Allergen Bureau

Informing the food industry

VITAL® Scheme Certification Body Requirements

Version 1.0

VITAL®
an initiative of the Allergen Bureau

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Contents

1 Scope

1.1 All applicable requirements of ISO/IEC 17065:2012 shall apply to Certification Bodies seeking accreditation to certify clients to the VITAL Standard. This document provides interpretation for Certification Bodies on the application of ISO/IEC 17065:2012 for certifying food products to the VITAL Standard.

The numbering of elements is as per ISO/IEC 17065:2012.

Where elements or phrases are indicated in "quotation marks" the references are taken directly from ISO/IEC 17065:2012.

2 References

2.1 The following references apply:

- HACCP guidelines developed and managed by the CODEX Alimentarius Commission. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application – Annex to CAC/RCP 1 – 1969, Rev. 3 (1997).
- ISO/IEC 17065:2012 Conformity assessment — Requirements for bodies certifying products, processes and services.
- ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17021, Conformity assessment — Requirements for bodies providing audit and certification of management systems
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- The VITAL Standard, edition 1, 2019
- VITAL Online https://vital.allergenbureau.net/

3 Definitions

3.1 The relevant definitions in *the VITAL Standard, Attachment 1: Definitions*, and in ISO/IEC 17065: 2012 section 3 apply.

'Client' means the manufacturer that applies to the Certification Body for VITAL certification.

4 General Requirements

4.1 Legal and Contractual Matters

4.1.1 Legal Responsibility

"The Certification Body shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be legally responsible for all its certification activities" (ISO/IEC 17065:2012)

4.1.2 Certification agreement

4.1.2.1 The Certification Body shall be accredited to ISO/IEC 17065:2012 by an Accreditation Body that meets the requirements of ISO/IEC 17011:2004, is a member of the International Accreditation Forum (IAF) and is a signatory to the IAF Multilateral Recognition Agreement.

The Certification Body shall have an agreement with the Allergen Bureau to certify clients to the VITAL Standard per current and subsequent versions of the VITAL Standard and VITAL Scheme management requirements.

The Certification Body shall have an agreement with its clients for the provision of certification services for the VITAL Scheme.

4.1.2.2 The client agreement shall meet the requirements of ISO/IEC 17065:2012, clause 4.1.2 and additionally identify:

- The products to be included in the scope of certification, and any products that may be exempted;
- The expected time to conduct and finalize the assessment to the VITAL Standard and the reporting requirements;
- The certification body's fee structure for completing the certification to the VITAL Standard, and
- The conditions under which the certificate is issued, withdrawn or suspended.

4.1.3 Use of license, certificates and marks of conformity

4.1.3.1 The Allergen Bureau has rules for use of the VITAL mark. Clients must have signed a Product Licence Agreement (PLA) with the Allergen Bureau and agree to abide by the VITAL Mark, Rules for Use, provided by the Allergen Bureau.

4.1.3.2 Misleading use of the VITAL mark, or VITAL certificate, or misrepresentation of the VITAL Standard, documentation or certification by the client shall be considered as grounds for suspension by the Certification Body.

The VITAL mark cannot be used by the client whilst certification is suspended, or if the certificate is withdrawn

4.2 Management Impartiality

4.2.1 The Certification Body shall ensure that all certification activities for the VITAL Standard are unbiased, objective, and independent of other activities, except as identified in the VITAL Scheme.

4.2.2 The Certification Body shall not allow commercial or financial pressures to compromise its ability to deliver VITAL certification.

4.2.3 The Certification Body shall review its risks to independence and objectivity on an ongoing basis, and at least annually.

4.2.4 If any risks to impartiality are identified then control measures shall be put in place to eliminate or minimize that risk.

4.2.5 The impartiality and independence of the Certification Body shall have senior management commitment.

4.2.6 The ownership and operation of the VITAL Scheme rests with the Allergen Bureau. The Certification Body, its management, staff, and auditors shall not be involved with the design, management, or review of the VITAL Scheme. The involvement of the Certification Body in the VITAL Scheme shall only be as assigned by the Allergen Bureau.

