Implementing an effective HACCP Program and prerequisite programs to ensure an environment that is capable of producing safe product is the first step to building a Food Safety Management System (FSMS)
Introduction to Vinca LLC and 22000-tools.com

Cynthia Weber, our president, is an SQF Registered Consultant and FSSC 22000 Lead Auditor for the Food Processing and Food Packaging Manufacturing industries.

Ms. Weber's 25 years of experience and expertise implementing Food Safety Management Systems is available to you in the Online Tools and Training we offer, and through the customer support we provide to customers throughout your implementation project.

Vinca is here to help you achieve GFSI recognized Certification for food safety management systems. Our customers use Online Training and Development Tools to learn and train staff, and to design and implement systems for:

- SQF
- FSSC 22000, and
- ISO 22000

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Introduction to HACCP

**Hazard Analysis and Critical Control Point (HACCP)** is an internationally recognized system for reducing the risk of safety hazards in food.

A HACCP System requires that potential hazards are identified and controlled at specific points in the process.

- Biological
- Chemical
- Physical

Any company involved in the manufacturing, processing or handling of food products can use HACCP to minimize or eliminate food safety hazards in their product.

What HACCP is not:

- HACCP is not a Quality Control system
- HACCP is not a government program (although there are regulatory requirements for companies to have a HACCP program in place. Visit FDA.gov for information)

Building a HACCP System

Implementing a HACCP System requires that both Prerequisite Programs and HACCP Plans are implemented.

- **Prerequisite programs** are programs that are put in place in the facility to control hazards in the environment, preventing contamination of the product. Prerequisite programs ensure a hygienic environment, and good manufacturing processes for personnel that reduce the risk of contamination of the food product.

- **HACCP Plans** are prepared for each process or product, and identify possible hazards and controls in place to make sure the hazards are eliminated or controlled to ensure acceptable levels in the food product.
Why use HACCP?

Awareness of food-borne illness is increasing and concern throughout the industry is driving the use of HACCP and HACCP based certification programs.

- Global market place
- Increasing incidents of food-borne pathogens
- New pathogens emerging
- Need to protect Brands, control risks

Food Safety Management Systems

To protect themselves, multinational food manufactures, retailers and grocers are asking their suppliers to implement a Food Safety Management System.

The Global Food Safety Initiative, GFSI has benchmarked a number of Food Safety Management Systems Certification programs, all of which are HACCP based.

- SQF
- FSSC 22000
- BRC
- IFS
- Others

Benefits of HACCP

The primary purpose of a HACCP system is to protect people from food borne illness, but the benefits of the system also extend to the company.

- Increased confidence in your products
- Ability to reach markets and customers that require a HACCP based system
- Reduced Liability
- Effective process management
- Improved quality and consistency
Prerequisite Programs

Introduction
Prerequisite Programs are programs and practices that are put in place to maintain a sanitary environment and minimize the risk of introducing a food safety hazard.

- Provide suitable building and equipment design and construction
- Plan and Implement Pre-requisite programs
- Address statutory, regulatory and customer requirements as well as other recognized guidelines
- Learn more about prerequisite programs for GFSI recognized certification programs

Consider the points below as you plan your prerequisite programs. If you are implementing a Food Safety Management System for certification, follow the prerequisite program requirements in the relevant standard.

Building and Equipment Design and Construction
Detailed requirements for the building and equipment construction and design requirements
- Site Requirements and Approval
- Food Handling Areas
- Water and Ice Supply
- Storage Facilities
- Separation of Functions
- On-site Laboratories
- Staff Amenities
- First Aid Facilities
- Waste Disposal
- Exterior

The first step to building an effective HACCP Program is to establish programs and practices that ensure a clean hygienic environment for your product processing or handling.

Consider your building and equipment. How do they contribute to the safety of your product?
Site Requirements and Approval

Your facility and site must be located so that other operations nearby do not jeopardize the safe and hygienic operations at your facility.

- Evaluate possible hazards in the area and establish control measures if needed
- Validate the efficiency of measures put in place
- Monitor and periodically review the measures
- Obtain approvals from relevant authorities for the construction and operation of your facility

Food Handling Areas

Use surface materials that do not contribute a food safety risk, are smooth, easy to clean, and not damaged by cleaners:

- Product contact surfaces
- Walls
- Ceilings
- Floors

Floors, Drains and Waste Traps

Floors in food handling areas must be:

- Smooth
- Impact resistant
- Graded and drained
- Impervious to liquids
- Easily cleaned
- Drained

Walls, Partitions, Doors and Ceilings

Internal surfaces in food handling areas must also be

- Durable
- Smooth
- Impervious

Use light colored finishes to enable cleaning to be evaluated.

