GUIDE TO CREATING AN HACCP PLAN

Developing and Implementing an Effective System

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WHAT IS HACCP?

Hazard Analysis and Critical Control Points (HACCP) is a 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 manufacturing, distribution and consumption of the finished product. While HACCP programs are currently mandatory only for juice, meat and seafood, they are found in all industries. The principles of HACCP can be applied throughout the food chain from harvest to consumption, from small independent organizations to national and regional companies. They can also be incorporated into the formulations and standard operating procedures of any type of plant. The following guide will help you understand how to develop and implement an effective HACCP plan. To form the foundation of support for an effective HACCP, begin with research.

Step 1: Know the Facts
Understand the concept of the HACCP and how it can reduce your risk exposure regarding a food safety failure.

Step 2: Gather Data
Before you institute a program, research your specific industry to find out how other similar organizations have created HACCP plans.

Step 3: Demonstrate a Commitment
Make sure all levels of employees recognize the importance of the HACCP to public safety. Everyone from upper management to hourly employees should understand the goals of HACCP and should devote themselves to verification efforts to ensure its continued success. HACCP systems are of little use if management does not support and recognize the need.

WHY INTRODUCE AN HACCP PLAN?

HACCP is a risk management tool that will support you in your efforts to prevent food safety failures and associated costs while ensuring legal compliance. The principles of HACCP have been accepted by government agencies, trade associations and the food industry around the world. It is also widely recognized as the most cost-effective system to control foodborne hazards. As a preventive system instead of an inspection system, it includes procedures to limit problems before they occur. Adopting an HACCP plan can produce tangible and demonstrable improvements in food safety performance while ensuring compliance with federal regulations. An HACCP plan demonstrates your organization's food safety commitments and enables your organization to:

- Communicate confidence to customers, demonstrating that food products are produced using safe processes.
- Comply with government regulations.
- Examine and prioritize potential hazards.
- Reduce product waste and product recall.
- Improve relations with food safety authorities.
- Improve efficiency.

WHO IS REQUIRED TO IMPLEMENT AN HACCP PLAN?

In the United States, HACCP is regulated in the meat and poultry industry by the Department of Agriculture (USDA) and in the seafood and juice industry by the Food and Drug Administration (FDA). While HACCP standards are distinct, there are some common components used to regulate HACCP, including:

- Consideration of good manufacturing practices (GMPs) and sanitation standard operating procedures (SSOPs) are prerequisites.
- Implementation of general HACCP principles
- Verification methods of industry development, implementation and maintenance of effective HACCP systems
- Establishment of performance standards
- Engagement in programs for education and training
- Research sponsorship to improve HACCP system functionality

Meat and Poultry Plants
The USDA and the FSIS have regulations requiring that:

- All meat and poultry establishments develop and implement an HACCP system.
- All meat and poultry plants develop and implement written sanitation standard operating procedures (SSOPs).
- Slaughter establishments perform regular microbial testing to verify the adequacy of process controls for the prevention and removal of fecal contamination and associated bacteria.
- Establishments that slaughter or produce raw, ground meat or poultry products must meet *salmonella* reduction performance standards.

Fruit and Vegetable Juices
The FDA juice regulations require juice processors to evaluate processing operations using HACCP principles, and if necessary, to develop and implement the HACCP system for these operations that do not include:

- Harvesting, picking or transporting raw agricultural ingredients for juice processing.
- Operations of retail establishments or businesses that make and sell juice directly to consumers.

According to the Juice HACCP regulations, both interstate and intrastate processors must comply with specific requirements. Some of these requirements include:

- Maintain the HACCP plan and other records of SSOPs and HACCP operations.
- Train employees involved in developing and implementing the HACCP plan.
- Reduce a theoretical population of a pertinent microorganism, the most resistant microorganism of public health significance, in the juice by 99.999 percent or 5-log cycles.
- Bear a warning label on juice that has not been treated to achieve a 5-log reduction in the most resistant pathogen.
- Follow Current Good Manufacturing Practices (cGMPs).