4.3 Liability and Financing

4.3.1 The Certification Body shall maintain worker's compensation insurance to cover all relevant staff, as well as public liability insurance in the amount of $20 million, professional indemnity insurance in the amount of $10 million for each and every claim, and product liability insurance in the amount of $10 million for each and every claim.

4.3.2 The Certification Body shall demonstrate to the Accreditation Body that it has resources available for all VITAL certification activities it conducts, and that they are carried out in a competent and reliable manner.

4.4 Non-Discriminatory Conditions

4.4.1 The Certification Body shall not impede or inhibit clients seeking VITAL certification for which the Certification Body has the technical expertise.

4.4.2 "The Certification Body shall make its services accessible to all applicants whose activities fall within the scope of its operations." (ISO/IEC 17065:2012)

4.4.3 "Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued." (ISO/IEC 17065:2012)

4.5 Confidentiality

4.5.1 The Certification Body shall ensure that all notes, records, data and information acquired from clients during a certification audit against the VITAL Standard remains confidential and the property of the client. Only with the authorization of the client can the Certification Body release assessment information to any entity other than the Allergen Bureau, or the Accreditation Body, unless required by law.

4.5.2 In instances where the Certification Body is required by law to release client information, the client and the Allergen Bureau shall be notified of the information provided within two (2) working days.

4.6 Publicly Available Information

4.6.1 The Certification Body shall maintain and make available on request:

- Information regarding the implementation, maintenance and certification of the VITAL Standard;
- The Certification Body's fees and charges;
- The rights and duties of applicants and clients, including the use of the VITAL Mark;
- The complaints and appeals procedure

5 Structural Requirements

5.1 Organizational Structure and Top Management

5.1.1 VITAL certification activities shall be managed within the Certification Body to maintain impartiality and to reduce the risk of any threat to impartiality (refer 4.2).

5.1.2 The Certification Body shall have a documented organisational structure showing responsibilities and authorities of senior management and key certification personnel involved with the VITAL scheme.

5.1.3 The organisational structure impacting the VITAL Scheme shall be made available to the Allergen Bureau including personnel having responsibility for:

- Management of certification activities;
- Assessment;
- Review of assessments;
- Decisions on certification;
- Contractual arrangements;

- Provision of adequate resources for certification activities; and
- Complaints and appeals.

Where there are any changes in any key personnel, the Allergen Bureau shall be notified.

5.2 Mechanism for Safeguarding Impartiality

5.2.1 The Certification Body shall have in place an impartial and independent committee selected from the Certification Body's food industry stakeholders to represent their interests. The functions of this committee shall include:

- Oversight of the decision-making process for VITAL certification;
- Review of unresolved complaints and appeals;
- Decisions on resolution of complaints and appeals;
- Review of actions taken to resolve accreditation issues; and
- Other matters affecting confidence in VITAL certification

The scope of the impartiality committee may include other food safety management schemes other than just the VITAL Scheme.

5.2.2 The impartiality committee appointed by the Certification Body shall comprise a balanced representation of technical food industry experts across a number of food industry sectors, but shall exclude manufacturers already certified to the VITAL Standard, or persons employed by the Certification Body in any capacity.

5.2.3 The impartiality committee shall have the full support of the senior management of the Certification Body. Decisions made by the impartiality committee shall be accepted and implemented by the Certification Body, or modified or rejected with a written explanation of the reason for modification or rejection.

6 Resource Requirements

6.1 Certification Body Personnel

6.1.1 General

6.1.1.1 The Certification Body shall employ, or have a contract with, sufficient personnel to cover its certification activities related to the VITAL Scheme.

6.1.1.2 The Certification Body shall demonstrate that it has auditors, technical reviewers and certification managers available who are trained in the current version of the VITAL Standard, competent in food safety management systems within particular industry sectors, and are accredited and registered with the Allergen Bureau.

