HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP)

Introduction

HACCP was originally designed by the Pillsbury Company in USA in the early 1960's as a means of providing assurance about safety of food used for astronauts in the United States space programme. Since then this concept has taken a global perspective.

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. For successful implementation of a HACCP plan, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food.

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. 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 following guidelines will facilitate the development and implementation of effective HACCP plans. While the specific application of HACCP to manufacturing facilities is emphasized here, these guidelines should be applied as appropriate to each segment of the food industry under consideration.

Prerequisite Programs

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs such as GMPs (Good Manufacturing Practices), SOP (Standard Operating Procedure), SSOP (Sanitation Standard Operating Procedure). Examples of common prerequisite programs are listed in Appendix A. The Good Manufacturing Practices define measures of general hygiene as well as measures that prevent food from becoming adulterated due to unsanitary conditions. The GMPs are broadly focused and encompass many aspects of plant and personnel operations. On the other hand, Sanitation Standard Operating Procedures (SSOPs) are procedures used by food processing firms to help accomplish the overall goal of maintaining GMPs in the production of food. Typically, SSOPs describe a particular set of objectives associated with sanitary handling of food and the cleanliness of the plant environment and the activities conducted to meet them.

Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. The existence and effectiveness of prerequisite programs should be assessed during the design and implementation of each HACCP plan. All prerequisite programs should be documented and regularly audited. Prerequisite programs are established and managed separately from the HACCP plan. Certain aspects, however, of a prerequisite program may be incorporated into a HACCP plan.

Education and Training

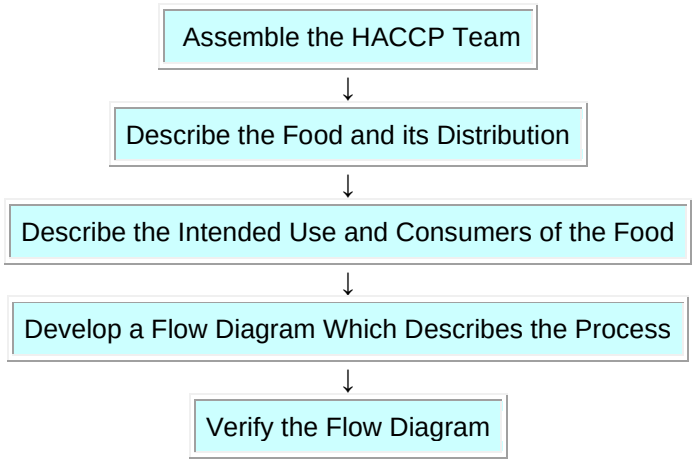
The success of a HACCP system depends on educating and training management and employees in the importance of their role in producing safe foods. This should also include information the control of food borne hazards related to all stages of the food chain. It is important to recognize that employees must first understand what HACCP is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP.

Management must provide adequate time for thorough education and training. Personnel must be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP plan.

Developing a HACCP Plan

In the development of a HACCP plan, five preliminary tasks need to be accomplished before the application of the HACCP principles to a specific product and process. The five preliminary tasks are given below:

Figure 1: Preliminary Tasks in the Development of the HACCP Plan



Assemble the HACCP Team

The first task in developing a HACCP plan is to assemble a HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is the team's responsibility to develop the HACCP plan. The team should be multi disciplinary and include individuals from areas such as engineering, production, sanitation, quality assurance, and food microbiology. The team should also include local personnel who are involved in the operation as they are more familiar with the variability and limitations of the operation The HACCP team may need assistance from outside experts who are knowledgeable in the potential biological, chemical and/or physical hazards associated with the product and the process. However, a plan which is developed totally by outside sources may be erroneous, incomplete, and lacking in support at the local level.

Due to the technical nature of the information required for hazard analysis, it is recommended that experts who are knowledgeable in the food process should either participate in or verify the

completeness of the hazard analysis and the HACCP plan. Such individuals should have the knowledge and experience to correctly: (a) conduct a hazard analysis; (b) identify potential hazards; (c) identify hazards which must be controlled; (d) recommend controls, critical limits, and procedures for monitoring and verification; (e) recommend appropriate corrective actions when a deviation occurs; (f) recommend research related to the HACCP plan if important information is not known; and (g) validate the HACCP plan.

