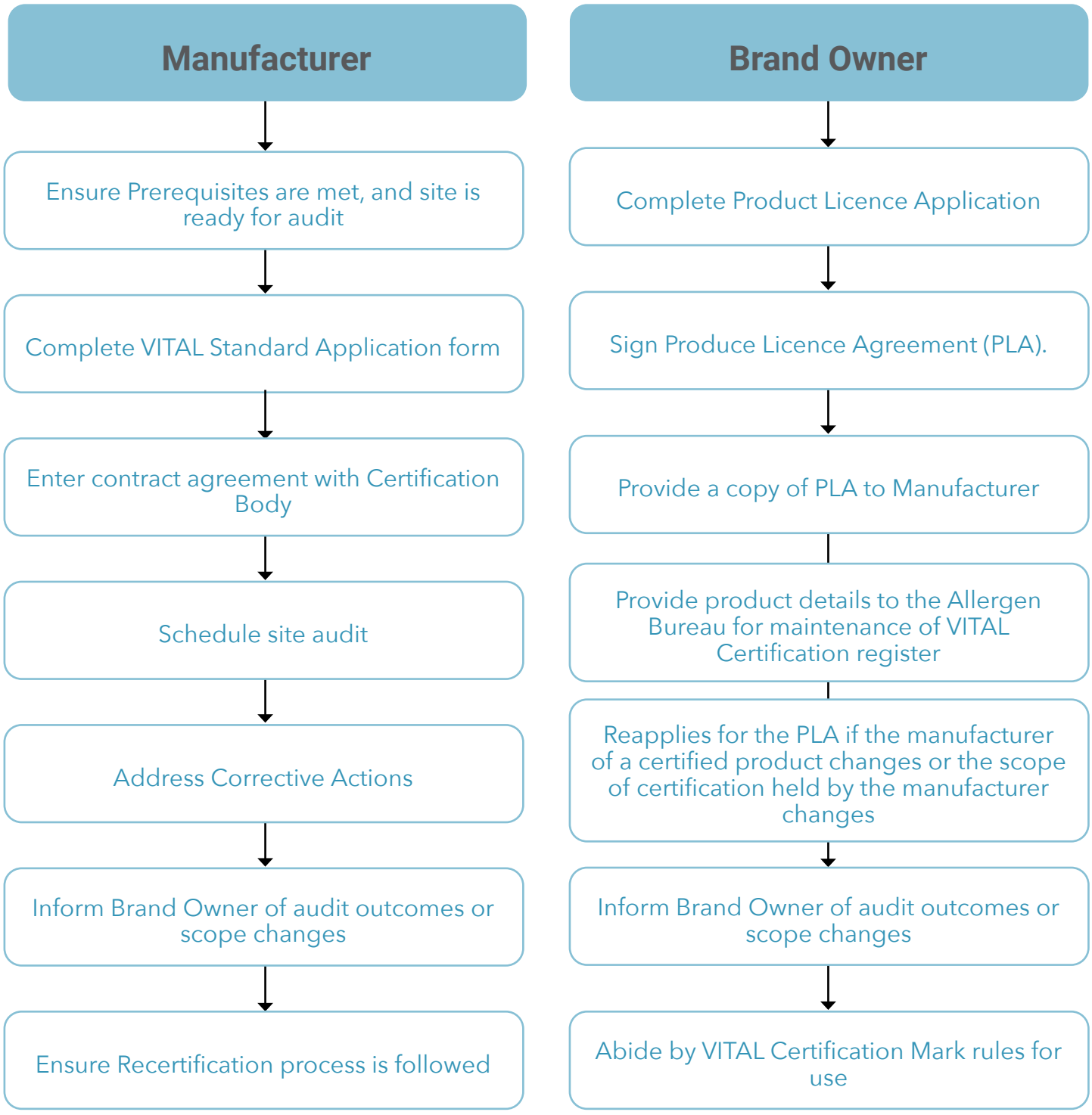
3.3 The Brand Owner is responsible for applying for the Product Licence Agreement (PLA), to use the VITAL Certification Mark on pack or online.

3.4 The Brand Owner is responsible for advising the Allergen Bureau of any certification scope changes or changes to the Manufacturer pertaining to the PLA application. This will be done by applying for a new PLA with updated details.

3.5 In the case where the Brand Owner is not the Manufacturer, a copy of the PLA application and authorisation for use of the VITAL Certification Mark, must also be provided to the Manufacturer for their records.

3.6 The holder of the PLA is responsible for providing information to the Allergen Bureau for use in the VITAL Certification register.

Figure 1: Main Roles and Responsibilities in the Certification and Licensing process



A manufacturer may apply for a PLA if they wish to use the VITAL Certification Mark in advertising for the site, or if requested by the Brand Owner to do so. It is expected that both parties agree with the use of the VITAL Certification Mark on pack or advertising material for the manufacturing facility.

4. Selection of a Certification Body

4.1 The Manufacturer must enter a contract or agreement with a Certification Body that is accredited to ISO/IEC 17065:2012 (scope VITAL) and is registered with the Allergen Bureau to certify the VITAL Standard.

Although it is not mandatory, The Allergen Bureau recommends that the same Certification Body that provides certification of the FSMS is also contracted to audit and certify the VITAL Standard.

