FSMA (Food Safety Modernization Act) – Certification Requirements

Contents

Revision History

Rev No	Revision Date	Author	Approved by	Page No	Sec. No	Brief Description of Change
1	December 2018	Mary Portelli	-	-	-	New document
2	February 2019	Mary Portelli	Alison Lord	Various	Various	Amendments as a result of an Internal Audit
3	June 2019	Mary Portelli	Todd Redwood	Various	Various	Amendments as a result of final accreditation

Related Documents

Document Number	Title

1 Introduction

This booklet is designed to assist your organization on the requirements for certification to FSMA (Food Safety Modernisation Act) throughout the BSI Group. This includes FSVP (Foreign Supplier Verification Program) and TPP (Third Party Program).

2 Accreditation Status

Certification to this standard is accredited.

BSI holds accreditation for this standard with ANAB (ANSI National Accreditation Board).

This scheme follows the requirements of ISO17065:2012

3 The Certification Process

The following section outlines the steps that apply during the BSI certification process FSMA (Food Safety Modernisation Act) .

BSI reserves the right to provide its clients and those that request quotations with marketing and technical information relating to standards, training and compliance services.

3.1 Initial Inquiry

BSI will respond to either verbal or written expressions of interest from organizations interested in one or more of our programs. If your organization is located near one of BSI's offices, an advisory visit may be arranged to discuss your requirements and how BSI can help your organization achieve them.

BSI will also, on request and receipt of a Request for Quotation, prepare a proposal tailoring our services to your organization's needs.

3.2 Application for Certification and Assessment

Receipt of your organization's Application form (or authorized acceptance of a valid BSI proposal), along with the accompanying payment of the non-refundable application fee (or invoicing instructions) together with this document forms the contract between your organization and BSI.

Your requirements will be entered into our database and a Auditor will be appointed to look after your certification or assessment requirements. The Auditor will be your primary point of contact with BSI and is responsible for ensuring that our certification/assessment services are delivered to your organization in the most effective manner possible.

3.3 Client Contact

As soon as practicable after receipt of your signed application/proposal, a BSI Auditor (or nominated representative) will contact your organization. The Auditor will seek to establish a working relationship between your organization and BSI, and to confirm your requirements in terms of the certification or assessment services, standards or codes of practice, locations, and activities and/or products to be included in the scope of certification.

The Auditor (or nominated representative) will seek to gain an appreciation of the structure of your organization and the activities being conducted. In particular the Auditor will:

- Seek an appreciation of the nature and scope of the organization's activities, structure and location(s), including any activities for which confirmation is being excluded; and
- Determine the status of system documentation and implementation including organizational policies, objectives and targets.

If you are working with a consultant it is often useful for that person to be party to the communication process.

3.4 Pre-Assessment (optional)

A Pre-Assessment often proves an invaluable tool in determining system implementation, particularly for new systems that are still in the early stages of development. This one-off assessment includes the identification of gaps against the requirement of the nominated Standard or Code of Practice. At the conclusion of the Pre-Assessment you will receive a report which highlights any gaps as well as options for next steps on your path to certification.

3.5 Certification Audit

The purpose of the Certification Audit is to establish whether your organization's food safety management system has been implemented and complies with the relevant standard by examining actual practices, documentation and records and comparing them against the organization's policies and procedures. The audit process is, effectively, an undertaking to establish that your documented policies and practices are understood by your personnel and have been effectively implemented.

The Audit will be led by appropriately qualified and experienced auditors and, where required, witness auditors, observers and/or technical specialists acting as advisers to the audit team may also be present. These specialists bring current specialized knowledge of the activities being audited to the audit team and ensure that the audit provides a relevant and practical review of aspects critical to the business.

BSI assessors use FSMA (Food Safety Modernisation Act) issued checklists to complete your assessment. These checklists form the basis of the report.

At least 50% of the assessment time will be spent auditing production and site facilities, interviewing staff, observing processes and reviewing documentation in the production areas with relevant staff.

1) Stage 1 - Consultative audit

This is a Mandatory stage to determine if the facility is in compliance with the applicable food safety requirements of the FD&C Act, regulations and industry standards.

The Consultative audit must be carried out before a Regulatory audit.

2) Stage 2 - Regulatory audit

An audit to determine if the facility is in compliance with the provision of the FDA, for the purpose of certification. All Regulatory audits are scheduled as unannounced facility audits.