6.1.1.3 All Certification Body personnel, including impartiality committee members, shall keep confidential all information obtained during the performance of VITAL certification activities, except as required by the Allergen Bureau, or by law (refer 4.5)

6.1.2 Management of competence for personnel involved in the certification process

6.1.2.1 The Certification Body shall establish, implement and maintain procedures to ensure that all auditors and contract auditors, technical reviewers, certification managers and administration personnel responsible for VITAL certification in part or in its entirety, are appropriately trained to undertake that role, and have undertaken authorised training in the current version of the VITAL Scheme as amended from time to time.

6.1.2.2 Records shall be maintained of all Certification Body personnel with responsibility for the VITAL Scheme, including their:

- Position held;
- Educational qualifications and professional status;
- Experience and training;
- Their assessment of competence;
- Performance monitoring;
- Date of most recent updating of each record.

An audit log shall be retained for all VITAL auditors indicating their record of all food safety and quality management audits undertaken within the food industry, including audits of the VITAL Standard.

6.1.3 Contract with the personnel

The Certification Body shall ensure that all VITAL auditors, technical reviewers and certification managers sign a contract or agreement that discloses any real or potential conflict of interest, including:

- Any association with the Allergen Bureau;
- Any association with the development of the VITAL Standard, VITAL Calculator, VITAL tools or associated documentation;
- Associations with businesses that are, or may become, clients of the Certification Body for VITAL certification; or
- Any other issue that could present the Certification Body or the auditor with a conflict of interest.

6.2 Resources for Evaluation

6.2.1 Internal resources

6.2.2.1 To be considered for VITAL certification, a client shall first 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. This includes only food safety management schemes that are recognised by the Global Food Safety Initiative (GFSI).

Although not mandatory, it is expected that Certification Bodies contracted to certify the base standard shall also be contracted to certify VITAL. Where the FSMS is FSSC 22000, the Certification Body shall require accreditation to ISO 17021:2015.

6.2.2 External resources (outsourcing)

6.2.2.1 The Certification Body shall not outsource the management of VITAL certification to any other Certification Body or agency.

7 Process Requirements

7.1 General

7.1.1 To be considered for VITAL certification, a client shall first 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. (refer 6.2.2.1).

The Certification Body shall offer clients the option that combines an assessment of the recognised FSMS with the VITAL certification.

7.1.2 The Certification Body shall adhere to the requirements outlined in the published edition of the VITAL Standard.

7.1.3 The Certification Body shall not offer clients advice on the implementation of the VITAL Standard, nor any information or guidance on VITAL save that which is published by the Allergen Bureau or its authorised representatives.

7.2 Application

To be considered for VITAL certification, an applicant shall complete the VITAL Standard Application form and submit it to the 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;
- 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)

7.3 Application Review

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.

The Certification Body's application review shall consider:

- The information about the client is sufficient;
- The client clearly understands the requirements of the VITAL Standard and its implementation;
- Availability of Certification Body resources;
- Any unresolved issues with the client.

7.4 Evaluation

7.4.1 The Certification Body shall develop a plan for each VITAL certification assessment that meets the requirements of the VITAL Scheme. The plan may be combined with assessments of other management standards, including the certification scheme that is designated as the FSMS. The certification plan shall ensure that:

- The timing of the assessment meets the requirements of the VITAL Scheme and other concurrent schemes;
- The assessment date has been agreed and confirmed with the client;
- Sufficient time has been allocated to complete all assessment activities;
- The scope of the VITAL assessment and other concurrent schemes have been defined and agreed by both the client and the Certification Body;
- Requests for any exemptions have been submitted by the client in writing, and a decision made by the Certification Body of their acceptance or otherwise. Where an exemption has not been made in writing before the certification audit, the auditor may determine their acceptance or otherwise while on site;
- The audit team or auditor has the competence and registration to cover the components of all applicable schemes;
- The client has been given the names of the audit team or auditor and has agreed to their access; and
- Location, travel and access details have been agreed between the Certification Body and the client.