4.2 Before entering an agreement with the Manufacturer, the Certification Body shall demonstrate that it has auditors and technical reviewers available who are trained in the VITAL Standard, experienced in the Manufacturer's industry sector, registered to audit one or more FSMS, and registered with the Allergen Bureau.

4.3 The Manufacturer shall ensure that their agreement with the Certification Body meets the requirements of ISO/IEC 17065:2012, clause 4.1.2 and additionally identifies

- the products to be included in the scope of certification, including any proposed Product groupings to be audited together, and any Products that may be exempted;
- the expected time to conduct and report the audit to the VITAL Standard and the reporting requirements;
- the Certification Body's fee structure for completing the certification to the VITAL Standard, including reporting and close out of non-conformances; and
- the conditions under which the certificate is issued, withdrawn, or suspended.

5. Application for Certification to the VITAL Standard

5.1 To be considered for VITAL Certification, the Manufacturer shall complete the *VITAL Standard Application Form* and submit it to the selected Certification Body, with a copy to the Allergen Bureau. The application will include:

- name and address of manufacturing site or sites;
- industry sector(s);
- the required Product scope; including the rationale for any group of Products to be audited collectively;
- current certifications held;
- the Allergen Bureau recognised FSMS that will be used to support the VITAL Standard;
- contact person and contact details (one person per site).

5.2 The decision to proceed to certification shall depend on the Certification Body's acceptance of the application, and the Manufacturer's acceptance of the terms offered by the Certification Body.

5.3 To facilitate documentation and implementation of the VITAL Standard, the Manufacturer is encouraged to register with and use VITAL Online.

6. The Initial Certification Audit

6.1 The timing of the initial certification audit is by agreement between the Manufacturer and their contracted Certification Body. The Manufacturer should have documented, implemented, and verified the application of the VITAL Standard before requesting an audit.

The Certification Body shall ensure that qualified registered auditors are available to conduct the audit. (Refer *VITAL Certification Body Requirements 6.1.1* and *6.1.2*)

6.2 The initial VITAL Certification audit can either be an extension of an existing FSMS audit, or a stand-alone audit conducted at any time during the currency of the Manufacturer's existing FSMS certification.

If conducted concurrently, VITAL Certification shall only be granted on successful FSMS certification, as well as successful VITAL Certification.

At all times, VITAL Certification is dependent on maintaining certification to the recognised FSMS.

6.3 The initial VITAL Certification audit comprises a full review of:

- VITAL Risk Assessment documentation as detailed in Part B of the VITAL Standard;
- Effective implementation of VITAL outcomes, including labelling;
- Effective management oversight and review of the VITAL Risk Assessment.

6.4 All applicable elements of the VITAL Standard shall be implemented. Where the Manufacturer considers some of the elements to be non-applicable, the Manufacturer shall submit a request for exemption to the Certification Body in writing before the certification audit, justifying the reasons for exemption. If accepted, the exempted element(s) shall be marked as non-applicable by the auditor.

6.5 Within the VITAL Standard, certain elements are considered **(Core)** elements. Elements that are marked **(Core)** are elements that shall be indicated as compliant for certification to be achieved. If a non-conformance is raised against any **(Core)** element, certification is not granted. (also Refer *Part A, 7.4* for all certification requirements)

6.6 All components of the VITAL audit shall be conducted on site and with at least one member of the VITAL technical team (refer *Part B, 3.1.3*)

6.7 The duration of the VITAL audit will vary greatly depending on the size of the manufacturing facility, number of processes, Products and identified Allergens, and whether the VITAL audit is an extension of the FSMS audit or a stand-alone audit (refer *Part A, 6.2*)

7. Reporting and Certification

7.1 Where the VITAL auditor finds deviations from the requirements of the VITAL Standard, the auditor shall advise the Manufacturer of the number, description, and level of non-conformance(s). Within the VITAL Standard, non-conformances are classified as:

A **Minor** non-conformance. An insignificant or infrequent deviation from the VITAL Standard that is unlikely to impact the VITAL calculation or Action Levels.

A **Major** non-conformance. A regular or systemic deviation from the VITAL Standard and likely to impact the VITAL calculation or Action Levels.

A **Critical** non-conformance. An undeclared Intentionally added Allergen, failure to provide a precautionary Allergen labelling (PAL) statement for identified Cross contact Allergens designated as Action Level 2 or use of a PAL for identified Cross contact Allergens designated as Action Level 1, without significant justification.

The auditor shall leave a summary of non-conformances with the Manufacturer before concluding the VITAL audit.

7.2 The auditor shall submit their recommended audit report to the Certification Body within five (5) business days from the day of the VITAL audit. The Certification Body shall technically review the audit report and advise the client within ten (10) business days from the day of the VITAL audit if there are any changes from the auditor recommendations.

7.3 Corrective actions for all minor and major non-conformances must be submitted to the Certification Body and accepted within thirty (30) calendar days from the day of receipt of the VITAL audit report.

7.4 The Manufacturer is considered to have successfully complied with the requirements of the VITAL Standard if:

- the Manufacturer remains certified to the recognised FSMS;
- no non-conformances are raised against Core Elements of the VITAL Standard;
- no critical non-conformances are raised against the FSMS or VITAL Standard;
- all minor and major VITAL non-conformances are submitted, and closed out by the Certification Body within thirty (30) calendar days of the VITAL audit.

The Manufacturer shall be considered to have failed the audit if any of the above are not achieved.