The auditor, no later than 45 days after completing a regulatory audit, must prepare and submit electronically, in English, to FDA and to ANAB a regulatory audit report

The auditor that completes the Stage 1 (Consultative) audit can not carry out the Stage 2 (Regulatory) audit.

3.6 Certification Audit Report

At the conclusion of the audit, the audit team will prepare a written report on the audit findings and the audit team leader will present these findings to your organization's senior management at the exit meeting.

The audit findings include a summary of the overall compliance of your system with the requirements of the relevant standard(s) or codes of practice. The final report will be subsequently provided after completion of the Audit.

The audit report will include the following information;

- An executive summary of the overall findings (conclusions) on the effectiveness of your system in meeting the requirements of the standard
- An overall statement of your organizations compliance to the FSMA (Food Safety Modernisation Act)
- Positive finding areas

Non-conformities will be discussed with your team during the auditor's visit and outlined at the exit meeting. Non-Conformities are categorized as Critical, Major and Minor.

Observations can only be raised at the Stage 1 assessment and these are recommended to the Stage 2 audit.

A critical non-conformance results in immediate notification to the FDA. Organizations that are already certified have their certification withdrawn or suspended until such time as the critical non-conformance is corrected, and affected product disposed of.

If you are unclear regarding the meaning of anything in your report, please contact your BSI Auditor. If non-conformances have been raised during your organisations' assessment BSI will provide guidance on the steps that are needed to take place to continue to certification.

Such guidance may include timeframes for close out or requirement for re-assessment. BSI cannot provide guidance on how to close out non-conformances.

It is your organization's responsibility to respond to the non-conformities detailed in your audit report by the designated time frame. Failure to do so may result in suspension or cancellation of your certification.

Definitions and close-out requirements for non-conformities are defined in the FSMA (Food Safety Modernisation Act) Audit Report.

3.7 Audit Cycle and Certification

Audits are conducted in accordance with the requirements of the Standard and this is dependent on the audit outcome received

Follow-up audits will be required to be conducted when there is a Critical rating against the FSMA (Food Safety Modernisation Act) requirements.

Production activities relevant to the scope of certification must be occurring at the time of the audit, in order for HACCP and control activities to be verified within your business.

3.8 Certification Decision

After confirmation that any necessary corrective actions have been taken, which may involve a follow up visit by the BSI Assessor, the findings and recommendations made in the audit report are subject to an internal review process prior to certification being granted.

BSI auditors undertake an extensive review process of audit reports and there may be occasions when audit report gradings are revised based upon discussions with the Compliance and Risk Food team.

3.9 Certificates

When your organization has achieved certification, BSI will provide you with a Certificate as a statement that your organization has achieved certification to the relevant standard(s). The certificate will include important data such as your organization's certification number, the standard for which certification has been granted, and the date of certification. The certificate should be displayed where it will be seen by customers and potential customers.

When copies or elements of the certificate are used in tenders or offered to potential or existing customers, the certificate should be accompanied by the scope of certification document (if issued separately) as it is important for them to understand the scope of activities for which certification has been granted (see 'scope' below).

Incorrect use of the certificate can result in a customer being misled as to the extent of your organization's certification. Clients are obliged to ensure that BSI has been formally notified of the latest address, ownership, changes to key management responsibilities, major management system changes and capability information so that the certificate maintains its currency. Failure to do so may compromise your organization's certification status.

All original certificates remain the property of BSI Group ANZ Pty Limited and must be returned on request.

3.10 Scope of Certification

The scope of certification fully details the scope of your organization's certification in terms of:

- Names and addresses of all locations covered by the certification;
- Achievement of certification to the relevant standard(s) or code(s) of practice
- The capability statement (range of products, services, and activities) for each location covered by the certification and
- Any specific exclusions from the scope of certification

Clients are obliged to ensure that BSI has been formally briefed in a timely manner when any variations occur. Clients should not wait until the next scheduled assessment to notify BSI. Failure to do so may compromise the organization's certification status.

3.11 Suspension or Refusal of Certification

In the event that your organization is unable to comply with the requirements of the relevant standard, BSI may refuse to grant certification or suspend your current certificate.

The decision to refuse certification, and the grounds for that decision, will be communicated to your organization in writing.