In addition, Juice HACCP regulations also specify requirements for imported juice. The juice importers must comply with one of the following requirements:

- Ensure that all juice imported by them has been processed in compliance with the Juice HACCP regulations.
- Import juice from a country that has an appropriate memorandum of understanding (MOU) with the United States that covers juice inspection and the inspection documents in equivalence or compliance with the U.S. system.

Seafood
Besides maintaining a documented HACCP plan, Seafood HACCP regulations require the seafood processors and importers to comply with certain prerequisite programs which include:
- cGMPs
- SSOPs
- Monitoring and recordkeeping of sanitation control points

According to seafood HACCP regulations, eight sanitation control points within safety assurance procedures are required to be monitored and recorded. These eight control points are:
- Safety of water that comes into contact with food and food-contact surfaces, or is used in the manufacture of ice.
- Cleanliness and condition of food-contact surfaces, utensils, gloves and outer clothing.
- Prevention of cross-contamination from unhygienic object to food-contact surfaces, utensils, gloves and outer clothing as well as from raw food to cooked food.
- Maintenance of hand washing, sanitizing and toilet facilities.
- Protection of food, packaging material and food-contact surfaces from contamination by lubricants, fuel, pesticides, cleansers, sanitizers, condensates and other hazards.
- Proper labeling, storage and use of toxic chemicals.
- Check and control on employee health conditions.
- Pest exclusion from food production, processing and handling sites.

Seafood HACCP regulations also specify requirements for imported seafood. The seafood importers must comply with one of the following requirements:
- Import products from a country that has an active equivalence or compliance agreement with FDA covering fish and fishery products.
- Ensure that all seafood imported by them has been processed in compliance with the Seafood HACCP regulations.

WHAT ARE THE PRINCIPLES OF HACCP?

Basic Principles
A quality management system is based upon seven basic principles.

1. **Conduct a hazard analysis.** Each plan should determine applicable food safety hazards (biological, chemical and physical properties that cause a food to be unsafe for human consumption) and identify preventive measures the plan can apply to control these hazards.
2. **Identify critical control points.** Identify critical control points, which are points, steps or procedures in a food manufacturing process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated or reduced to an acceptable level.
3. **Establish critical limits for each critical control point.** A critical limit is the maximum or minimum value to which a physical, biological or chemical hazard must be controlled at a critical point to prevent, eliminate or reduce to an acceptable level. Critical limits can be derived from various sources, including:
   - Regulatory standards and guidelines
   - Scientific literature
   - Experimental studies

- Consultation with experts

Each CCP will have one or more preventive measures for which critical limits must be established and controlled for prevention, elimination or reduction of hazards to an acceptable limit. Parameters might include time, temperature, physical dimensions, humidity, water activity, pH, salt concentration and moisture content.

4. **Establish procedures to monitor each critical control point.** Monitoring results should be used to adjust and control processes. Monitoring mainly consists of observations and measurements taken to determine that a CCP is properly controlled. Monitoring tracks the system's operation so that a loss of control can be recognized, indicates when a loss of control has occurred and provides written documentation to verify the HACCP plan.

5. **Establish corrective actions.** When monitoring indicates a deviation from an established critical limit, implement corrective actions to ensure that no unsafe product enters commerce as a result of that deviation. Corrective actions serve the following purposes:
   - Determine the disposition of the noncompliant product.
   - Identify and correct the cause of the deviation.
   - Maintain records of corrective actions.

6. **Establish recordkeeping procedures**. All plants should maintain certain documents, including a hazard analysis and written HACCP plan, documenting the monitoring of critical control points, critical limits, verification activities and the handling of processing deviations.

7. **Establish procedures for ensuring the HACCP system is working as intended.** Validation ensures that plants are successful in ensuring the production of a safe product. Each plant should validate its own HACCP plan. The FSIS reviews HACCP plans for conformance with the fine rule before approving them.