Manufacturers that fail their initial certification audit can re-apply for another certification audit once non-conformances issued at the initial audit have been closed. In general, the auditor who performed the initial audit shall perform the follow up audit.

7.5 The Certification Body shall make the final audit report available to the Manufacturer and the Allergen Bureau within forty (40) calendar days from the day of the VITAL audit. The final audit report shall include completed and approved corrective actions, the Certification Body's decision on certification and the reasons for non-certification if applicable.

7.6 The VITAL audit report is the property of the manufacturing client and shall only be distributed to, and retained by, the Manufacturer, the Certification Body, and the Allergen Bureau. It cannot be distributed to other parties without the permission of the Manufacturer.

7.7 Within ten (10) calendar days of granting certification, the Certification Body shall provide an electronic and/or hard copy of the Manufacturer's VITAL certificate. The certificate is valid for twelve months from the date of issue. The certificate shall be in a form approved by the Allergen Bureau and include:

- The heading "The VITAL Standard" and corresponding VITAL Certification Mark;
- The name, address, and logo of the Certification Body;
- The logo of the Accreditation Body and the Certification Body's accreditation number;
- The manufacturing site's name;
- The manufacturing site's address;
- The Manufacturer's VITAL registration number;
- The Products included in the scope of registration;
- Products exempted from certification (may be listed on the back of the certificate);
- Date of audit;
- Date of next re-certification audit;
- Date of certificate expiry (12 months from the date of issue);
- Signatures of the authorized officer and issuing officer.

7.8 An electronic copy of the certificate shall be sent to the Allergen Bureau on the same day as it is distributed to the manufacturing client.

8. Use of the VITAL Certification Mark

8.1 Where VITAL Certification is achieved, the VITAL Certification Mark may be used for Products within the scope of the certification (refer *Part A, 2.0*)

8.2 A signed PLA with the Allergen Bureau (Refer *Part A 3.3*) and agreement to abide by the *VITAL Certification Mark Rules* for use, provided by the Allergen Bureau is required before the mark can be used.

8.3 In the case where the Manufacturer is not the Brand Owner, the Brand Owner shall apply for the PLA. In this case if the Manufacturer wishes to use the VITAL Certification Mark in advertising material for the site, they may also apply for a PLA. (Refer *Figure 1, Part A Section 3.*)

8.4 Where the scope of certification changes or the Manufacturer of a Product changes the Allergen Bureau must be notified and a new PLA must be applied for by the Brand Owner. Failure to apply for a new PLA under these circumstances shall result in the withdrawal of authorisation to use the mark.

8.5 The VITAL Certification Mark cannot be used for a Product unless the manufacturing information provided for the PLA reflects the current manufacturing location.

8.6 The VITAL Certification Mark cannot be used by those who hold a PLA whilst certification is suspended, or if the certificate is withdrawn (refer *Part A, 9.3, 9.4, 9.5, 9.8*).

9. Maintaining Certification

9.1 To maintain VITAL Certification, the Manufacturer shall:

- Maintain FSMS certification;
- Successfully complete a recertification audit to the VITAL Standard on the anniversary of the initial certification audit +/- thirty (30) days, (or as designated by the base FSMS standard).

9.2 If the requirements indicated in Part A, 7.4 are achieved at the recertification audit, then a new certificate (refer *Part A, 7.8*) shall be issued by the Certification Body. The timing for the certification decision, issue of the audit report, and issue of the certificate are as per the initial certification audit (refer Part A, 7.5, 7.7)

9.3 In the event of a Product recall involving Allergens, the Manufacturer shall notify their Certification Body within three (3) business days. The holder of the PLA for the Products impacted must notify the Allergen Bureau of the decision to recall prior to public notification.

9.4 The Manufacturer's certification shall be suspended if:

- The requirements indicated in Part A, 7.4 are not met;
- The Manufacturer fails to allow the recertification audit within the required timeframe;
- The Manufacturer and/or Brand Owner uses the VITAL Certification Mark incorrectly or on Product that is not included in the scope of certification, or
- The Manufacturer and/or Brand Owner misrepresents the Allergen Bureau, the VITAL Standard, documentation, or certification.

The Certification Body shall issue the Manufacturer with notice of suspension, and copy the Allergen Bureau. In the case where the Manufacturer is not the Brand Owner the Manufacturer is expected to notify the Brand Owner of the suspension within 24 hours of suspension and copy the Allergen Bureau. If this notification does not occur the Allergen Bureau will notify the Brand Owner.

9.5 Suspended Manufacturers shall be re-audited by the Certification Body within thirty (30) days of the suspension notice to ensure corrective actions have been effectively implemented. Manufacturers that do not permit a re-audit, or fail to meet the requirements of Part A, 7.4 at re-audit, shall have their certificates withdrawn. The Certification Body shall issue the Manufacturer with notice of withdrawal.

9.6 Certification shall also be withdrawn if the Manufacturer is placed into receivership, liquidation and/or is declared bankrupt, or choses to voluntarily withdraw from VITAL Certification.

9.7 Manufacturers that have been withdrawn shall seek permission from the Allergen Bureau before applying for a new VITAL Certification audit.

9.8 The Allergen Bureau shall be notified of any certificate withdrawals within twenty-four (24) hours of the notice of withdrawal, and shall include the withdrawn Manufacturer Products on a public register on the Allergen Bureau website allergenbureau.net until the withdrawn site re-applies and is re-certified.