Describe the food and its distribution

The HACCP team first describes the food. This consists of a general description of the food, ingredients, and processing methods. The method of distribution should be described along with information on whether the food is to be distributed frozen, refrigerated, or at ambient temperature.

Describe the intended use and consumers of the food

Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g., infants, immune compromised individuals, the elderly, etc.).

Develop a flow diagram which describes the process

The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process which are directly under the control of the establishment. In addition, the flow diagram can include steps in the food chain which are before and after the processing that occurs in the establishment. The flow diagram need not be as complex as engineering drawings. A block type flow diagram is sufficiently descriptive. Also, a simple schematic of the facility is often useful in understanding and evaluating product and process flow.

Verify the flow diagram

The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modifications should be made to the flow diagram as necessary and documented.

After these five preliminary tasks have been completed, the seven principles of HACCP are applied.

HACCP PRINCIPLES

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.
Principle 2: Determine the critical control points (CCPs).
Principle 3: Establish critical limits.
Principle 4: Establish monitoring procedures.
Principle 5: Establish corrective actions.
Principle 6: Establish verification procedures.
Principle 7: Establish record-keeping and documentation procedures.

Conduct a hazard analysis (Principle 1)

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 ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. 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. Thus, the word hazard as used in this document is limited to safety.

The process of conducting a hazard analysis involves two stages. The first, hazard identification, can be regarded as a brain storming session. During this stage, the HACCP team reviews the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution, and the intended use and consumers of the product. Based on this review, the team develops a list of potential biological, chemical or physical hazards which may be introduced, increased, or controlled at each step in the production process. Appendix B lists examples of questions that may be helpful to consider when identifying potential hazards.

After the list of potential hazards is assembled, stage two, the hazard evaluation, is conducted. In stage two of the hazard analysis, the HACCP team decides which potential hazards must be addressed in the HACCP plan. During this stage, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled. In addition, consideration should be given to the effects of short term as well as long term exposure to the potential hazard. The team must consider the influence of likely procedures for food preparation and storage and whether the intended consumers are susceptible to a potential hazard. However, there may be differences of opinion, even among experts, as to the likely occurrence and severity of a hazard. The HACCP team may have to rely upon the opinion of experts who assist in the development of the HACCP plan.

Upon completion of the hazard analysis, the hazards associated with each step in the production of the food should be listed along with any measure(s) that are used to control the hazard(s). More than one control measure may be required for a specific hazard. On the other hand, more than one hazard may be addressed by a specific control measure (e.g. pasteurization of milk).

For example, if a HACCP team were to conduct a hazard analysis for the production of frozen cooked shrimp, enteric pathogens (e.g., *Salmonella* and verotoxin-producing *Escherichia coli*) in the raw shrimp would be identified as hazards. Cooking is a control measure which can be used to eliminate these hazards.

Step	Potential Hazard(s)	Justification	Hazard to be addressed in plan? Y/N	Control Measure(s)
Cooking	Enteric pathogens: e.g., *Salmonella*, verotoxigenic-*E. coli*	enteric pathogens have been associated with outbreaks of foodborne illness from undercooked shrimp	Y	Cooking

Determine critical control points (CCPs) (Principle 2)

A critical control point is defined as a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. The potential hazards that are reasonably likely to cause illness or injury in the absence of their control must be addressed in determining CCPs.

Complete and accurate identification of CCPs is fundamental to controlling food safety hazards. One strategy to facilitate the identification of each CCP is the use of a CCP decision tree (Examples of decision trees are given in Appendices C and D).

Critical control points are located at any step where hazards can be either prevented, eliminated, or reduced to acceptable levels. Examples of CCPs may include: thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing product for metal contaminants. CCPs must be carefully developed and documented. For example, a specified heat process, at a given time and temperature designed to destroy a specific microbiological pathogen, could be a CCP. Likewise, refrigeration of a precooked food to prevent hazardous microorganisms from multiplying, or the adjustment of a food to a pH necessary to prevent toxin formation could also be CCPs.

Establish critical limits (Principle 3)

A critical limit is a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Critical limits should not be confused with operational limits which are established for reasons other than food safety.

Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated or reduced to acceptable levels. Each control measure has one or more associated critical limits. Critical limits may be based upon factors such as: temperature, time, physical dimensions, humidity, moisture level, water activity (a_w), pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information such as aroma and visual appearance.

