HACCP Plan Development and Implementation Guidelines

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. Preventing problems from occurring is the paramount goal underlying any HACCP system.

Seven basic principles are employed in the development of HACCP plans that meet the stated goal. These principles include hazard analysis, CCP identification, establishing critical limits, monitoring procedures, corrective actions, verification procedures, and 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.

In accordance with the U.S. National Academy of Sciences recommendation, the HACCP plan must be developed by each food processing facility and tailored to its individual product, processing and distribution conditions. The following guidelines will facilitate the development and implementation of effective HACCP plans.

Prerequisite Programs

Prerequisite programs describe the specific activities of a facility that provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Prerequisite programs such as Current Good Manufacturing Practices (CGMPs) are an essential foundation for the development and implementation of successful HACCP plans. Other fundamental prerequisite programs may include, but are not limited to Standard Operating Procedures (SOPs), Quality Assurance procedures; Sanitation SOPs, glass control; allergen control, pest control, preventative maintenance, procedures for receiving, storage and shipping; labeling; and employee food and ingredient handling practices. Additionally, the Codex Alimentarius General Principles of Food Hygiene also describe the basic conditions and practices expected for foods intended for international trade.

While prerequisite programs may impact upon the safety of a food, they also are concerned with ensuring that foods are wholesome and suitable for consumption. HACCP plans are narrower in scope, being limited to ensuring food is safe to consume.

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. While prerequisite programs may impact upon the safety of a food, they also are concerned with ensuring that foods are wholesome and suitable for consumption. HACCP plans are narrower in scope, being limited to ensuring food is safe to consume.

Certain aspects of a prerequisite program may be incorporated into a HACCP plan. For example, many food processing facilities have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production. During the development of a HACCP plan, the HACCP team may decide that the routine maintenance and calibration of an oven should be included in the plan as an activity of verification. This would further ensure that all the food in the oven is cooked to the minimum internal temperature that is necessary for food safety.

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 regarding the control of foodborne hazards related to all stages of the food chain. Employees must first be educated to understand what the HACCP system 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 Critical Control Point. Employees must also be given the materials and equipment necessary to perform these tasks.

Management must provide sufficient time for thorough education and training. Effective training is an important prerequisite to successful implementation of a HACCP plan.

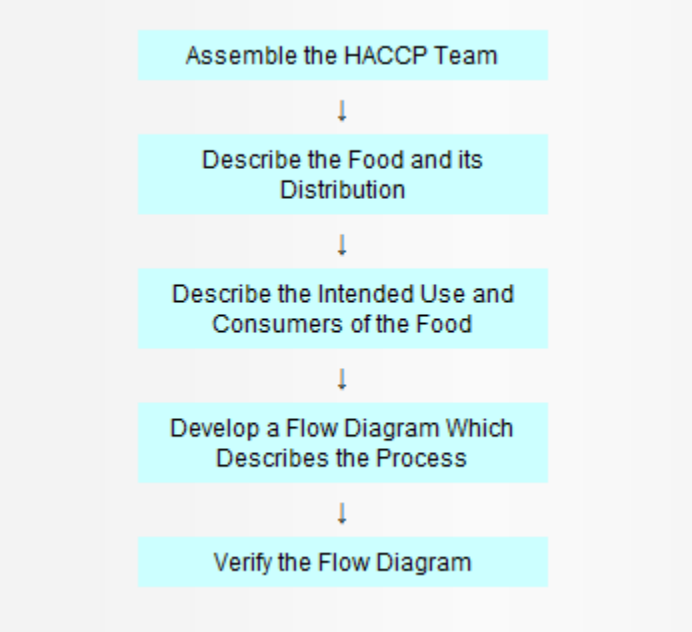
Developing a HACCP Plan

The HACCP Plan must be developed specifically for the product and process implemented. Therefore, HACCP plans will vary depending on the actual product being processed. Generic HACCP plans can serve as useful guides in the development of process and product HACCP plans. However, it is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan. Therefore, each facility must create the plan to suit the specific circumstances of its own products and production processes

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

1. Assemble the HACCP Team
2. Describe the food and its distribution
3. Describe the intended use and consumers of the food
4. Develop a flow diagram which describes the process
5. Verify the flow diagram

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 HACCP team's responsibility to develop the HACCP plan. The team should be multi-disciplinary and include individuals from areas such as production, sanitation, quality assurance, engineering 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. Additionally, this creates a sense of ownership among those who must implement the plan. 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 HACCP plan that is developed only 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. These experts 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 must first describe 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

The normal expected use of the food must be describeed. The intended consumers may be the general public or a particular segment of the population (e.g., infants, children, 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 facility. In addition, the flow diagram can include steps in the food chain which are before and after the processing that occurs in the facility. The flow diagram is not required to be as complex as engineering drawings. A block type flow diagram is sufficiently descriptive (see Appendix B). 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.