9.9 If a Manufacturer is withdrawn, any Product that carries the VITAL Certification Mark must be immediately risk assessed by the Manufacturer. The rationale and outcome of the risk assessment shall be shared with the Allergen Bureau and Brand Owner (if applicable) and if required a withdrawal of that Product from the market shall be undertaken. Where a food safety risk is identified, the Brand Owners product recall process should apply.

10. Changing Certification Bodies

10.1 The Manufacturer may elect to change Certification Bodies at any time if all non-conformances have been closed out, the certification is not under suspension, and there are no adverse events that could impact the Manufacturer's FSMS or VITAL Certification.

11. Change of Scope

11.1 If a Manufacturer wishes to add or change a process or Product(s) within its scope of certification, the manufacture shall request the change with the Certification Body in writing.

The Certification Body may choose to conduct a full interim VITAL audit, including the additional process or Products, and shall either issue a new certificate, or advise the Manufacturer in writing why the new VITAL certificate cannot be issued.

It is recommended that any request for change in scope occurs immediately preceding a recertification audit to prevent the need for an additional audit mid-cycle.

12. Complaints and Appeals

12.1 The Certification Body shall include its procedure for handling and resolving appeals, and complaints in the agreement with the Manufacturer. This shall include complaints made by a Manufacturer about the Certification Body, auditor, or audit outcome, or made by another party about the Manufacturers or Brand Owners' application of the VITAL Standard or use of the VITAL Certification Mark.

When a Manufacturer registers a complaint about a Certification Body's activities, or appeals a decision made by an auditor or Certification Body, the Certification Body shall investigate and resolve these matters with thirty (30) days and keep a record of all complaints, appeals and disputes and their resolution.

12.2 If a complaint or appeal cannot be satisfactorily resolved by the Certification Body within thirty (30) days, the complainant may register the matter with the Allergen Bureau Secretariat for resolution by the Allergen Bureau Independent VITAL Committee.

13. Compliance Program

13.1 The Allergen Bureau may from time to time monitor the activities of the Certification Bodies and their VITAL Standard auditors, including witnessing VITAL audits. On any such occasions, the Allergen Bureau shall raise any observed concerns or issues with the Certification Body and request an appropriate course of action with the Certification Body.

Anyone witnessing a VITAL audit on behalf of the Allergen Bureau shall have no conflict of interest related to the company or their Products.

Part B lists the VITAL Standard requirements to be implemented by Manufacturers undertaking VITAL Certification and audited by approved Certification Bodies. Definitions used by VITAL® are listed in Attachment 1: Glossary.

All applicable elements of the VITAL Standard shall be implemented. Where the Manufacturer considers some of the elements to be non-applicable, the Manufacturer shall submit a request for exemption to the Certification Body in writing before the certification audit, justifying the reasons for exemption. If accepted, the exempted element(s) shall be marked as non-applicable by the auditor.

Elements that are marked **(Core)** are elements that must be indicated as compliant for certification to be achieved. If a non-conformance is raised against any **(Core)** element, certification is not granted.

All minor and major non-conformances raised by a Certification Body during an audit of the VITAL Standard shall be closed out within thirty (30) calendar days for certification to be granted.

1. Management Commitment

1.1 Management Responsibility

1.1.1 Senior site management shall include reference to the Manufacturer's commitment to Allergen identification and management in the site's food safety policy statement.

1.1.2 **(Core)** All site personnel shall be made aware of management's commitment to Allergen management.

1.1.3 **(Core)** Senior site management shall ensure that adequate resources are available to implement and maintain the Allergen management program and the requirements of the VITAL Standard.

1.1.4 The Manufacturer's Allergen management program, including application of the VITAL Standard, shall be documented in the site's food safety manual, and effectively implemented.

1.2 Management Review

1.2.1 **(Core)** Senior site management shall review the application of the site's Allergen management program, including the VITAL Standard, regularly and at least once per year.

2. Pre-requisites

2.1 Food Safety Management Standard

2.1.1 **(Core)** To be considered for VITAL Certification, the manufacturing site shall firstly be certified to a recognised Food Safety Management Standard (FSMS) by a Certification Body that is accredited to ISO/IEC 17065:2012 or ISO/IEC 17021:2015, recognised by the Global Food Safety Initiative (GFSI).

2.1.2 Only Products that are included in the scope of FSMS certification shall be considered for certification to the VITAL Standard.

2.2 Allergen Management Pre-requisites

2.2.1 **(Core)** The Manufacturer shall have documented and implemented a HACCP based Allergen Management Plan, using the HACCP principles and steps outlined in *Codex Alimentarius International Food Standards, General Principles of Food Hygiene CXC 1-1969 (Revised 2022)*, or subsequent revisions, irrespective of the requirements of the certified standard (refer *Part B, 2.1.1*).

2.2.2 **(Core)** HACCP Plans shall include Allergens either as a subset of chemical hazards, or as an independent category of food safety hazard.

2.2.3 All members of the HACCP Team, and other management and staff involved in the effective implementation of the Allergen management program, shall be trained, and assessed in awareness of food Allergens, the risk to consumers with food allergy of inadvertent consumption, identification of Cross contact Allergens, and management of food Allergens.

2.2.4 The impact of ingredient changes, new Product development and Product reformulations on the Allergen status of Products shall be considered and documented, and the Allergen management plan revised to reflect the changes.

