



Basics of Food Safety Certification and Audit Preparation

The foundational purpose of any food safety audit is to verify good manufacturing practices (GMP) for the assurance of public safety. Specific standards have been developed by government authorities and industry to elucidate the rules and requirements to achieve this goal. Auditing provides a transparent process to demonstrate compliance with these safety-first standards and helps drive collaboration among stakeholders across the supply chain and within individual organizations.

Audits and Certifications

Audits may be conducted first party as an internal self-assessment, second party as in a proprietary supplier audit, or third party as conducted by an independent certification body. Although each has its value in the GMP environment, this document will focus on preparation for an independent third-party standards-based audit toward achieving or renewing facility certification.

Third-party food safety certification is further classified into:

- Basic Food Safety (HACCP) Certification
- Global Food Safety Initiative (GFSI) Accredited Food Safety Certification Schemes (e.g., BRCGS, FSSC 22000, Global GAP, Primus GFS, SQF)
- Regional Regulatory Certification (e.g., foods imported into the United States must comply with Food Safety Modernization Act [FSMA] and Foreign Supplier's Verification Program [FSVP] requirements)

HACCP Certification

HACCP (Hazard Analysis Critical Control Point) is a food safety management system based on the Codex Alimentarius General Principles of Food Hygiene CXC 1-1969 (2020)¹. It addresses the analysis and control of biological, chemical and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and finished product consumption. HACCP is internationally recognized and is designed to prevent, eliminate or reduce hazards to an acceptable level. Certification can only be achieved through an audit by a HACCP-certified third-party entity such as NSF International. HACCP certification is a legal requirement in several countries, including the United States, the United Kingdom, the European Union (for imported foods), Australia/New Zealand, Japan, China (for imported meat products) and Mexico (for imported meat products).

GFSI Accredited Safety Scheme Certification

With the complexities of increased globalization, the international Global Food Safety Initiative (GFSI) was formed in 2000 to help harmonize food safety standards worldwide. Because GFSI-recognized auditing bodies are benchmarked against well-recognized food safety and quality criteria, GFSI certification allows for consolidation of auditing efforts, thereby reducing the expense and time investment required with multiple audits.

Table 1. Major GFSI Accredited Food Safety Certification Schemes

GFSI Accredited Food Safety Certification Scheme	Official Name	Region	Accreditation Details
BRCGS²	British Retail Consortium Global Standards	United Kingdom EU	BRCGS is used by suppliers in more than 100 countries to ensure food safety. BRCGS certification allows companies to demonstrate compliance with the GFSI and gain access to EU retailers. BRCGS certification is suitable for processing, packing, and manufacturing operations in which open food is handled, packed, stored, and distributed.
FSSC 22000³	Foundation for Food Safety Certification	Global	FSSC 22000 is a food safety management standard and certification scheme similar to ISO 22000 but with additional requirements to meet the requirements of a GFSI standard. An NSF International Certification (ISO 22000) is accredited for FSSC 22000.
Global GAP⁴	Global Good Agricultural Practices	Global	Global GAP certification addresses good agricultural and environmental management practices toward satisfying the basic food safety and sustainability specifications of retailers and major buyers worldwide. The Global GAP Integrated Farm Assurance (IFA) standard is recognized in more than 100 countries. Certification is suitable for agricultural producers, packers, and processors.
Primus GFS⁵	Primus Global Food Safety	Global	Primus GFS is a food safety certification scheme currently recognized by 22 countries. It is designed to be used for primary production (including horticultural, grains, and pulses) and manufacturing sectors at a global level.
EFI	Equitable Food Initiative	Americas	EFI partners with growers, retailers and farmworkers to build the necessary skills and adopt a culture of continuous improvement on farms and brings increased assurance to retailers and consumers about how the fresh fruits and vegetables they purchase are grown (Equitable Food Initiative Food Safety Standards, Guidance, & Interpretations Version 2.0 (2018))
Global Seafood Alliance	Global Seafood Alliance®	Global	GSA advances responsible seafood practices worldwide through education, advocacy and demonstration. GSA convenes seafood industry leaders, academia and NGOs to collaborate on cross-cutting issues like environmental and social responsibility, animal health and welfare, food safety and recently expanded coverage to wild seafood.
Freshcare	Freshcare	Global/Australia	Freshcare (Australian-owned and operated) provides internationally recognized assurance standards for the fresh produce and wine grape industries. Focus is on Food Safety and Quality (FSQ4.2) and Environmental Code of Practice (ENV3).
SQF⁶	Safe Quality Food	Global	Safe Quality Food (SQF) Program, based on the HACCP codex is a rigorous and credible food safety and quality program that is recognized by retailers, brand owners, and food service providers world-wide. The SQF family includes several certification levels: Food Safety Fundamental Program, Food Safety Program, and Food Quality Program. SQF certification is suitable for any food processing or packing operation in which food is produced, handled, processed, packed, stored, and distributed.