Conduct a hazard analysis - Principle 1

The HACCP team must conduct a hazard analysis and identify the appropriate control measures. The purpose of the hazard analysis is develop a list of the food safety hazards reasonably likely to cause injury or illness if not effectively controlled and identify the preventive measures the establishment can apply to control those hazards. Hazards that are not reasonably likely to occur would not require further consideration within a HACCP plan. 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. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns. 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. The word hazard is limited to safety in the HACCP system.

A thorough hazard analysis is the key to preparing an effective HACCP plan. If the hazard analysis is not done correctly and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

The hazard analysis and identification of associated control measures accomplish three primary objectives: (1) Identification of the hazards and associated control measures; (2) Identification of modifications to a process or product so that product safety is further assured or improved; (3) Provision of the basis for determining Critical Control Points in Principle 2.

Stage 1 – Identification of the Hazards

The process of conducting a hazard analysis involves two distinct stages. The first stage is the identification of the hazards. 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. Examples of questions that may be helpful to consider when identifying potential hazards are listed in Appendix C. Hazard identification focuses on developing a list of potential hazards associated with each process step under direct control of the food operation. Therefore, knowledge of any adverse health-related events historically associated with the product will be of value in this analysis.

Stage 2 – Hazard Evaluation

After the list of potential hazards is developed, 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. Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g., impact of sequelae, and magnitude and duration of illness or injury) can be helpful in understanding the public health impact of the hazard. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature.

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. When determining whether a hazard is reasonably likely to occur, it is recommended that the actual hazard is listed. For example: Physical: metal contamination from equipment; Biological: Salmonella, Escherichia coli, Staphylococcus aureus.

During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled. 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.. The HACCP team may have to rely upon the opinion of experts who assist in the development of the HACCP plan.

Hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product. For example, due to differences in equipment and/or an effective maintenance program, the probability of metal contamination may be significant in one facility but not in another. A summary of the HACCP team deliberations and the rationale developed during the hazard analysis should be kept for future reference. This information will be useful during future reviews and updates of the hazard analysis and the HACCP plan.

Logic sequences should be utilized in conducting a hazard analysis. Examples of logic sequences used in the hazard analysis process are provided in Appendix D to further explain the stages of hazard analysis for identifying hazards. Hazard identification and evaluation may also be assisted by biological risk assessments. Therefore, as risk assessments addressing specific hazards or control factors become available, the HACCP team should take these into consideration.

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). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. 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).

For example, if a HACCP team were to conduct a hazard analysis for the processing of cashew kernels (Appendices A and C) enteric pathogens (e.g. *Salmonella, Escherichia coli, Staphylococcus aureus*) in the cashew kernels would be identified as hazards. Pasteurization is a control measure which can be used to eliminate these hazards. The following is an excerpt from a hazard analysis summary table for this product.

Step	**Potential Hazard(s)**	**Justification**	**Hazard to be addressed in plan? Y/N**	**Control Measure(s)**
Pasteurization	Enteric pathogens: e.g., *Salmonella*, *E. coli, Staph Aureus*	enteric pathogens have been associated with outbreaks of foodborne illness from cashew kernels	Y	Pasteurization

The hazard analysis summary could be presented in several different ways. One format is a table such as the one given above. Another could be a narrative summary of the HACCP team's hazard analysis considerations and a summary table listing only the hazards and associated control measures.

Determine Critical Control Points (CCPs) - Principle 2

The second HACCP principle is to identify the Critical Control Points (CCPs) in the food production process. 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. For each food safety hazard that is reasonably likely to occur, you must identify a CCP to control that hazard either at the step at which the hazard is identified or at a later step in the process.

Complete and accurate identification of CCPs is fundamental to controlling food safety hazards. The information developed during the hazard analysis is essential for the HACCP team in identifying which steps in the process are CCPs. 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 D and E). Although application of the CCP decision tree can be useful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. A CCP decision tree is not a substitute for expert knowledge.

Critical control points are located at any step where hazards can be prevented, eliminated, or reduced to acceptable levels. The HACCP team must determine the critical points in the process at which those preventive measures must be applied.

Examples of CCPs may include: pasteurization, cooking, chilling, acidification, addition of preservatives, metal detection, labeling, testing product for chemical residues, and testing product for microbiological pathogens. CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. 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. Different facilities preparing similar food items can differ in the hazards identified and the steps which are CCPs. This can be due to differences in each facility's layout, equipment, selection of ingredients, and processes utilized.