2.2.5 The manufacturing plant and premises shall be designed, where possible, to minimise the risk from Cross contact Allergens. Where design limitations exist, the risk from Allergen Cross contact shall be included in the VITAL Risk Assessment (refer *Part B, 4.3.1*).

2.2.6 Manufacturing tools and equipment used for Allergen containing Materials, work-in-progress, and finished Products shall be dedicated to that use, or managed to minimise the risk of Cross contact.

2.2.7 The Manufacturer shall identify, segregate and or manage all Ingredients and Raw materials containing Allergens on receipt. Materials containing Allergens shall be stored to avoid spillage and Cross contact.

2.2.8 Product processing, packing, and cleaning shall be scheduled to minimise or eliminate the risk of Cross contact between Allergen and non-Allergen containing Products and between Products containing different Allergens.

2.2.9 Where Allergen containing material is present, Product changeover procedures shall be implemented to eliminate or minimise the risk of Cross contact. If Cross contact cannot be eliminated, the potential for Cross contact at Product changeover shall be considered in the VITAL Risk Assessment (refer *Part B, 4.3.1*).

2.2.10 Cleaning and sanitation of Product contact surfaces and tools following production of Allergen containing Products and between Product changeovers shall be sufficient to remove or reduce all potential Allergens to the lowest practical level. Procedures used must be validated.

2.2.11 Verification of the effectiveness of cleaning and sanitation of Product contact surfaces and tools following manufacture of Products containing Allergens and between Product changeovers shall be effectively implemented.

2.2.12 The Allergen management plan shall be reviewed at least annually or when changes occur (refer *Part B, 2.2.4*) or when notified of a documented consumer reaction to the Product.

3. Allergen Identification

3.1 Determination of relevant Allergens

3.1.1 The Manufacturer shall ensure that regulations in the country of sale or the country of further manufacture relating to mandatory and precautionary Allergen labelling requirements, and to ingredient statements/listings for labelled Products, are known, current and documented.

For food Products that are not packaged and labelled at the point of sale (i.e. food service Products) regulations concerning purchaser/consumer information shall be documented.

3.1.2 The Manufacturer shall determine the Allergens to be included in the VITAL Risk Assessment. All Allergens regulated for mandatory or precautionary Allergen labelling (refer *Part B, 3.1.1*) shall be considered, including both intentionally added and potential Cross contact Allergens.

3.1.3 Determination of relevant Allergens shall be conducted by a technical team that is trained and demonstrates competency in HACCP principles, Allergen management, and Allergen regulatory compliance. The Allergen technical team may be the site HACCP Team or may be revised or expanded to include internal or external technical experts in Allergen management and regulations.

3.1.4 Determination of relevant Allergens shall be reviewed at least annually and when changes in Ingredients, processes, Products, regulations occur or there are new or emerging Allergen risks reported.

3.1.5 Records shall be retained of Allergens that may be present on site, as well as reviews of regulations and Allergen considerations.

3.2 Identification of Intentionally added Allergens

3.2.1 Intentionally added Allergens are listed Allergens (refer *Part B, 3.1.1*) which form an intrinsic part of an Ingredient, Raw material, or Processing aid.

The technical team (refer *Part B, 3.1.3*) shall ensure that specifications for all ingredient, raw material, and Processing aids used in food manufacture or preparation are complete and include the presence of Allergens where relevant.

3.2.2 Records of Allergen calculations shall be maintained

3.2.3 **(Core)** Intentionally added Allergens that are present shall be listed on 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.

3.3 Identification of unintentional (i.e. Cross contact) Allergens from Materials/Ingredients

3.3.1 The technical team (refer *Part B, 3.1.3*) shall establish the possible presence of Cross contact Allergens within each type of Ingredient, Raw material, and Processing aid that is brought on site for use in manufacturing, or that is stored on site for transfer to other sites.

The investigation shall include a review of each material specification. It may also require visits/audits of one or more supplier, and/or analytical testing of some Ingredients if deemed necessary by the technical team.

3.3.2 For each identified Cross contact Allergen from Materials or Ingredients, the technical team shall investigate whether the Cross contact Allergen can be avoided, reduced, or eliminated without adversely impacting the safety or quality of the Product.

The technical team shall document and implement a corrective action plan to reduce or eliminate the presence of Cross contact Allergens from Materials or Ingredients. The corrective action plan shall be incorporated into the Manufacturer's existing FSMS corrective action plan.

3.3.3 For each identified Cross contact Allergen from Raw materials or Ingredients, that cannot practicably be avoided, the technical team shall determine the likelihood of its presence, and if present, whether it is in a Readily dispersible or Particulate form.

3.3.4 The technical team shall be advised of any changes to Ingredients or Raw materials or their suppliers, and shall investigate (refer *Part B, 3.3.1*) the impact of any intended new Ingredient or supplier before the Ingredient or new Material is used in manufacturing.

3.3.5 The review of potential Cross contact Allergens from Ingredients, Raw materials, work-in progress, and Processing aids shall be repeated at least annually.

3.3.6 Records of ingredient or Raw material Cross contact review shall be maintained.

3.4 Identification of unintentional (i.e. Cross contact) Allergens due to Processing

3.4.1 The technical team (refer *Part B, 3.1.3*) shall establish the possible presence of one or more Cross contact Allergens due to storage conditions, manufacturing processes, or the design and layout of the premises.