Regional Regulatory Requirements

In addition to HACCP and globally recognized food safety schemes, regulatory requirements vary by region. The table below provides a representative listing of region-specific agencies and guidance.

Table 2. Regional Food Safety Agencies and Guidance, Partial Listing

Country	Regulatory Agencies and Guidance
Canada	• Health Canada (Canadian Food Safety and Quality Program) • Canadian Food Inspection Agency (CFIA) • Agriculture and Agri-Food Canada (AAFC)
United States	• U.S. Food and Drug Administration (FDA) • Food Safety and Inspection Service (FSIS) of the USDA • Environmental Protection Agency (EPA) • National Marine Fisheries Service (NMFS)
Australia/New Zealand	• Food Standards Australia-New Zealand (FSANZ) • Biosecurity Act 2015 and Imported Food Control Act 1992
European Union	• European Food Safety Authority (EFSA)
China	• China Food and Drug Administration (CFDA) • Peoples Republic of China (PRC) Food Safety Law (2015)
India	• Food Safety and Standards Authority of India (FSSAI) • Food Safety and Standards Act, 2006
Latin America	• Scheme in Chile facilitated by FAO (Food & Agriculture Organization of the United Nations) • Under development in many other countries - some based on US agencies, others on FAO or Codex Alimentarius standards

1 Planning

2 Execution

3 Corrective and Preventative Action

4 Verification

5 Evaluation

Food Safety Audit Process

Typically, a comprehensive food safety audit follows a 5-step process:

Here, we will focus on the steps of audit execution (Step 2 above, Execution) with a detailed discussion of facility-based, pre-audit preparation.

Phase 1. Desk Audit

The initial phase of a food safety audit is referred to as a **desk audit**. This stage focuses on document review. From an auditor's perspective, proper documentation is the only acceptable evidence that required food safety procedures have been followed. Documents reviewed during the desk audit include:

- Standard Operating Procedures/ Sanitation Standard Operating Procedures
- Work Instructions
- Food Safety Policies
- Food Safety Forms and Templates
- Records (3+ months)
- Other Food Safety Related Documents

Phase 2. Initial Food Safety Audit

Following the correction and documentation of any non-compliance identified in the desk audit, the initial food safety audit focuses on evaluating evidence of program efficacy. This phase includes evaluation of the following processes:

- Food Safety Hazard Risk Assessment
- Employee Training
- Preventative and Corrective Action Implementation
- Process Control Implementation
- Record Keeping Practices