The example given below applies to the first facility.

Process Step	CCP	Critical Limits
Cooking	YES	Oven temperature:___° F Time; rate of heating and cooling (belt speed in ft/min): ____ft/min Oven humidity: ____% RH

Establish monitoring procedures (Principle 4)

Monitoring is 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. Monitoring serves three main purposes. First, monitoring is essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs. Second, monitoring is used to determine when there is loss of control and a deviation occurs at a CCP, i.e., exceeding or

not meeting a critical limit. When a deviation occurs, an appropriate corrective action must be taken. Third, it provides written documentation for use in verification.

Ideally, monitoring should be continuous, which is possible with many types of physical and chemical methods. Continuous monitoring is always preferred when feasible. Monitoring equipment must be carefully calibrated for accuracy.

All records and documents associated with CCP monitoring should be dated and signed or initialed by the person doing the monitoring.

When it is not possible to monitor a CCP on a continuous basis, it is necessary to establish a monitoring frequency and procedure that will be reliable enough to indicate that the CCP is under control.

Establish corrective actions (Principle 5)

The HACCP system for food safety management is designed to identify health hazards and to establish strategies to prevent, eliminate, or reduce their occurrence. However, ideal circumstances do not always prevail and deviations from established processes may occur. An important purpose of corrective actions is to prevent foods which may be hazardous from reaching consumers. Where there is a deviation from established critical limits, corrective actions are necessary. Therefore, corrective actions should include the following elements: (a) determine and correct the cause of non-compliance; (b) determine the disposition of non-compliant product and (c) record the corrective actions that have been taken. Specific corrective actions should be developed in advance for each CCP and included in the HACCP plan. As a minimum, the HACCP plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken. Individuals who have a thorough understanding of the process, product and HACCP plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

Establish verification procedures (Principle 6)

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.

One aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. An effective HACCP system requires little end-product testing, since sufficient validated safeguards are built in early in the process.

Another important aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled.

Information needed to validate the HACCP plan often include (1) expert advice and scientific studies and (2) in-plant observations, measurements, and evaluations. Verification activities are carried out by individuals within a company, third party experts, and regulatory agencies. It is important that individuals

doing verification have appropriate technical expertise to perform this function. Examples of verification activities are included as Appendix E.

Establish record-keeping and documentation procedures (Principle 7)

Generally, the records maintained for the HACCP System should include the following:

1. A summary of the hazard analysis, including the rationale for determining hazards and control measures.
2. The HACCP Plan
    - Listing of the HACCP team and assigned responsibilities.
    - Description of the food, its distribution, intended use, and consumer.
    - Verified flow diagram.
    - HACCP Plan Summary Table that includes information for:
        - Steps in the process that are CCPs
        - The hazard(s) of concern.
        - Critical limits
        - Monitoring*
        - Corrective actions*
        - Verification procedures and schedule*
        - Record-keeping procedures*

    * A brief summary of position responsible for performing the activity and the procedures and frequency should be provided

    The following is an example of a HACCP plan summary table:

CCP	Hazards	Critical limit(s)	Monitoring	Corrective Actions	Verification	Records

3. Support documentation such as validation records.
4. Records that are generated during the operation of the plan.

Examples of HACCP records are given in Appendix F.

APPENDIX A

Examples of Common Prerequisite Programs

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This has traditionally been accomplished through the application of cGMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Common prerequisite programs may include, but are not limited to:

Facilities.

The establishment should be located, constructed and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw to cooked materials.

Supplier Control.

Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification.

Specifications.

There should be written specifications for all ingredients, products, and packaging materials.

Production Equipment.

All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.

Cleaning and Sanitation.

All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place.

Personal Hygiene.

All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene.

Training.

All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP program.

Chemical Control.

Documented procedures must be in place to assure the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant.

Receiving, Storage and Shipping.

All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to assure their safety and wholesomeness.

Traceability and Recall.

All raw materials and products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.

Pest Control.

Effective pest control programs should be in place.

Other examples of prerequisite programs might include quality assurance procedures; standard operating procedures for sanitation, processes, product formulations and recipes; glass control; procedures for receiving, storage and shipping; labeling; and employee food and ingredient handling practices.

