HACCP Certification Process

Hazard Analysis Critical Control Point (HACCP) is an effective management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to processing, distribution and consumption of the finished product. HACCP is an effective and rational means of assuring food safety with the primary goal of preventing problems from occurring through the implementation of a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles: (1) Hazard Analysis; (2) Critical Control Points; (3) Critical Limits; (4) Monitoring; (5) Corrective Actions; (6) Verification; and (7) Record Keeping and Documentation.

HACCP CERTIFICATION

HACCP Certification is an internationally recognized approval system that verifies and acknowledges a food facility has successfully developed, documented and implemented systems and procedures in accordance with HACCP. HACCP certification requires a rigorous review of a facility's HACCP Plan and HACCP system in order to verify it meets all compliance standards. A food facility must successfully pass a certification audit provided by a qualified independent third-party food safety auditor from a registered external certification body in order to obtain HACCP certification. Upon successful completion of the certification audit, the facility will receive a HACCP certificate verifying the facility is certified.

It is important to understand that HACCP certification is not a one-time process. A facility's HACCP certification is generally valid for a period of three years. After the completion of the three year period, a facility must obtain a new certification through the successful completion of another HACCP certification audit. Additionally, HACCP auditors will perform surveillance audits to verify the facility is continuing to comply with HACCP standards between the issuance of a facility's certification and its expiration.

BENEFITS OF HACCP CERTIFICATION

There are many benefits of implementing HACCP in a food facility and obtaining HACCP certification. The principal benefit is the facility's demonstrated commitment to food safety which results in the production of high quality food that is safe from biological, chemical and physical hazards. A facility's HACCP certification demonstrates the facility's commitment to food safety and communicates to its customers and the wider community that it has documented control systems in place to control hazards.

HACCP certification can transform a facility's brand and act as an effective entry-to-market tool, opening up new business opportunities around the world. Many customers, particularly those in the U.S., require suppliers to have a HACCP based food safety management system in place and will request HACCP certification to provide evidence of this. HACCP certification and successful implementation and compliance with the internationally recognized standards of the HACCP system will greatly benefit international trade business opportunities and can be particularly beneficial when a facility is subject to inspection and audit by customers implementing a Foreign Supplier Verification Program as required by the FDA in order to facilitate imports of the facility's products.

HACCP certified facilities are empowered to prevent food safety problems from occurring enabling them to avoid the serious effects of product recalls due to the production of unsafe food, including damage to the reputation of the facility and the accompanying financial loss.

HACCP CERTIFICATION PROCESS

There are many steps in the HACCP certification process. Implementing the HACCP system and successfully obtaining HACCP certification takes considerable planning, management commitment and human resources that have been trained in the process of HACCP. The principal steps in the HACCP certification process include:

1. Training

2. HACCP Plan Development

3. Certification Provider Selection

4. Stage 1 Audit

5. Stage 2 Audit

6. Certification

1. HACCP TRAINING

The first step in obtaining HACCP certification is to provide training in the principles and application of HACCP to ensure the facility's personnel fully understand the requirements of HACCP. A facility may choose to engage an external food safety consultant to provide the necessary training if they do not have a qualified expert on staff or they may choose to utilize training courses accredited by the International HACCP Alliance and/or the FDA.

The facility's HACCP team members and the personnel responsible for implementing and monitoring critical control points must successfully complete training in the development and application of the HACCP system at least equivalent to that received under a standardized curriculum recognized as adequate and accredited by the FDA and/or the International HACCP Alliance by FDA or be otherwise qualified through job experience to develop and apply a HACCP food safety system. All applicable training in the development and application of the HACCP system must be documented in records, including the date of the training, the type of training, and the persons trained.

2. HACCP PLAN DEVELOPMENT

A HACCP plan must be developed by the food processing facility and tailored to its individual product, processing and distribution conditions. Seven basic principles are employed in the development of the HACCP plan including hazard analysis, critical control point identification, establishing critical limits, monitoring procedures, corrective actions, verification procedures, and record-keeping and documentation. The HACCP plan must also address any regulatory requirements in the country of processing and any country where the product is exported.