STEPS TO CREATING AN HACCP PLAN

1. *Assemble an HACCP Team.* Your HACCP team will identify the scope of the HACCP plan and should consist of individuals with specific knowledge and skills appropriate to the product and process. The team should include one HACCP-trained person who in not necessarily an employee, but who is available for plan development and certain functions, like re-evaluating the HACCP plan. Your team should also contain the following participants:
   - Team leader
   - Specialist with detailed knowledge of the commodity system
   - Specialists with knowledge of particular hazards and risks, such as a microbiologist, chemist, toxicologist, process engineer or environment specialist
   - Individuals such as suppliers, packagers or production staff knowledgeable about the process
   - Technical secretary to record team progress and results of the analysis

2. *Describe the product and its distribution.* To identify hazards associated with the process, the HACCP team should prepare the complete product description, including its method of production, distribution and customer specification. This description should include the following information on the product(s):
   - Safety concerns
   - Composition
   - Physical and chemical properties of the raw materials and final product
   - Water activity

- pH
- Type of packaging to be used
- Storage and transportation conditions
- Shelf life and recommended storage temperatures
- Labeling information
- Method and temperature of distribution

3. *Identify the product's intended use.* Here, the HACCP team describes the normal expected use of the product, useful in hazard analysis. The description should include whether the product will be consumed directly, cooked or further processed, and it will also include information about susceptible populations in the target group, such as infants, the elderly, malnourished and immune-compromised. The description should also mention any possibility of misuse, such as the consumption of pet food as human food.

4. *Develop a commodity flow diagram.* Develop a process flow diagram that provides a clear and simple outline of the steps involved in the process. The diagram should include all process steps in detail that are directly under the control of the company. Data might include:
   - Ingredients and packaging
   - Sequence of process operations
   - Time and temperature history of all raw materials, intermediate and final products
   - Flow conditions for liquids and solids
   - Product recycle/rework loops
   - Equipment design features

5. *On-site confirmation of flow diagram.* Verify the accuracy and completeness of the flow diagram by the HACCP team through an on-site review of the process. Check that all relevant information has been considered in the flow diagram, including:
   - Time of harvest
   - Drying procedures
   - Storage conditions
   - Marketing chain
   - Socio-economic factors
   - Grading systems
   - Processing systems

IMPLEMENTING THE HACCP PLAN

The success of an HACCP plan depends heavily on the commitment of top management to the HACCP concept, which will convey to employees the importance of producing safe food. The HACCP team should be adequately trained for developing the initial plan and coordinating its implementation. The continual application of monitoring, recordkeeping and corrective action procedures are important aspects of the plan's execution, and employees responsible for these activities should be trained accordingly.

Verification Activities
An effective HACCP system depends mainly on periodical verification activities. The plan should be updated and revised to ensure that it results in effective control of hazards. Training of all individuals involved in the plan is an important aspect of HACCP maintenance.

All personnel must understand their role and implement their responsibilities to apply HACCP as an effective food safety system.

PREREQUISITE PROGRAMS

Prerequisites for successful HACCP systems include the basic environmental and operating conditions that are essential for the production of safe and wholesome foods. A company might use an existing system or set up auditing teams to evaluate prerequisite programs in conjunction with HACCP implementation. Examples of prerequisite programs include:

- **Good Manufacturing Practices (GMPs)**, which should be developed based on the specific operation and followed by all employees, including management and maintenance employees as well as all visitors.
- **Good Agricultural Practices (GAPs)** for raw agricultural commodities, which should be a requirement for suppliers of food handling facilities as well.
- **Standard Operating Procedures (SOPs)**, which must be specific for each function in the facility and written in a usable format that is monitored and documented periodically. They should provide sufficient details to be effectively understood and applied by employees. Some specific functions that might require SOPs include:
  - Facilities and equipment
  - Pre-start-up inspection
  - Specification systems
  - Supplier/material control
  - Cleaning procedures and sanitization
  - Storage, shipping and handling
  - Recall and material traceability
  - Environmental control
  - Allergen control
- **Sanitation Standard Operating Procedures (SSOPs)** are written documents that detail sanitation procedures, and are obligatory prerequisites for plants that are required to implement HACCP systems.

CONCLUSION

Gilroy, Kernan & Gilroy, Inc. knows that a successful HACCP does not only help your organization stay in compliance; it ensures an effective use of resources, meaning cost savings, and minimizes exposure to the risk of product recall or liability related to foodborne illness. For more information about risk management strategies, contact us today at 315.768.8888.

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