APPENDIX B

Examples of Questions to be Considered When Conducting a Hazard Analysis

The hazard analysis consists of asking a series of questions which are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

A. Ingredients
    1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
    2. Are potable water, ice and steam used in formulating or in handling the food?
    3. What are the sources (e.g., geographical region, specific supplier)
B. Intrinsic Factors - Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.
    1. What hazards may result if the food composition is not controlled?
    2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
    3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
    4. Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?
C. Procedures used for processing
    1. Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
    2. If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging which biological, chemical or physical hazards are likely to occur?
D. Microbial content of the food
    1. What is the normal microbial content of the food?
    2. Does the microbial population change during the normal time the food is stored prior to consumption?
    3. Does the subsequent change in microbial population alter the safety of the food?
    4. Do the answers to the above questions indicate a high likelihood of certain biological hazards?
E. Facility design
    1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?
    2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
    3. Is the traffic pattern for people and moving equipment a significant source of contamination?
F. Equipment design and use
    1. Will the equipment provide the time-temperature control that is necessary for safe food?
    2. Is the equipment properly sized for the volume of food that will be processed?
    3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
    4. Is the equipment reliable or is it prone to frequent breakdowns?
    5. Is the equipment designed so that it can be easily cleaned and sanitized?
    6. Is there a chance for product contamination with hazardous substances; e.g., glass?
    7. What product safety devices are used to enhance consumer safety?
        - metal detectors
        - magnets

- sifters
- filters
- screens
- thermometers
- bone removal devices
- dud detectors

8. To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
9. Are allergen protocols needed in using equipment for different products?

G. Packaging
1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
2. Is the package clearly labeled "Keep Refrigerated" if this is required for safety?
3. Does the package include instructions for the safe handling and preparation of the food by the end user?
4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
5. Are tamper-evident packaging features used?
6. Is each package and case legibly and accurately coded?
7. Does each package contain the proper label?
8. Are potential allergens in the ingredients included in the list of ingredients on the label?

H. Sanitation
1. Can sanitation have an impact upon the safety of the food that is being processed?
2. Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?
3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

I. Employee health, hygiene and education
1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?
2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?
3. Will the employees inform management of a problem which could impact upon safety of food?

J. Conditions of storage between packaging and the end user
1. What is the likelihood that the food will be improperly stored at the wrong temperature?
2. Would an error in improper storage lead to a microbiologically unsafe food?

K. Intended use
1. Will the food be heated by the consumer?
2. Will there likely be leftovers?

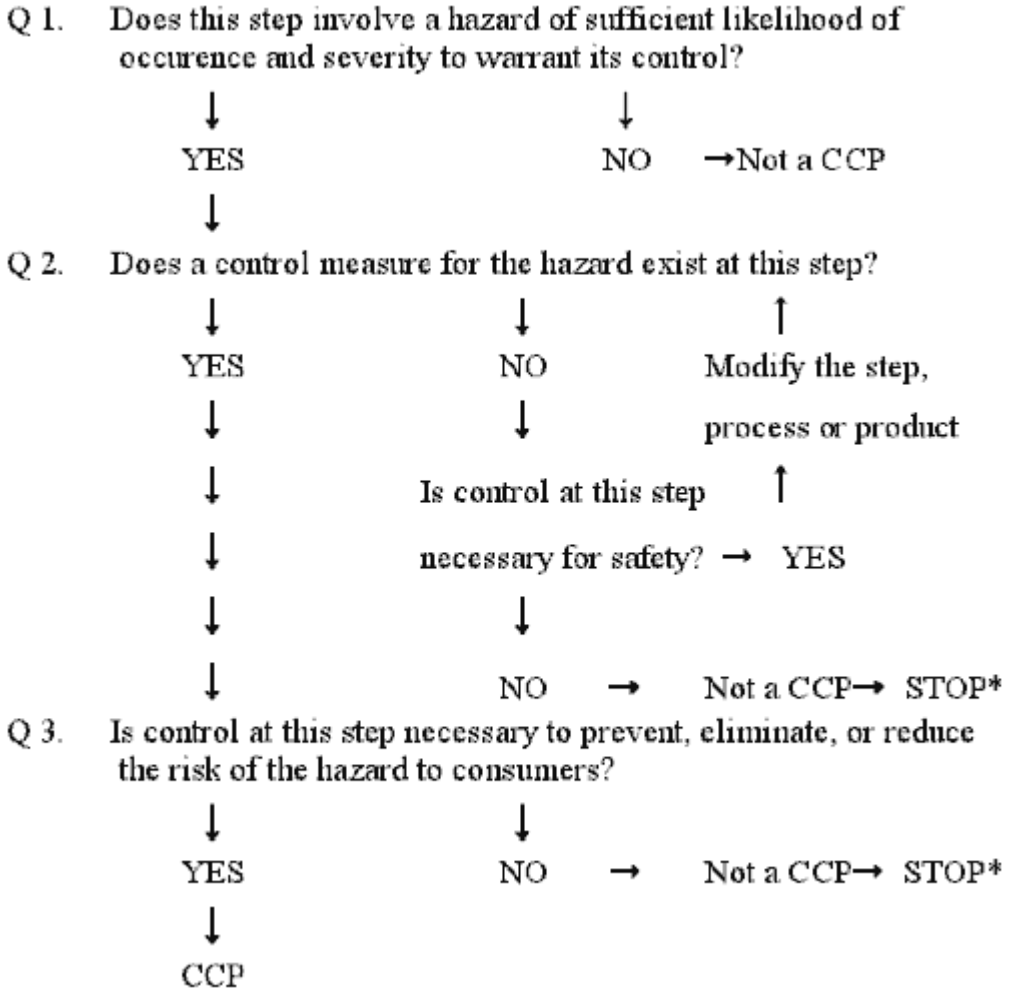
L. Intended consumer
1. Is the food intended for the general public?
2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?
3. Is the food to be used for institutional feeding or the home?