Consideration shall be given to all areas of the manufacturing facility and all stages of manufacturing and storage from receipt to despatch.

3.4.2 For each identified Cross contact Allergen due to Processing, the technical team shall investigate whether the Cross contact Allergen can be avoided, reduced, or eliminated without adversely impacting the safety or quality of the finished Product.

The technical team shall document and implement a corrective action plan to reduce or eliminate the presence of Cross contact Allergens due to Processing. The corrective action plan shall be incorporated into the Manufacturer's existing FSMS corrective action plan

3.4.3 For each identified Cross contact Allergen that cannot be avoided, the technical team shall determine the likelihood of its presence in the final Product, and if present, whether it will be in a Readily dispersible or Particulate form.

3.4.4 The technical team shall identify potential hang up points in the Production processes that may cause accumulation of Particulate residues which could result in significant variations in the quantity of Cross contact Allergens present or could impact other Products.

3.4.5 The technical team shall be advised of any changes to process design or equipment (refer *Part B, 3.4.1*) and shall assess the impact of the change on Cross contact Allergens before implementation in manufacturing.

3.4.6 The review of potential Cross contact Allergens due to Processing shall be conducted at least annually.

3.4.7 Records of process Cross contact reviews shall be maintained.

4. Quantification of Cross Contact Allergens

4.1 Particulate Cross contact Allergens

4.1.1 **(Core)** Particulate Cross contact Allergens are separate and distinct particles of material which do not mix homogenously with other parts of the food, and consist of, or are likely to aggregate into, an entity which contains equal to or greater than the relevant Reference Dose. They may be identified in Ingredients, Raw materials, or Production processes. (Refer *Part B, 3.3.3, 3.4.3*, and Appendix 1: Glossary)

Particulate Cross contact Allergens may be present in Materials, Ingredients and finished Products and, if present, the amount may vary.

Where Particulate Cross contact Allergens cannot be eliminated, the Allergens shall be declared on the label (for Packaged Product), or in consumer information (for non-Packaged Product) as per VITAL Action Level 2 (refer *Part B, 5.3.1*), which requires a Precautionary Allergen Labelling statement if legally permitted in the country of sale or the country of further manufacture (refer *Part B, 3.1.1*)

4.1.2 Particulate Allergens shall be included in the annual Cross contact Allergen review (refer *Part B, 3.3.5*) and records maintained (refer *Part B, 3.3.6*).

4.2 Readily dispersible Cross contact Allergens from Materials or Ingredients

4.2.1 **(Core)** Readily dispersible Allergens are powders or liquids that may be homogenously distributed in the final Product.

Where Readily dispersible Cross contact Allergens from Materials or Ingredients cannot be eliminated (Refer *Part B, 3.3.3*), the technical team shall calculate the maximum amount of Total Protein from each Cross contact Allergen present in the final Product. The technical team may choose to calculate protein levels manually or can opt to use the VITAL Calculator, available at VITAL Online vital.allergenbureau.net. Use of the VITAL Calculator can assist, but is not mandatory.

The technical team shall 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

4.2.2 The total concentration of a particular Allergenic protein from all ingredient sources shall be considered.

4.3 Readily dispersible Cross contact Allergens due to Processing

4.3.1 **(Core)** Where Readily dispersible Allergens due to Processing cannot be eliminated (Refer *Part B, 3.4.2*), the technical team shall calculate the maximum amount of Total Protein from each Processing Cross contact Allergen present in the final Product. The VITAL Calculator may be used, but is not mandatory vital.Allergenbureau.net.

The technical team shall determine the Total Protein concentration from each Cross contact Allergen, and the 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, the technical team shall divide the answer above by the amount of Product into which this Cross contact can become incorporated.

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

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

4.4 Calculation of total Cross contact Allergen in finished Product

4.4.1 **(Core)** For each Cross contact Allergen, the technical team shall sum the concentration of Allergen protein from Raw materials/Ingredients (Refer *Part B, 4.2.1*) and Processing (Refer *Part B, 4.3.1*).

4.4.2 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 (e.g. a concentrated gravy or soup premix which will be diluted prior to consumption). However, the maximum possible concentration should be used to 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%))

4.4.3 Records shall be maintained of all calculations of Cross contact Allergens from Material/Ingredient and Processing sources.

4.4.4 A review of calculations of Cross contact Allergens from Material/Ingredient and Processing sources shall be conducted annually or when changes to suppliers, Ingredients, Products and/or processes occur.

5. Determination of Action Levels

5.1 Determination of Reference Amounts for Packaged Products and Bulk Product Calculations

5.1.1 **(Core)** In the VITAL Standard, the term 'Reference Amount' is considered as 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 shall never be less than the normal or declared serving size.

The technical team shall determine the Reference Amount for each Packaged Product included in the scope of certification.

5.1.2 Reference Amount calculations are not relevant for Bulk Products (i.e. Products intended for food service or further Processing). The outcome of the VITAL Risk Assessment for Bulk Products shall be expressed as parts per million (ppm) or milligrams per kilogram of Allergenic protein for Readily Dispersible Allergens and expressed as present for Particulate Allergens.

5.1.3 Reference Amounts and Bulk Product calculations for each Product shall be reviewed annually or when changes to finished Products occur.

5.2 Determination of the application of Reference Doses for Packaged Products

5.2.1 **(Core)** In the VITAL Standard, the term 'Reference Dose' is considered as the amount of 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 adverse reaction.