Figure 1. Food Safety Audit Topics

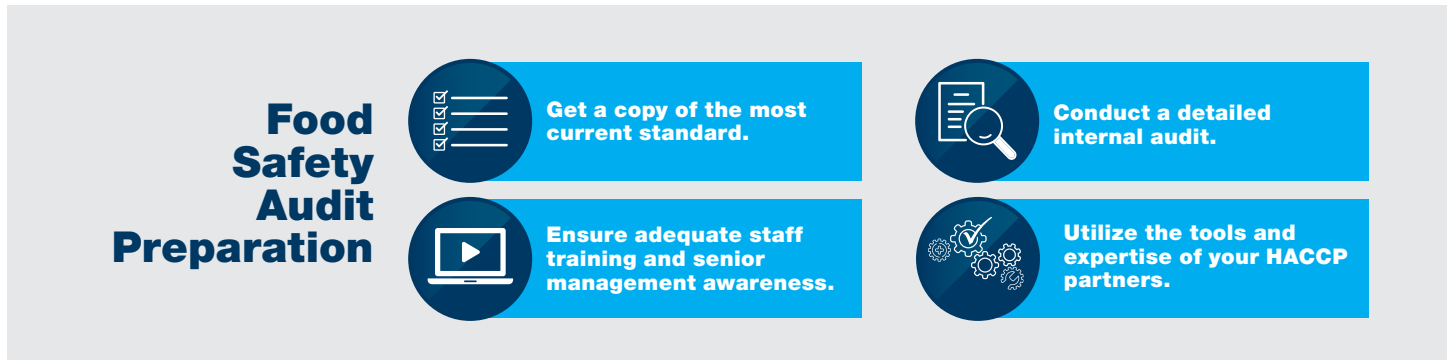


Although it is standard practice for the Food Safety Audit to include an in-person visit, remote and partially remote audits have become more common. For example, audits have been conducted using (Google) Glass with NSF International's EyeSucceed™ software. In these cases, a pre-audit package containing Glass, thermometer, alcohol wipes, flashlight, etc., are sent to the facility in advance. The auditee then live streams with the auditor who walks through the audit from a remote location as if physically present.

Food Safety Audit Preparation

The primary goal of audit preparation is an essential understanding of the specific certification scheme requirements and thorough, well-documented compliance with them.

Figure 2. Steps for Audit Preparation



1. Obtain a copy of the most recent certification scheme requirements to ensure auditor expectations and requirements are very clear.

It is critical to have a thorough understanding of what the auditor will be evaluating so you can be adequately prepared. Standards change over time, so be certain you are referencing the most current certification scheme. If not provided by your auditor in advance, this information can be sourced from the specific certification body.

Also, keep in mind the value of flawless record-keeping. Your auditor will expect your records, including previous audits and corrective actions, to be organized and accessible. This level of preparation will not only support audit efficiency, but will also assure the auditor that your processes are well-controlled, and that management prioritizes the food safety program.

2. Conduct a detailed internal audit to ensure compliance with the certification scheme.

Nothing prepares an organization quite like an internal audit. It provides the opportunity to discover and correct potential deficiencies and prepare the team for audit day. Keep in mind that from the auditor's perspective, if it is not documented, it did not happen.

- In addition to the specific scheme requirements, ensure the foundational prerequisite processes are in place, including Good Manufacturing Processes (GMP), Sanitation Standard Operating Procedures (SSOP), and Allergen Control Programs.
- Ensure the risk-based food safety management systems (HACCP) is proactive, comprehensive, and well-documented.
- Review checklists, monitoring forms, progress reports and other related documents to ensure they are complete, accurate and easily accessible.
- Ask questions of the team to get them comfortable with addressing possible inquiries and providing informed responses.
- Resolve discovered process or documentation issues prior to audit day.



3. Ensure adequate staff training and senior management awareness to demonstrate internal knowledge and commitment to food safety processes.

Be certain the team is current with all required HACCP protocol training and documentation. Senior management should also be well-acquainted with the goals and structure of the food safety program. This knowledge base will demonstrate commitment, confidence and compliance.

- Ensure training records are complete and up to date.
- Invite senior management to emphasize the importance of the food safety program and the team commitment required to maintain compliance toward a successful audit.
- Prepare the internal team for auditor questions – educate them on how to best respond, including details and documents.

4. Utilize the tools, support and expertise of your HACCP partners to demonstrate verification accuracy, data integrity and transparency.

Now is the time to be certain that all your tools are operating at peak performance. Partnership with a profoundly knowledgeable HACCP partner like Hygiena® can help streamline this process, providing you with the third-party certifications, validation data, consolidated reporting and integrated trend analyses most likely to impress your auditor.