APPENDIX C

Example I of a CCP Decision Tree

Important considerations when using the decision tree:

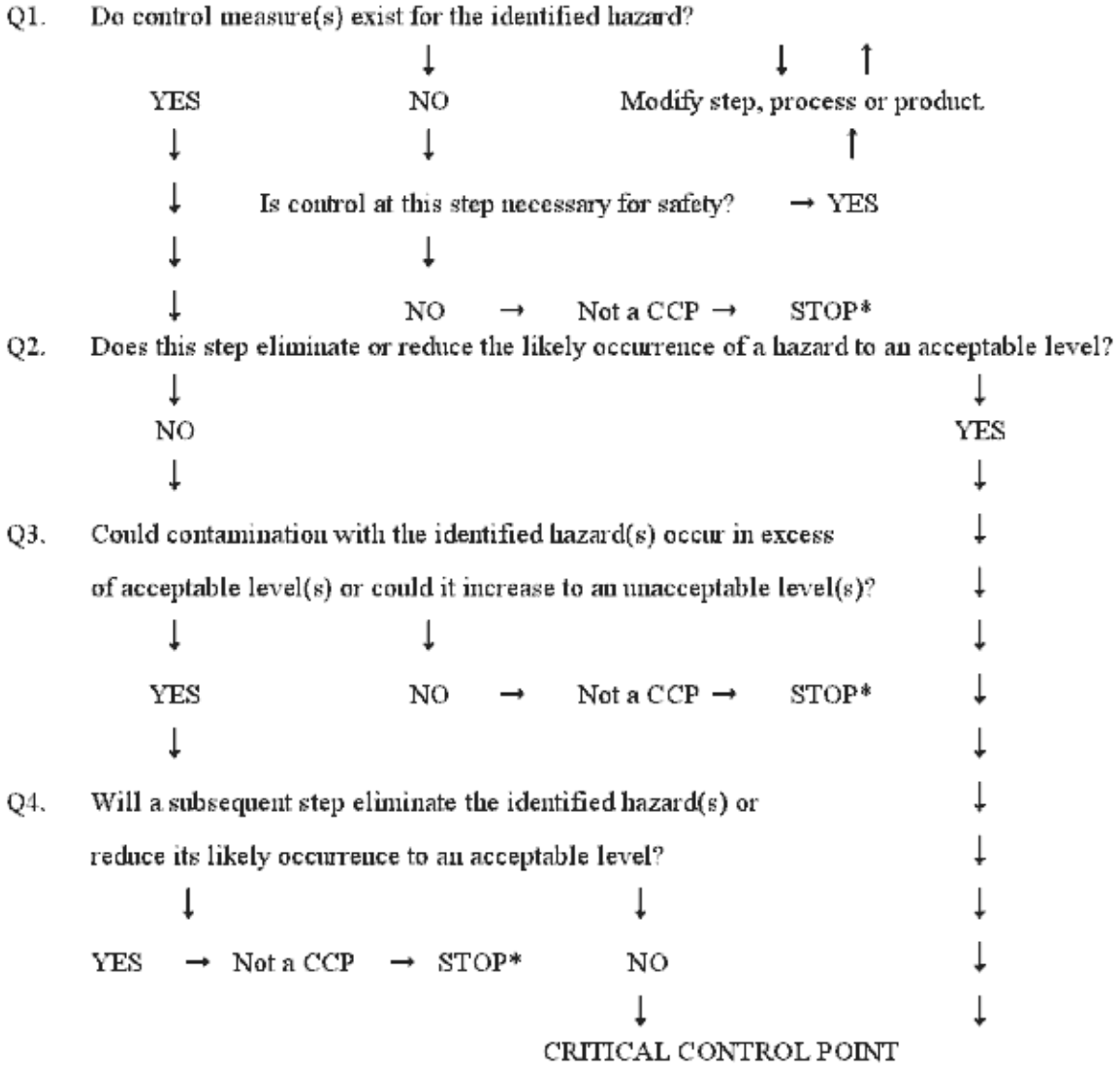
- The decision tree is used after the hazard analysis.
- The decision tree then is used at the steps where a hazard that must be addressed in the HACCP plan has been identified.
- A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP.
- More than one step in a process may be involved in controlling a hazard.
- More than one hazard may be controlled by a specific control measure.