The technical team shall establish the application of Reference Doses for each identified Cross contact Allergen. Reference Doses can be accessed via VITAL Online or in the VITAL 4.0 Summary and FAQ document VITAL Resources - VITAL.

5.3 Establish Action Levels for each identified Allergen in a Packaged Product

5.3.1 **(Core)** 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 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 if legally permitted in the country of sale or the country of further manufacture (refer *Part B, 3.1.1*)

The technical team shall determine the Action Levels for each identified Cross contact Allergen in every Packaged Product within the scope of the certification. For accuracy and simplicity, it is recommended that the interactive VITAL Action Level Grid, which is incorporated into the VITAL Calculator, be used. However, the technical team may choose to calculate Action Levels manually.

The 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)

Example:

A biscuit Manufacturer uses the 40g Serving Size as Reference Amount.

Action Level transition for egg (40g Reference Amount) = 2.0mg x (1000/40g) =50 ppm

Where cross contact egg is 43ppm, this is less than the transition point, and will be Action Level 1.

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

Where cross contact soy is 270 ppm, this is greater than the transition point, and will be Action Level 2

5.4 Validation of the VITAL Risk Assessment

5.4.1 The concentration of Cross contact Allergens in one or more Products or Product groups may be validated using analytical testing. Where the concentration of Allergens identified by analytical testing is greater than that resulting from the VITAL Risk Assessment, the technical team shall consider reviewing the risk assessment for other factors.

6. Precautionary Allergen Labelling

6.1 **(Core)** Where Cross contact Allergens cannot be eliminated (refer *Part B, 3.3.3, 3.4.2*), Packaged Products shall 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 shall be labelled with an appropriate Precautionary Allergen Labelling statement if legally permitted in the country of sale or the country of further manufacture (refer *3.1.1*). If not prescribed by legislation, the recommended Precautionary Allergen Labelling statement should be:

May be present: Allergen x, Allergen y.

6.2 The senior site management shall ensure that all Packaged Product labels are designed, printed, and used to indicate the presence of Allergens and Cross contact Allergen status appropriately per the below.

- Intentionally added Allergens are declared on the Product label, as per regulations (refer *Part B, 3.2.4*)
- Products that are determined to be Action Level 2 require a Precautionary Allergen Labelling statement
- Products that may contain Cross contact Allergens that are determined to be Action Level 1 do not require a Precautionary Allergen Labelling statement.

6.3 Precautionary Allergen Labelling Statements are not appropriate for Bulk Products. The Allergen status of Bulk Products (refer *Part A, 5.1.2*) shall be made available to food service or industrial customers when requested for use in determining the Cross contact Allergen status of their finished Products. The level of Cross contact allergen should be provided as a concentration (parts per million, mg/kg), based on the outcome of the risk assessment.

6.4 There shall be an established procedure to ensure labels (and/or Bulk Product Allergen information, as appropriate) are approved as meeting regulatory requirements (refer *Part B, 3.1.1*) and the VITAL Risk Assessment before commercial use.

6.5 The technical team shall review Packaged Product label compliance at least annually and when changes in Ingredients, processes, Products, or labels occur.

6.6 Records of label reviews for Allergen labelling compliance shall be maintained.

7. Verification of the VITAL Risk Assessment

7.1 Verification procedures

7.1.1 The Manufacturer shall integrate internal audits of the VITAL Risk Assessment into the FSMS internal audit schedule, including:

- The Allergen management plan (refer *Part B, 2.2.1*)
- Applicable regulations (refer *Part B, 3.1.1*)
- Determination of relevant Allergens (refer *Part B, 3.1.4*)
- Identification of unintentional Allergens (refer *Part B, 3.3.5, 3.4.6*)
- Quantification of Cross contact Allergens (refer *Part B, 4.4.4*)
- Determination of Reference Amounts (refer *Part B, 5.1.3*)
- Determination of Action Levels (refer *Part B, 5.3.1*)
- Label accuracy and consistency (refer *Part B, 6.5*)

7.1.2 Where the internal audit identifies non-conformances, corrective actions shall be implemented, and their progress noted in the senior management review of the application of the VITAL Standard.

7.1.3 Staff conducting internal audits of the VITAL Standard shall be trained in the application of the VITAL Standard, but shall be independent of the VITAL technical team and shall not have been directly involved in the VITAL Risk Assessments.

7.2 Use of the VITAL Certification Mark

7.2.1 The VITAL Certification Mark shall only be used in accordance with the *"VITAL Certification Mark; Rules for Use"*, and only on Products that are within the scope of certification and that have been subject to a VITAL Risk Assessment. A Product License Agreement is required before the mark can be used on pack or digitally. (Refer *Part A 8 Use of the VITAL Certification Mark*).