Walls, Partitions, Doors and Ceilings

Round junctions for easy cleaning and to prevent food debris accumulating. If junctions are not rounded, document a cleaning process.
Ducting, Conduits and Pipes
Prevent contamination from dust or material buildup on pipes by:
- Recessing into walls or ceilings, or
- Mounting far enough away from surfaces to allow for effective cleaning

Doors, Hatches and Windows
Requirements are that:
- Doors and hatches must be solid
- Windows must be shatterproof glass in processing or food handling areas
- Pest and fly proof windows
- Ceilings must be in place to prevent contamination of product

Stairs, Catwalks and Platforms
When in food handling areas:
- Design and construct to prevent contamination risks
- If they cross over production or processing areas make sure that the structure and the traffic do not contaminate the areas underneath

Lighting and Light Fittings
When in food handling areas:
- Lighting must be sufficient, and appropriate intensity for people to carry out tasks

Inspection Area
Provide a suitable area if inspection of product in the processing area is needed:
- Easy access to hand washing facilities
- Sufficient lighting for the inspection of product
Dust, Fly and Vermin Proofing

Prevent access by:
- Making sure openings are effectively sealed when closed
- Providing personnel access doors fitted with self closing device and fly proofed
- Fly proofing external doors
- Locating pest control devices so they do not pose a risk of contamination

Ventilation

Provide adequate ventilation
- In enclosed processing and food handling areas
- In cooking areas
- Use extractor fans and canopies where large amounts of steam are generated

Equipment, Utensils and Protective Clothing

Minimize the risk of contamination from equipment:
- Equipment
  - Design and construct of appropriate materials, and make them easy to clean, dismantle and properly maintain

Equipment, Utensils and Protective Clothing

Minimize the risk of contamination from utensils:
- Utensils such as containers, tubs, bins
  - Constructed of non toxic materials, smooth and easy to clean

Equipment, Utensils and Protective Clothing

Minimize the risk of contamination from drainage:
- Equipment that drains
  - Make waste and overflow water discharge directly to floor drainage systems
Equipment, Utensils and Protective Clothing

Minimize the risk of contamination from clothing:

- Protective Clothing
  - Made of material that is non toxic and easily cleaned

Cleaning of Processing Equipment, Utensil and Protective Clothing

Provide for effective cleaning:

- Processing Equipment, utensils and clothing
- Make sure there is a suitable area, properly equipped for cleaning operations
- Provide racks to store cleaned items

Hand Washing Facilities

Provide hand washing signage and facilities at all personnel access points and near processing areas as required.

Hand basins must be non-corrodible and supplied with:

- Potable water
- Liquid soap in dispenser
- Paper towels
- Waste container for paper towels

Hand Washing Facilities

High risk or areas where food is exposed must also have

- Hands free taps
- Hand sanitizer

Protective Clothing Racks

Keep racks for storage of protective clothing near personnel access doorways

- To provide temporary storage when staff leaves the area

Vehicles

Design and operate vehicles used in processing zones or for food contact or handling in a manner that prevents food safety hazards.

- Do not use diesel or gasoline powered vehicles.

- Include the vehicles on your cleaning schedule
Water and Ice Supply
Water and air often come in contact with product and must be controlled to prevent introducing contaminants.
- Provide clean potable water for processing, for use as an ingredient and for cleaning purposes
- Make sure that supplies of hot and cold water are sufficient to meet requirements
- Do not allow cross contamination of potable and non-potable lines
- Clearly identify non-potable lines
- Use non-return devices on non-potable lines

Water and Ice Supply
Where ice is used during processing or as an ingredient
- An adequate supply made from potable water must be provided
- Storage areas must comply with requirements and minimize contamination

Storage Facilities
Cold Storage, Freezing and Chilling of Foods
- Confirm performance of freezing and chilling
- Design to allow for hygienic refrigeration
- Make areas easily accessible for inspection and cleaning
- Provide sufficient capacity
- Meet requirements for walls, ceilings, floors and light fittings
- Defrost and condensate lines must be controlled and discharge into drainage system
- Monitor conditions, use temperature recording devices
- Design loading and unloading docks to protect product

Storage Facilities
Dry Ingredient and Shelf Stable Goods Storage
- Locate away from wet areas
- Designed to protect product from contamination and deterioration
- Light fittings must comply with requirements where product is not enclosed or cased