7.4.2 Auditors assigned to conduct VITAL assessments shall be employed by or contracted to the Certification Body and have the required competence. (refer 6.1.2.1).

The use of Technical Experts in lieu of registered auditors is not permitted.

7.4.3 "The Certification Body shall ensure all necessary information and/or documentation is made available for performing the evaluation tasks." (ISO/IEC 17065:2012)

7.4.4 The VITAL audit shall be conducted only against the requirements of the VITAL Standard.

7.4.5 Within the VITAL Standard, certain elements are considered 'Core' elements. 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 to be granted.

7.4.6 The auditor shall advise the client of the number and level of any non-conformities raised against the VITAL Standard prior to leaving the client's site. A written summary of non-conformances shall be left with the client before concluding the VITAL audit.

7.4.7 The auditor shall complete the assessment irrespective of non-conformities raised, unless requested to cease the audit by the client.

7.4.8 If the client requests that the assessment ceases and the auditor is unable to complete all assessment tasks as agreed in the assessment plan (refer 7.4.1), then the auditor shall note the request and the reasons for the request on the assessment report and submit it to the Certification Body.

No certification decision shall be made for an incomplete audit. The client shall be required to re-apply for certification (initial certification) or shall be suspended (re-certification).

7.4.9 The assessment results, including non-conformities, shall be recorded on the VITAL Assessment report template and submitted to the Certification Body for review within five (5) business days of the VITAL assessment day.

7.5 Review

7.5.1 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. The technical review shall be conducted by a person who has been trained in the current version of the VITAL Standard, but has not been involved in the VITAL audit.

7.5.2 "Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person." (ISO 17065:2012)

7.6 Certification Decision

7.6.1 "The Certification Body shall be responsible for, and shall retain authority for, its decisions relating to certification." (ISO/IEC 17065:2012).

7.6.2 The Certification Body shall assign a person(s) to make the certification decision using the information related to the assessment and technical review and including any other relevant information. This person(s) shall not be involved in the VITAL audit assessment but may be the technical reviewer or another competent technical officer trained in the VITAL Standard.

7.6.3 The person making the certification decision and the technical reviewer shall be employed by the Certification Body and have positions of authority in the organisational structure.

7.6.4 Certification shall only be granted by the Certification Body if:

- The client 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 the 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.

7.6.5 The Certification Body shall make the final audit report available to the client and 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.

7.6.6 "The Certification Body shall notify the client of a decision not to grant certification, and shall identify the reasons for the decision." (ISO/IEC 17065:2012)

7.7 Certification Documentation

7.7.1 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 logo
- The name, address and logo of the Certification Body
- The logo of the Accreditation Body and the Certification Body's accreditation number;
- The client's name;
- The client's address;
- The client'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 assessment;
- Date of certificate expiry (12 months from date of issue).
- Signatures of the authorized officer and issuing officer.

A copy of the certificate shall be sent concurrently to the Allergen Bureau.

7.8 Directory of Certified Products

All certified clients shall be listed in the database on the Allergen Bureau web-site. The information shall include:

- The client's name and town/city;
- The client's VITAL certification number;
- The base standard;
- Certified products;
- Date of certification;
- Expiry date.

7.9 Surveillance (i.e. maintaining and certification and recertification)

7.9.1 To maintain VITAL certification, the client shall be required to maintain FSMS certification, and successfully complete a recertification assessment to the VITAL Standard on the anniversary of the initial certification assessment +/- thirty (30) calendar days, (or as designated by the base FSMS standard).