When an organization's certification is suspended the organization shall, for the period of suspension or refusal:

- Withdraw and cease to use any advertising or promotional material that promotes or advertises the fact that the organization is certified
- Ensure that all copies of certificates and scopes of certification are removed from areas of public display and
- Cease to use the certification mark on stationery and other documents including media and packaging that are circulated to existing and potential clients, or in the public domain

The organization shall advise BSI in writing of action taken with respect to the requirements listed above;

- BSI shall advise the organization in writing of the certification processes that will need to be completed to restore certification; and
- During the period of suspension the organization shall continue to pay all fees levied by BSI

3.12 Cancellation of Certificate

When an organization's certification is cancelled, the organization shall immediately:

- Cease any advertising and promotional activities that promote the fact that the organization holds certification
- Withdraw and cease to use any advertising and promotional material that promotes the fact that the organization holds certification
- Cease to use relevant certification marks in any way to promote the fact that the organization holds certification and
- Return all certificates and pay outstanding fees

3.13 Variations to Certification

Your organization is required to advise BSI if there are any significant changes to your organization or the product.

Variations to certification may originate from:

- Variations to the scope of certified product
- Major nonconformities
- Voluntary withdrawals
- Withdrawal of certification by BSI Group
- Change of certification scope
- Change of ownership
- Change of management
- Change of company name
- Change of ABN etc.

BSI will determine if the degree of change is significant to require an additional assessment or if the changes can be assessed at the next schedule audit or if the product requires re-assessment.

3.14 Reduction in Scope of Certification

When an organization's scope of certification is reduced, BSI shall issue revised certificates and scopes of certification as appropriate and the certified organization shall:

- Return all superseded certificates
- Ensure that use of the certification mark is adjusted to reflect the reduced scope of certification
- Ensure that all advertising and promotional activities and materials are adjusted to reflect the reduced scope of certification and
- Pay any fees that are applicable for the facilitation of this activity

4 Use of the FDA Logo

The official FDA logo may not be used by the private sector (see FDA Logo Policy at https://www.fda.gov/about-fda/website-policies/fda-logo-policy).

5 Standard Owner Information

The FDA is the owner of this standard.

Additional information, including copies of the Standards may be obtained through their website at https://www.fda.gov/food/guidanceregulation/fsma/

6 Confidentiality

BSI will treat all information in accordance with the Privacy Amendment (Enhancing Privacy Protection) Act 2012

7 Additional Obligations

Following certification, there are a number of managerial responsibilities which your organization will need to observe to maintain BSI's certification. These include:

- Continued compliance with the relevant systems standard(s) or code(s) of practice;
- Compliance with the BSI Standard Commercial Terms and Conditions and obligations as specified in this document as well as other guidance documentation that may be specifically provided from time-to-time;
- Conduct of regular internal reviews of your system, with appropriate documentation of such reviews and of any subsequent corrective actions;

- Notification to BSI of any significant changes in the structure (key responsibilities and management system), ownership and operations of your organization to enable the impact of such changes on the certified ownership system to be evaluated; and
- Notification to BSI of any litigation or serious events or matters that relate to the scope of your certification.
- In case of public food safety events (such as e.g. public recalls, calamities, food safety outbreaks, etc.) that a BSI office becomes aware of, the FCoE (Food Centre of Excellence) shall be notified through food.recall@bsigroup.com within 24 hours of becoming aware.

  There is no obligation to communicate product withdrawals to BSI. The definitions of product withdrawal and product recall are listed below for reference:

  - Product Recall: The removal by a supplier of a product from the supply chain that has been deemed to be unsafe and has been sold to the end consumer and is available for sale (GFSI v7.2:2018).
  - Product Withdrawal: The removal of a product by a supplier from the supply chain that has been deemed to be unsafe and which has not been placed in the market for purchase by the end consumer (GFSI v7.2:2018).
- In case your organization is affected by serious events that impact the FSMS, legality and/or the integrity of the certification which includes legal proceedings, prosecutions, situations which pose major threats to food safety, quality or certification integrity as a result of natural or man-made disasters (e.g. war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.), BSI shall be contacted within 03 working days through critical.food@bsigroup.com.
- BSI will assess the risks of continuing certification and establish a documented policy and process, outlining the steps it will take in consultation with certified organizations, for a reasonable planned course of action. This includes situations where, due to security and/or visa issues in a Country, an audit cannot be performed as unannounced (e.g. when an auditor requires to be in contact with the organization at all times, due to security reasons or a visa must be requested in advance with the assistance/invitation of the certified organization).
- BSI will document and manage the situation using PF1411 (Food Safety - Product Incident Form).
- Based on the information provided, BSI may need to notify the FDA about some recalls.