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Storage Facilities

Packaging
• Locate away from wet areas
• Designed to protect packaging from contamination and deterioration
• Light fittings must comply with requirements
• Use storage racks made of impervious materials
• Allow room for cleaning of floors and room
• Room must protect from vermin

Storage Facilities

Equipment and Receptacles
• Provide storage areas that allow hygienic and efficient storage
• Store utensils and packaging away from hazardous chemicals and toxic substances

Storage Facilities

Hazardous Chemicals and Toxic Substances
• Store securely to prevent hazards to staff, product, packaging, product handling equipment or areas
• Separate pesticides, fumigants and insecticides from sanitizers and detergents
• Store chemicals in original containers
Storage Facilities
Hazardous Chemicals and Toxic Substances
Requirements for storage areas:
• Comply with regulations
• Prevent cross contamination
• Be lockable
• Adequate ventilation
• Appropriate signs
• Instructions on safe handling
• An up to date inventory
• Emergency equipment and protective equipment, shower and wash facilities

Alternative Storage and Handling of Goods
If alternative storage conditions are used, risk analysis must ensure that there is no risk to the goods:
• Contamination
• Adverse affect on food safety

Separation of Functions
Design the flow of processes in the facility:
• To prevent cross contamination
• Provide a continuous flow or product through the process

Receipt of Raw Materials
Separate the receiving of dry ingredients and frozen and chilled materials.
• Segregate unprocessed raw materials at receipt to prevent cross contamination

Thawing of Product
If processes include thawing of product:
• Provide appropriate rooms and equipment
• Water thawing must be continuous flow
• Air thawing requires monitoring of temperature and time
• Contain and dispose of cartons and packaging
High Risk Processes
Control conditions for processing:
• Segregate sensitive areas where a "kill" step or "food safety intervention" takes place
• Limit access to staff dedicated to that function
• Provide areas for putting on protective clothing specific to the area
• Design product transfer points to protect and minimize cross contamination

Other Processes
Specialty foods (Kosher, HALAL, Organic, or other foods requiring segregation such as those segregated from allergen containing foods) require:
• A method of physically separating ingredients
• Separate rooms for processing, or
• That production is carried out after thorough cleaning and sanitation of the line, and
• Separate transport units or isolation from non-specialty product

On-Site Laboratories
Locate laboratories away from food processing or handling and:
• Limit access to authorized personnel
• Isolate and contain waste
• Display signs to identify the area as restricted

Staff Amenities
Provide areas for staff with appropriate lighting and ventilation, including:
• Facilities for staff and visitors to don protective clothing
• Changing rooms for staff of high risk processing operations where clothing can be soiled
• Areas for storage of street clothing and personal items
• Showers if required
Laundry
Laundry services must be available for clothing worn in high risk areas, or areas where clothing can be heavily soiled.
• Provide laundry service
• Provide changing rooms

Sanitary Facilities
Provide sufficient restroom facilities:
• Easily accessible
• Located away from processing and production
• Sanitary drains separate from other drains in the facility
• Have hand wash facilities and signage immediately outside toilet rooms

Lunch Rooms
An area for eating must be provided separate from food handling and processing areas:
• Ventilated and well lit
• Adequate tables and seating areas
• Be equipped with a sink with hot and cold water
• Have refrigeration and heating equipment
• Display hand washing requirements prominently

First Aid Facilities
Make sure that first aid facilities are available, and arrangements made if an injury or illness requires additional care.

Waste Disposal
Waste materials should be identified, collected and removed to prevent introducing or spreading contaminants:
• Dry waste
• Liquid waste
Exterior
Make sure that grounds surrounding the facilities are well maintained
• Minimize dust
• Free of waste and debris
• Limit harborage for pests and vermin
• Keep paths, roadways, loading areas maintained
Managing Prerequisite Programs

Plan and Document your Program
Design and document Prerequisite Programs.

Use information from:
• Your gap analysis
• The certification standard you are using, if applicable.
• Regulations
• Industry and other sources

Identify Verification Activities
How will you verify that the program is implemented and in compliance? Document the responsibility, frequency, methods and records of planned verification activities. This may be an audit of the program, or other activity.

Identify a Corrective Action Plan
What will be done if this program is found to be out of compliance? Identify who is responsible for determining if any product might have been affected, and identifying and controlling the product. How will the underlying problem be corrected.

Who must be trained on the Prerequisite Program?
Consider who’s activities or responsibilities might affect the effectiveness of the program. Identify who should be trained, and include training requirements on the table for the PRP.