* Proceed to next step in the process.

APPENDIX D

Example II of a CCP Decision Tree



*Proceed to next step in the described process

APPENDIX E

Examples of Verification Activities

A. Verification procedures may include:
    1. Establishment of appropriate verification schedules.
    2. Review of the HACCP plan for completeness.
    3. Confirmation of the accuracy of the flow diagram.
    4. Review of the HACCP system to determine if the facility is operating according to the HACCP plan.
    5. Review of CCP monitoring records.
    6. Review of records for deviations and corrective actions.
    7. Validation of critical limits to confirm that they are adequate to control significant hazards.
    8. Validation of HACCP plan, including on-site review.
    9. Review of modifications of the HACCP plan.
    10. Sampling and testing to verify CCPs.
B. Verification should be conducted:
    1. Routinely, or on an unannounced basis, to assure CCPs are under control.
    2. When there are emerging concerns about the safety of the product.
    3. When foods have been implicated as a vehicle of foodborne disease.
    4. To confirm that changes have been implemented correctly after a HACCP plan has been modified.
    5. To assess whether a HACCP plan should be modified due to a change in the process, equipment, ingredients, etc.
C. Verification reports may include information on the presence and adequacy of.
    1. The HACCP plan and the person(s) responsible for administering and updating the HACCP plan.
    2. The records associated with CCP monitoring.
    3. Direct recording of monitoring data of the CCP while in operation.
    4. Certification that monitoring equipment is properly calibrated and in working order.
    5. Corrective actions for deviations.
    6. Sampling and testing methods used to verify that CCPs are under control.
    7. Modifications to the HACCP plan.
    8. Training and knowledge of individuals responsible for monitoring CCPs.
    9. Validation activities.

APPENDIX F

Examples of HACCP Records

A. Ingredients for which critical limits have been established.
    1. Supplier certification records documenting compliance of an ingredient with a critical limit.
    2. Processor audit records verifying supplier compliance.
    3. Storage records (e.g., time, temperature) for when ingredient storage is a CCP.
B. Processing, storage and distribution records
    1. Information that establishes the efficacy of a CCP to maintain product safety.
    2. Data establishing the safe shelf life of the product; if age of product can affect safety.
    3. Records indicating compliance with critical limits when packaging materials, labeling or sealing specifications are necessary for food safety.
    4. Monitoring records.
    5. Verification records.
C. Deviation and corrective action records.
D. Employee training records that are pertinent to CCPs and the HACCP plan.
E. Documentation of the adequacy of the HACCP plan from a knowledgeable HACCP expert.