7.1 Complaints

Your organization is required to keep a record of all known complaints. These records must be made available to the audit team and BSI when requested.

Your organization is required to demonstrate that you have taken appropriate action to address these complaints through investigation and correct any deficiencies found. These actions must be documented.

It may be necessary for BSI to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes or as follow up.

In such cases BSI shall describe and make known in advance to the certified clients the conditions under which such audits will be conducted.

7.2 Certification Agreement

Your Organization is required to meet the requirements of the Certification Agreement. This requires that your organization and products remain compliant with the scheme requirements at and the conditions of certification at all times.

Your organization is required to implement appropriate changes as communicated by BSI in a time appropriate manner.

7.3 Assessment Scheduling

Your organization is required to make all necessary arrangements to allow the evaluation and surveillance activities to take place. This includes but is not limited to; Equipment, Product, Locations, Personnel and Sub-contractors.

7.4 Misleading Statements

Your organization is not permitted to use its product certification in a manner that could bring the BSI into disrepute. This includes making misleading or unauthorized statements. If you are unsure if a statement could be misleading you are advised to contact BSI prior to making the statement. Statements include but are not limited to the use of the logo on non-certified product, advertising (including your website) and internal communication.

If your organization is required to provide copies of their certification documents these must be reproduced in its entirety. Failure to do so may be misleading to the recipient as to the scope of certification.

7.5 Changes to Circumstances

Your organization is required to advise BSI of any changes without delay to circumstances that may affect certification. Examples of such changes include but are not limited to;

- Authorized Representative
- Business name (Legal entity) and Trading Name (where applicable), ABN
- Ownership
- Contact details
- Location, site addresses
- Business activity/ies, scope of certification (Products and Processes
- System Management Number of employees, covering all shifts and sites
- Billing Details

7.6 Observers

From time to time BSI requires an Observer to be in attendance at an audit. This may be related to training of new staff and witness assessment of existing staff. It is a requirement of certification that your organization allows these activities to occur.

Failure to allow this activity to occur may result in cancellation of your certification.

BSI will, at all times, ensure that the use of observers is kept to a minimum and your organization will be advised prior to the assessment activity.

The Observer does not take an active part in an assessment.

As part of the FSMA (Food Safety Modernisation Act) requirements and ANAB, auditors may be accompanied on audits at sites to observe their performance.

8 Complaints and Appeals

Appeals against certification decisions and / or complaints against service delivery levels may be raised with your Auditor. If you remain dissatisfied, contact the BSI Scheme Manager.

All complaints will be investigated and the originator of a complaint will be advised of the outcomes, as appropriate.

BSI will also investigate legitimate documented complaints, relevant to operation of the system, from customers of certified organizations and the accreditation body. Certified organizations shall, at all reasonable times, provide representatives of BSI with access to its premises and records for the purposes of investigating such complaints.

If your organization's application for certification has been refused; or your certified organization' certification has been suspended, withdrawn, or reduced in scope, you may appeal against the decision to a Review Committee constituted and operated as set out below:

- The appellant shall, within 28 days of the disputed advice from BSI, lodge a notice of appeal with an affidavit as to the grounds of appeal;
- The Global Food and Retail Supply Chain Operations and Compliance Director shall be advised within 14 days of receiving the appellant's notice;
- The Global Food and Retail Supply Chain Operations and Compliance Director shall establish a Review Committee;
- The Review Committee shall consist of three persons considered as experts in the area of technology or business relevant to the appeal. The Review Committee shall be constituted as follows:
    - One person expert in the relevant area of technology or business
    - Two persons selected by the appellant from a list of four persons

- The appellant shall represent himself and no legal representation will be allowed unless approved by the Review Committee; and
- The Review Committee will carry out investigations as are required, including assessment of information supplied by the appellant and, within a reasonable time, decide by majority vote whether or not to reverse the original decision.
- The Global Food and Retail Supply Chain Operations and Compliance Director shall give notification of the decision to the appellant within 14 days of the Review Committee decision

To raise a complaint or appeal against the service delivery by BSI or audit outcome please notify;

- Mary Portelli

  Global Scheme Manager

  Email: mary.portelli@bsigroup.com

9 FSMA (Food Safety Modernisation Act) Directory

It is a FSMA (Food Safety Modernisation Act) requirement for your organization's details to be updated on FDA Industry Systems database