The day of the audit can be stressful, but proper preparation will instill confidence in the team and the auditor. Use your audit as an opportunity to learn, highlight your expertise, and recognize your team for a job well done.



Hygiena® | Your HACCP Partner

With in-depth cleaning and sanitation verification expertise, Hygiena provides the tools and services to support food safety program excellence and exceptional audit performance.

Integrated, Quantified and Scalable ATP and Allergen Testing: Tools and Tests

EnSURE® Touch Luminometer for Cleaning Verification

EnSURE Touch is an advanced, hand-held luminometer-based monitoring system that collects, analyzes and consolidates data for a wide range of ATP and allergen tests, across multiple locations, for rapid and reliable sanitation verification and documentation accuracy.



SureTrend®: An All-in-One Food Safety Data Management Solution

SureTrend® is a comprehensive, cloud-based data management solution that streamlines and centralizes food safety testing data from EnSURE Touch and other data sources. It empowers food safety professionals to gain actionable insights, assess risks and generate audit-ready reports effortlessly.



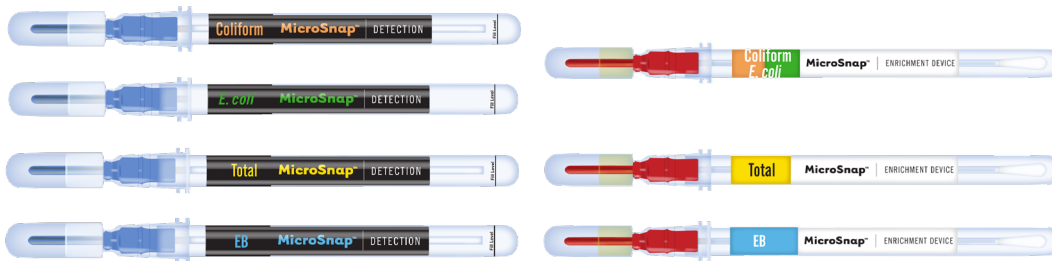
Hygiena Allergen Tests

Hygiena allergen tests provide the tools for quantitative on-site results. Fully compatible with the SureTrend management system, consolidated cleaning verification reports and trend analysis are customizable and readily accessible.



Hygiena Indicator Organism Tests & PCR Assays

Hygiena indicator organism and pathogen ATP tests offer full compatibility with EnSURE Touch and SureTrend Cloud data analysis software for comprehensive test result consolidation and reporting. Hygiena's MicroSnap® product line utilizes a novel bioluminogenic reaction for the detection and quantification of TVC, coliforms, *E. coli*, and *Enterobacteriaceae*.



Moreover, Hygiena's expertise expands beyond operations-based HACCP support, providing gold standard, real-time, quantitative PCR tools and tests for method validation and reference laboratory testing needs.



As your dedicated HACCP partner, Hygiena provides the tools, tests and support toward a successful audit experience. To learn more about Hygiena, visit: www.hygiena.com.

Food Safety Acronym Glossary

Acronym	Description
ANZFA	Australian New Zealand Food Authority
AFGC	Australian Food and Grocery Council
BRC	British Retail Consortium
EFSA	European Food Safety Authority
FDA	Food and Drug Administration
FSA	Food Standard Agency
FSI	Food Standards Industry
FSQ	Food Safety & Quality
FSMA	Food Safety Modernization Act
FSMS	Food Safety Management Systems
FSSC 22000	Foundation for Food Safety Certification
GFSI	Global Food Safety Initiative
GSA	Global Seafood Alliance
HACCP	Hazard Analysis and Critical Control Point
HARPC	Hazard Analysis and Risk-Based Preventative Controls
IFS	International Food Standard
ISO	International Organization for Standardization
NSF	The National Sanitation Foundation
SFBB	Safer Food, Better Business
SQF	Safe Quality Food
SSOP	Sanitation Standard Operating Procedures

¹ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf

² <https://www.brcgs.com/our-standards/food-safety/>

³ <https://www.fssc22000.com>

⁴ <https://www.fssc22000.com>

⁵ <https://primusgfs.com>

⁶ <https://www.sqfi.com>