After the HACCP plan has been developed, it is imperative to ensure the plan is implemented correctly. A facility generally will be required to have at least 4 to 8 weeks of HACCP records to be able to demonstrate system compliance to a certification provider in order to receive HACCP certification.

3. CERTIFICATION PROVIDER SELECTION

HACCP certification is granted by an independent third-party external certification provider that has auditors with the necessary knowledge and skills to undertake an assessment of the HACCP system and HACCP plan. A food processing facility should always ensure that the external third-party certification provider has the necessary qualifications and accreditation to provide this certification service. A facility should also request a documented quote that outlines the certification activities to be performed and details all of the expected costs.

The Accredited Third-Party Certification Program is a voluntary program in which the FDA recognizes accreditation bodies that have the responsibility of accrediting third-party certification providers. The certification providers listed in this FDA program have received accreditation to conduct food safety audits and issue certifications of foreign food facilities. It is recommended that food processing facilities select a HACCP certification provider that is recognized by the FDA and listed in this program. The FDA's Accredited Third-Party Certification Program list of certification providers and accreditation bodies can be accessed at the following website: https://datadashboard.fda.gov/ora/fd/tpp.htm .

4. STAGE 1 AUDIT

A food processing facility must successfully complete a certification audit of its facility by a qualified independent third-party food safety auditor from a registered external certification body in order to obtain HACCP certification. The purpose of the audit is to verify and validate that a facility's HACCP Plan and HACCP system implementation meets all HACCP compliance standards regarding food safety and the control of the hazards identified for the food being processed.

Once a facility has selected a certification provider, the audit process will normally occur in two stages. During the Stage 1 audit, the auditor will assess the facility's overall preparedness for the certification process. The auditor will conduct a document review of the facility's HACCP plan and accompanying documents including the Current Good Manufacturing Practices and Standard Operating Procedures. The auditor will also conduct a gap analysis of the facility's HACCP plan against the HACCP standards.

The purpose of the stage 1 audit is to evaluate and determine if the facility's HACCP plan complies with the HACCP standards to properly control the hazards that exist for the food product being processed. This process will identify areas of compliance the facility has fulfilled and identify anything the facility has missed in their HACCP plan that the HACCP standard requires the facility to address before proceeding to the stage 2 audit.

The auditor will provide a Stage 1 Audit Report to the facility. The Stage I Audit Report outlines any identified shortfalls and areas with which the auditor was concerned. These specific shortfalls and areas identified in the Stage 1 Audit Report may be deemed 'nonconformance' during the Stage 2 audit.

One of the primary purposes of the Stage 1 Audit Report is to enable the facility to take action prior to undergoing the next stage. Once the facility has completed any required changes to their HACCP plan to comply with the HACCP standards, the auditor will provide a Stage 2 audit plan and work with the facility to schedule the stage 2 audit.

5. STAGE 2 AUDIT

The Stage 2 Audit is conducted at a suitable period after the Stage I Audit, giving the facility time to implement any action resulting from the stage 1 findings.

The purpose of the Stage 2 Audit is to evaluate and determine the facility's compliance in its actual implementation of its HACCP plan against the HACCP standards to properly control the hazards that exist for the food product being processed. It includes an in-depth evaluation of your processes and documented information to assess your food safety management system and HACCP standards. The auditor will do this by performing the following:

- An onsite inspection of the facility;
- Interviews of the relevant staff members to determine their level of understanding;
- Examination of the food safety / HACCP records generated as part of system implementation
- Review of the HACCP plan and any associated policies, procedures, documents and forms

For example, the HACCP standards require that a system for monitoring is established for each critical control point (CCP). The auditor would, depending on the type of CCP:

- Check that monitoring records exist for a defined time frame
- Ask staff to demonstrate the monitoring process
- Review the HACCP plan to determine monitoring relevance to the identified food safety hazard

All assessment conclusions are based on sampling of audit evidence, providing the opportunity for the facility to demonstrate effective implementation of the HACCP plan and system, control over the processes and progress made towards achieving the facility's stated quality objectives.

On conclusion of the Stage 2 Audit, the auditor will hold a 'closing meeting' during which the Stage 2 Audit Report will be presented and the findings of the audit will be explained including any non-conformances observed that need to be addressed by the facility. The facility will also have an opportunity to ask any questions related to the process.

