HACCP Principles & Application Guidelines

The U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and comprised of participants from the USDA, U.S. Food and Drug Administration and the Centers for Disease Control and Prevention. NACMCF created guidelines and defined the seven basic principles of Hazard Analysis Critical Control Point (HACCP) as an effective and rational means of assuring food safety from harvest to consumption.

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 processing, distribution and consumption of the finished product. Preventing problems from occurring is the paramount goal underlying any HACCP system.

HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption. Prerequisite programs such as Current Good Manufacturing Practices (CGMPs) are an essential foundation for the development and implementation of successful HACCP plans. Food safety systems based on the HACCP principles have been successfully applied in food processing plants, retail food stores, and food service operations. The seven principles of HACCP have been universally accepted by government agencies, trade associations and the food industry around the world.

The Seven Principles of HACCP

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on seven principles. The seven basic principles are employed in the development of HACCP plans that meet the stated goal. These principles include:

1. Hazard Analysis
2. Critical Control Points
3. Critical Limits
4. Monitoring
5. Corrective Actions
6. Verification
7. Record Keeping and Documentation.

Under such systems, if a deviation occurs indicating that control has been lost, the deviation is detected and appropriate steps are taken to reestablish control in a timely manner to assure that potentially hazardous products do not reach the consumer.

Principle 1: Conduct a Hazard Analysis

A Hazard Analysis is defined as the process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan. A hazard is defined as a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

A thorough hazard analysis is the key to preparing an effectively designed HACCP System and Plan. The purpose of the hazard analysis is to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. It is important to consider in the hazard analysis the hazards which might be introduced before, during, and after production, considering each step in the process, product storage and distribution.

Conducting a hazard analysis is generally a two-step process. The first step is to identify the potential hazards that may be introduced, controlled, or enhanced at each step in the manufacturing process. . Once those hazards are identified, the second step is to identify existing controls for those hazards. Each step where a hazard must be controlled is termed a control point (CP).

Principle 2: Identify Critical Control Points

A Critical Control Point (CCP) is defined as a point, step, or procedure in a food production process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. A control measure is defined as any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

The second HACCP principle is to identify the Critical Control Points (CCPs) in the food production process. For each significant hazard, a control measure must be implemented that will prevent, eliminate, or reduce the risk to an acceptable level. A control measure is implemented at the CCP to control the hazard either at the step at which the hazard is identified or at a later step in the process. CCPs are typically process control steps, which can include inspection test results upon receipt of raw materials, pasteurization, cooking, chilling, acidification, addition of preservatives, metal detection, and labeling.

Principle 3: Establish Critical Limits

A Critical Limit is defined as a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a Critical Control Point to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

The next step in the development of a HACCP plan is to establish Critical Limits for each CCP. Critical limits (CL) are the parameters that indicate whether the control measure at the CCP is in or out of control. Critical limits are most often based on process parameters such as temperature, time, physical dimensions, or presence of target pathogens.

Critical limits must be actual values that can be measured or quantified that are based on scientific literature and/or regulatory standards. Critical limits need to be exact and specific. A critical limit can be an upper limit, at which a set amount or level cannot be exceeded, or a lower limit, at which a minimum amount is required to produce the safe effect. Regardless of the parameter used, the critical limit must be sufficient to prevent, eliminate, or reduce to an acceptable level the occurrence of the hazard it is designed to control.

Principle 4: Establish Monitoring Procedures

Monitoring is defined as conducting a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Once critical limits are set for each CCP in the HACCP plan, monitoring procedures must be established for the measurement of the critical limit at each critical control point to determine whether the critical limits are being met. Monitoring procedures should describe how the measurement will be taken, when the measurement is taken, and how frequently the measurement is taken during production.

Monitoring procedures usually involve either a measurement or an observation. If the critical limit is a numerical value, then monitoring usually involves a measurement. If the critical limit is defined as the presence or absence of an attribute, then the monitoring procedure may involve observation. Monitoring procedures should be well planned, supportable, and effectively designed to determine when deviations from the critical limit occur so that appropriate corrective actions can be initiated.

Principle 5: Establish Corrective Actions

A Corrective Action is defined as the procedures followed when a deviation in a critical limit occurs. A deviation is defined as a failure to meet a critical limit.

The corrective actions must be determined for each CCP in cases where the critical limit is not met. When there is a deviation from the critical limit, corrective actions are required to prevent potentially hazardous foods from reaching consumers. The HACCP plan must include corrective actions to be taken when a deviation from the critical limit occurs at a critical control point. HACCP plans should specify what corrective action is to take place when a deviation occurs, who is responsible for implementing corrective actions, and that corrective actions will be documented as part of the HACCP records.

The corrective actions consist of the following steps: (1) Identifying and eliminating the cause of the deviation, (2) Ensuring the CCP is under control after the corrective action is taken, (3) Ensuring measures are established to prevent recurrence, and (4) Ensuring no product affected by the deviation is shipped.

Principle 6: Establish Verification Procedures

Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. Validation is defined as that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

The establishment of verification procedures is required to ensure the HACCP plan is working correctly. Three primary processes are involved in the verification of the HACCP system: (1) Initial Validation; (2) Ongoing Verification; and (3) Reassessment. The first is the scientific and technical process, known as validation for determining that the CCPs and associated critical limits are adequate and sufficient to control likely hazards. The second process is to ensure, initially and on an ongoing basis, that the entire HACCP system functions properly. The third process consists of documented, periodic, reassessment and verification of the HACCP plan conducted by an unbiased, independent authority.

Verification includes activities such as instrument calibration, product testing, observing monitoring activities and corrective actions, auditing of CCP's and critical limits, and reviewing HACCP records.

Principle 7: Establish Record Keeping and Documentation Procedures

Records are defined as written evidence documenting the operation of the HACCP system.

A key component of the HACCP system is the establishment of effective record keeping and documentation procedures. These records can be used to trace the production history of a finished product and determine whether the product was produced in a safe manner according to the HACCP plan.

The National Advisory Committee on Microbiological Criteria for Foods recommends that four types of records are maintained: (1) Summary of the hazard analysis including the rationale; (2) HACCP plan; (3) Support documentation such as validation records; and (4) Daily operational records generated during the operation of the HACCP plan.

The summary of the hazard analysis covers the basis and justification for the HACCP plan. This includes all the information about the hazard analysis, including justification for CCPs and critical limits. The HACCP plan outlines the formal procedures followed to meet the seven HACCP principles. HACCP plan records should include information such as the HACCP team, product description, manufacturing process flow chart, the CCP's, critical limits, monitoring procedures, corrective actions, verification procedures, and the recordkeeping system.

The supporting documentation includes the rationale used to establish CCPs, critical limits, monitoring procedures, corrective action procedures, and verification procedures. This documentation includes all scientific references, regulatory resources, and materials from other sources (extension services, academic experts, consultants) that have been used in the development of the HACCP plan. The daily operational records include the actual records from the implementation of the HACCP plan, such as the measurements taken at a CCP, the monitoring, the corrective actions, and the verification.