7.9.2 To maintain certification, the requirements of 7.6.4 shall be met at the recertification assessment.

7.9.3 Re-certification assessments shall include a review of the use of the VITAL mark (refer 4.1.3.2).

7.10 Changes Affecting Certification

7.10.1 When the Allergen Bureau publishes new or revised requirements regarding the VITAL Standard, the Certification Body shall ensure that these changes are communicated to all clients and auditors. The Certification Body shall verify the implementation of these changes with their clients.

7.10.2 If a client wishes to add or change a process or product(s) within its scope of certification, the client shall request the change with the Certification Body in writing.

The Certification Body may choose to conduct an interim VITAL audit of 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.

7.10.3 The decision by the Certification Body with regards to an interim assessment shall be dependent on the extent of the proposed change, the risk to the client's VITAL certification, and the timing of the request for change.

7.11 Termination, Reduction, Suspension or Withdrawal of Certification

7.11.1 The client's VITAL certification shall be suspended by the Certification Body if:

- The requirements indicated in 7.6.4 are not met;
- The client fails to allow the recertification audit within the required timeframe;
- The client uses the VITAL mark incorrectly or on product that is not included in the scope of certification;
- The client misrepresents the Allergen Bureau, the VITAL Standard, documentation or certification.

7.11.2 The Certification Body shall issue the manufacturer with notice of suspension, and copy the Allergen Bureau.

7.11.3 Suspended clients shall be re-assessed by the Certification Body within 30 days of the suspension notice to ensure corrective actions have been effectively implemented.

Clients that do not permit a re-assessment, or fail to meet the requirements of 7.6.4 at re-assessment, shall have their certificates withdrawn. The Certification Body shall issue the manufacturer with a notice of withdrawal.

7.11.4 The Allergen Bureau shall be notified of any certificate withdrawals within 24 hours of the notice of withdrawal, and shall include the withdrawn client on a public register on the Allergen Bureau web-site until the withdrawn client re-applies and is re-certified.

7.11.5 "If certification is terminated at the request of the client, the Certification Body shall take actions specified by the Allergen Bureau and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified." (ISO/IEC 17065:2012)

7.11.5 Withdrawn clients shall seek permission from the Allergen Bureau before applying for a new VITAL certification assessment.

7.12 Records

7.12.1 "The Certification Body shall retain records to demonstrate that all certification process requirements (those in this International Standard and those of the certification scheme) have been effectively fulfilled." (ISO/IEC 17065:2012)

7.12.2 "The Certification Body shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained." (ISO/IEC 17065:2012).

7.12.3 Records shall be kept for at least two (2) years (two certification cycles).

7.13 Complaints and Appeals

7.13.1 "The Certification Body shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The certification body shall record and track complaints and appeals, as well as actions undertaken to resolve them." (ISO/IEC 17065:2012)

7.13.2 The Certification Body shall address all complaints and appeals received concerning the VITAL certification process. This shall include complaints made by a client about the Certification Body, auditor, or assessment outcome, or made by another party about the client's application of the VITAL Standard or use of the VITAL mark.

7.13.3 "The Certification Body shall acknowledge receipt of a formal complaint or appeal." (ISO/IEC 17065:2012).

7.13.4 "The Certification Body shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision." (ISO/IEC 17065:2012).

7.13.5 Investigation of the complaint or appeal shall be conducted by a person within the Certification Body who was not involved in the VITAL certification activities related to the complaint or appeal.

7.13.6 The impartiality committee established by the Certification Body shall be responsible in part for review of unresolved complaints and appeals, and review of decisions on resolution of complaints and appeals (refer 5.2.1).

7.13.7 When a client 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) calendar days and keep a record of all complaints, appeals and disputes and their resolution.

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

Any decision reached by the Allergen Bureau Independent Committee is final and binding on all parties.

8 Management System Requirements

8.1 Options

8.1.1 The Certification Body shall establish and maintain a management system that is capable of achieving the requirements of ISO/IEC 17065:2012 and the VITAL Scheme.

8.1.2 The requirements of ISO/IEC 17065:2012 8.2 to 8.8 shall apply.