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.*
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).
Allergen	Within the VITAL Standard, this is limited to 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.
Allergen Bureau	A not-for-profit organisation established in 2005 with a vision of a world where individuals with food allergies can trust the safety of the food supply chain and the transparency of food allergen labelling. The Allergen Bureau shares information, experience and resources to support this vision.
Allergen Bureau Independent Committee	An impartial and independent committee selected from the Allergen Bureau's food industry stakeholders to represent their interests. The functions of this committee shall include the following: • Oversight and technical review of the VITAL Scheme requirements. • Review of unresolved complaints and appeals. • Decisions on resolution of complaints and appeals. • Other matters affecting confidence in VITAL Certification.
Brand Owner	**"Brand Owner"** means the entity which owns the branded Product to which the VITAL Certification Mark will be applied. In some instances, the Brand Owner does not produce the food Product and may use a Manufacturer to make the food Product on their behalf.
Bulk Product	Within the VITAL Standard, Bulk Product is one of the two categories of food Product that is the outcome of the Manufacturer's Production process. Bulk Product includes Products intended for food service or further Processing, where the Reference Amount cannot be calculated (see also 'Packaged Product', 'Product' and 'Reference Amount').

Term	Definition
Core Element	A step or action in either the Allergen management program or the Allergen risk assessment that must be completed adequately to show appropriate due diligence and commitment to Allergen management. Identified by (Core) and to meet the VITAL Standard and gain/maintain certification, there needs to be conformance with all Core Elements. Other requirements (considered non Core Elements) are also important in an Allergen management program but some allowance may be made for temporary or partial non-conformance.
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 processes. Cross contact Allergen is also known in other parts of the world as Unintentional Allergen Presence (UAP).
HACCP Plans	Food hazard analysis and risk mitigation plans developed according to the HACCP principles and steps outlined in the Codex Alimentarius International Food Standards, General Principles of Food Hygiene CXC 1-1969 (Revised 2022).
HACCP Team	A multi-disciplinary team responsible for documenting, implementing, and reviewing HACCP Plans.
Hang Up Point	A point on a manufacturing line where material may accumulate instead of flowing through freely.
Ingredients	Secondary substances used in the manufacture of food Products, and include 'Food additives' (See also 'Raw Materials')
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.
ISO/IEC 17021:2015 (or subsequent version)	The International Standards Organisation's (ISO) standard for "Conformity assessment -- Requirements for bodies providing audit and certification of management systems".
ISO/IEC 17065:2012 (or subsequent version)	The International Standards Organisation's (ISO) standard for "Conformity assessment -- Requirements for bodies certifying Products, processes and services".
Manufacturer	The individual site or facility in which the Products are processed or prepared, as Packaged Product, Bulk Product, or a combination thereof, and to which the VITAL Risk Assessment applies. (Also commonly referred to as Food Manufacturer).
Packaged Product	Within the VITAL Standard, Packaged Product is one of the two categories of food Product that is the outcome of the Manufacturer's Production process. Packaged Product includes Products that are packaged ready for sale to the consumer where the Reference Amount can be calculated (see also 'Bulk Product', 'Product' and 'Reference Amount').

Term	Definition
Particulate Cross contact Allergen	For the purpose of the VITAL Risk Assessment, Separate and discreet particles of allergen containing material that • 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 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). (See also 'Readily dispersible form'.)
ppm	Parts per million e.g. milligrams per kilogram (mg/kg)
Precautionary Allergen Labelling (PAL)	A voluntary statement listing all Allergens that are present because of cross contact and at Action Level 2 as per the VITAL Program. Where no legislation exists, the precautionary Allergen labelling statement that is recommended with the VITAL Program on packaged food for sale is **May be present: Allergen x, Allergen y.**
Product	The food Product that is or are produced as the outcome of the Manufacturer's Production or preparation process. Products that are certified under this standard are identified by pack size (retail or commercial as appropriate). Products may be simple (i.e. made up of only one ingredient) or compound, (i.e. food that is made from two or more Ingredients, e.g. spaghetti, which is made from flour, egg, and water). In the VITAL Standard, Products are further categorised as either 'Packaged Product' or 'Bulk Product' (see separate definitions).
Processing aid	Processing aids are substances that are approved by food regulators in the country of origin and the country of sale, to be used. They are used in the manufacture of foods to perform a technological purpose during Processing.
Raw materials	The primary Materials or substances used in the manufacture of food Products. Also referred to as 'Materials' (See also 'Ingredients').
Readily dispersible Cross contact Allergen	A powder or liquid in homogenous form that is easily distributed throughout a food Product e.g. milk powder, soy flour. A Readily dispersible Cross contact Allergen which 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. The Reference Amount should never be less than the "serving size".
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.
Scheme Rules	Part A of the VITAL Standard.

Term	Definition
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.
VITAL Online Calculator	An on-line tool that is available through the Allergen Bureau to assist Manufacturers with the calculations required by the VITAL Program (to calculate Action Levels and concentrations of Allergens in food Products). vital.allergenbureau.net.
VITAL Certification	This means certification that a particular Product conforms with the VITAL Standard and the Scheme Rules following an audit conducted by an auditor nominated by an Allergen Bureau approved Certification Body. VITAL Certification is site and Product specific. To become an Authorised user of the VITAL Certification Mark by the Allergen Bureau Limited, the Manufacturer and or Brand Owner must ensure the Product has obtained VITAL Certification.
VITAL Certification Mark	VITAL Certification Mark means the following trade mark: 
VITAL Risk Assessment	The process developed as a part of the VITAL program for quantifying the amount of residual Cross contact Allergen present from Raw materials, Ingredients, Processing aids and/or other production processes that determines whether a Precautionary Allergen Label is required.
VITAL Scheme	The program for certification including Scheme Rules, the certification process required to confirm compliance with the Vital Standard and requirements for Certification Bodies as set out in the VITAL Scheme Certification Body Requirements Version 2.1.

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