Consider:
• Those that have responsibilities for the program
• Those that have verification responsibilities
• Those that work in areas of the facility included in the PRP
• Information that should be included in general employee training programs
The Principles of HACCP

HACCP:

- It is a system designed to prevent food safety hazards
- It is used in a wide variety of food industries, and used around the world
- HACCP has been incorporated into many food safety management systems

Seven Principles of HACCP

HACCP is based on seven principles:

- Conducting hazard analysis
- Determining critical control points
- Establishing critical limits
- Establishing monitoring procedures
- Establishing corrective action procedures
- Establishing verification procedures
- Establishing records and documentation procedures

Principle 1: Hazard Analysis

The food safety team must conduct a hazard analysis for each product, identifying all potential hazards for the product.

Types of hazards include:

- Microbiological hazards
- Chemical hazards
- Physical hazards

Microbiological Hazards

Microbial organisms can be dangerous contaminants in your ingredients or products. These can include:

- Harmful bacteria (pathogens)
- Viruses
- Parasites
- Molds
Chemical Hazards:
- Pesticides
- Antibiotics
- Sulfites
- Toxins from bacteria
- Allergens

Physical Hazards
Physical hazards include those that are introduced during processing, for example:
- Metal
- Glass
- Plastic
Physical hazards can also be those that are in the food but must be removed, for example:
- Bones

Flow Diagrams
The hazard evaluation starts with an in-depth look at the product, its distribution and use.

The production process is documented as a flow diagram to:
- Enable each step to be evaluated for safety hazards
- Include each step from incoming ingredients to shipping of final product

Verification of flow diagrams:
- The food safety team assigns responsibility for verifying the accuracy of the flow diagrams
- The responsible person signs the flow diagram as an indication of successful validation

Identification of hazards
The food safety team analyzes the flow diagrams to identify potential hazards. The team evaluates:
- Raw materials
- Processes
- Control measures
- Allergens
- Intended use
Principle 2: Critical Control Points

Definition of a Critical Control Point (CCP)
• A step at which control can be applied and which is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.

Definition of Control Measures
• Actions taken at the critical control point to prevent, eliminate or reduce the hazard

Look for critical control points in these areas:
• Raw materials
• Receiving and handling
• Processing
• Distribution

Decision trees are used to identify critical control points (CCPs)
• Decision trees are a sequence of questions used to evaluate the points on the prepared process flow diagrams
• The series of questions on the decision tree are asked for each process step, and CCPs identified and documented

Principle 3: Critical Limits

Definition of Critical Limits:
• A maximum or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce the hazard to acceptable levels.

Examples:
• Temperature
• Time
• Humidity
• pH
Principle 4: Monitoring Procedures

Definition of Monitoring Procedures:
- Scheduled or continuous testing or observation of the control parameters at a CCP to ensure that limits are not exceeded.

  Checking temperatures
  Sampling raw materials
  Monitoring pH
  Humidity monitoring
  Sampling for bacteria

For each monitoring procedure, responsibilities and actions must be defined to make sure that:
- The correct information is collected
- The information is collected at the correct point in the process
- It is analyzed effectively and can be compared to established limits
- Action can be taken in a timely manner if limits are exceeded
- Data is recorded
- Personnel involved are qualified and trained appropriately

Principle 5: Corrective Action Procedures

When a critical control limit is exceeded, corrective action is taken to bring the process back into control
- The appropriate corrective action must be identified in the HACCP plan so that when a limit is exceeded it is clear what action must be taken

Goals of corrective action:
- Identify the cause of the loss of control
- Determine the scope of the problem
- Identify what product was affected and bring it under control
- Correct the deviation and eliminate the cause

Identify the cause of the loss of control
- Find the root cause: analyze what happened and find not only the immediate cause but the underlying cause of the problem
- Identifying the correct root cause is critical to being able to prevent the same thing from happening again

Identify the scope of the problem
- When did the out of control situation begin?
- What process steps were affected?
Principle 6: Verification

Verification:
- Verify that the HACCP plan is valid, implemented as written and working properly
- Validate that the critical control limits are sufficient for preventing food safety hazards
- Demonstrate that hazards are being controlled at the CCPs

Methods for ongoing verification include:
- Analytical testing
- Review of monitoring results and methods
- Review of the HACCP plan and flow diagrams
- Internal Audits
- Other methods

Principle 7: Records and Documentation

Documentation and Record Keeping
- The foundation of a HACCP system is a documented plan addressing each of the HACCP principles
- Record keeping provides evidence that the activity has been adequately performed, and performed according to the documented plan

HACCP Records include:
- The HACCP plan
- Hazard analysis
- Monitoring records and data
- Testing data and results
- Records of corrective action
- Nonconforming product disposition records
- Validation records
- Audit reports