The auditor will confirm whether or not a recommendation for certification can be made at this stage. This recommendation will reflect the level of findings identified during the audit. Observations will also be made where there are identified opportunities for improvement or best practice. Consequently, if the auditor identifies major non-conformances, a follow-up audit will be required. In this case, the facility will then be granted a specified time frame to fix any non-conformances identified before the follow-up audit is performed.

Upon successful completion of the certification audit, the auditor will compile a detailed Final Report to be reviewed and approved by a certification signatory of the certification provider. Once the certification decision has been confirmed the HACCP certificate is issued to the facility along with the final report.

A facility's HACCP certificate will generally be valid for a period of three years. So, re-certification must be done every three years. The certification provider will also continue to audit the facility and system through surveillance audits on a routine basis and the HACCP certificate can be revoked at any time if the facility is found to breach any certification or regulatory requirements. A facility will need to continuously maintain, improve, review and update the HACCP system. HACCP standards, food law and customer requirements are always changing so a facility must ensure it remains relevant, current and compliant.

APPENDIX A

Frequently Asked Questions Regarding the HACCP Certification Process

What should a facility do to prepare for the HACCP certification audit process?

The most important thing a facility should do in preparation for the HACCP Certification audit process is to conduct an internal audit to ensure the facility's HACCP plan reconciles with its documentation and correctly employs the HACCP principles. However, there are some additional things a facility can do to help the process run smoothly.

First, a facility should nominate a primary contact to manage the relationship with the certification provider. This person will be responsible for coordinating the certification process and acting as a liaison for the auditing personnel.

Second, a facility should be prepared to provide all the required documentation upfront. The facility should ensure that all documentation is available, complete, and accurate. The documentation available should also include copies of your internal audit, complaints and resolutions, and any management reviews. A successful and efficient documentation review will make an audit much easier.

Third, a facility will increase the efficiency of the audit by providing timely responses to all the identified nonconformities and respond promptly with corrective actions. The auditor will provide the facility with a nonconformity report and which will include a due date. The facility must implement and document corrective actions that identify the root of the nonconformity and eliminate it. A facility will not receive a HACCP certificate while those nonconformities remain open.

How long does a HACCP audit take?

HACCP audits normally take between one and five days depending on the size of the facility and the scope of the audit. It is important to note that audits take less time when a facility complies with their HACCP plan in its entirety. It is imperative that a facility not schedule their Stage 2 Audit prematurely.

Once a facility successfully completes the initial certification audit, the facility will also need to pass a surveillance audit that will take place over the following two years. A facility's certification body may or may not inform the facility about the timing of the surveillance audit in advance. So, a facility needs to keep their HACCP standards up-to-date at all times.

Looking holistically, the entire HACCP certification process can take anywhere between 3 to 12 months upon consideration of each individual phase of the process which includes learning the HACCP principles, HACCP plan development, implementation, audit, review and issuing the HACCP certificate.

What does it cost to gain HACCP certification?

This will depend on the scope of the HACCP food safety system. When budgeting for HACCP certification, costs to be considered include: (1) Developing the HACCP plan; (2) Implementing the HACCP plan; (3) Training all the food handlers and other relevant staff; (4) Laboratory testing of product; (5) Auditing costs of certificate provider; and (5) Annual HACCP Accreditation fees. The cost of HACCP certification can range from 5 to 10 thousand U.S. dollars depending on the size and location of the facility, as well as the certification provider, the audit criteria and the number of audits required to pass.

APPENDIX B

HACCP Certification Process Flow Chart

HACCP CERTIFICATION PROCESS

ASSESSMENT   YEAR 1   YEAR 2   YEAR 3

STEP A Agree Contract

STEP B Optional Pre-Audit

STEP C Stage 1 Certification Audit

STEP D Stage 2 Certification Audit

Issue Certificate after successful audit

STEP E Visit 2

Visit 3

Visit 4

Visit 5

Visit 6

STEP F Recertification Visit 1R

VISIT FREQUENCY NOTES:
Annual surveillance – 2 visits;
Twice-yearly surveillance – 5 visits