Establish Critical Limits - Principle 3

The next step in the development of a HACCP plan is to establish Critical Limits for each CCP. A Critical Limit is defined as a maximum 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. Critical limits are the parameters that indicate whether the control measure at the CCP is in or out of control and are therefore, the boundaries of safety for preventive measures put in place at CCPs, and are used to distinguish between safe and unsafe operating conditions. Some critical limits for identified CCPs have been established, either through regulatory requirements or through the technical and scientific literature. Critical limits are different than 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 are most often based on process parameters such as temperature, time, physical dimensions, humidity, moisture level, pH, or presence of target pathogens. Critical limits must be actual values that can be measured or quantified and need to be exact and specific. Critical limits must be scientifically based. For each CCP, there is at least one criterion for food safety that is to be met. An example of a criterion is a specific lethality of a cooking process such as a 5D reduction in *Salmonella*. The critical limits and criteria for food safety may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental results, and experts.

An example is the processing of cashew kernels (Appendix B). The process should be designed to ensure the production of a safe product. The hazard analysis for processed cashew kernels identified enteric pathogens (e.g. *Salmonella, Escherichia coli, Staphylococcus aureus*) as significant biological hazards. Pasteurization is the step in the process at which control can be applied to reduce the enteric pathogens to an acceptable level. To ensure that an acceptable level is consistently achieved, accurate information is needed on the probable number of the pathogens in the cashew kernels, their heat resistance, and the factors that influence the heating of the kernels. Collectively, this information forms the scientific basis for the critical limits that are established.

Some of the factors that may affect the thermal destruction of enteric pathogens are listed in the following table. In this example, the HACCP team concluded that a thermal process equivalent to 80° C for 2 minutes would be necessary to assure the safety of this product. To ensure that this time and temperature are attained, the HACCP team for the facility determined that it would be necessary to establish critical limits for the pasteurization machine temperature and belt speed (time in machine).

Control of these factors enables the facility to process a wide variety of cashew kernel grades, all of which will be processed to a temperature of 80° C for 2 minutes. In another facility, the HACCP team may conclude that the best approach is to use a different thermal process, temperature and time as critical limits depending on their product and equipment. The example given below applies to the first facility.

Process Step	**CCP**	**Critical Limits**
Pasteurization	YES	80° C kernel o/p temp for 2 minutes to achieve a 5-log kill for pathogens Salmonella, E.coli and Staphylococcus aureus. Belt speed 3.1 meters per minute +/- .02 meters per minute

Establish Monitoring Procedures - Principle 4

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 CCP to determine whether the critical limits are being met. 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. 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 serves three main purposes. First, monitoring is essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates 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, 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.

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. Monitoring procedures must also be carefully implemented due to the potentially serious consequences of a critical limit deviation resulting in an unsafe food product if a process is not properly controlled.

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 activities include: visual observations and measurement of temperature, time, pH, and moisture level. Consequently, the equipment used for monitoring must be carefully calibrated for accuracy.

Physical and chemical measurements are preferred monitoring activities because they are rapid and usually more effective for assuring control of microbiological hazards. Microbiological tests are considered less effective for monitoring due to their time-consuming nature. For example, the safety of cashew kernels is based upon measurements of time and temperature of heating during processing rather than testing the kernels during processing to assure the absence of surviving pathogens. Most monitoring procedures need to be rapid because they relate to "real-time" processes and there will not be time for lengthy analytical testing. However, microbiological testing is recognized as effective for verifying the absence of pathogens in packaged food products, particularly in facilitation of its export and import.

Ideally, monitoring should be continuous, which is possible with many types of physical and chemical methods. For example, the temperature and time for the scheduled thermal process of cashew kernels is recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the effected product is retained and the disposition determined according to the corrective principles established (Principle 5).

There are many ways to monitor critical limits on a continuous or batch basis and record the data on charts. Continuous monitoring is preferred when feasible. However, 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 the CCP is under control. Statistically designed data collection or sampling systems lend themselves to this purpose.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs, the control measures and the complexity of monitoring. Employees who monitor CCPs are often associated with production, such as line supervisors, selected line workers, maintenance technicians and, as required, quality control managers. Those individuals must be trained in the monitoring technique for which they are responsible, fully understand the purpose and importance of monitoring, be unbiased in monitoring and reporting, and accurately report the results of monitoring. Additionally, employees should be trained in procedures to follow when there is a trend towards loss of control so that adjustments can be made in a timely manner to assure the process remains under control. It is imperative that the person responsible for monitoring immediately report a process or product that does not meet critical limits. All records and documents associated with CCP monitoring should be dated and signed or initialed by the person doing the monitoring.

Establish Corrective Actions - Principle 5

The HACCP team must establish corrective actions to be taken when monitoring shows there is a deviation from a critical limit. 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 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 critical limits may occur. Therefore, it is necessary to have a plan to ensure those deviations do not lead to unsafe food products. The 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.

Corrective actions consist of the following steps: (1) Identify and eliminate the cause of the deviation; (2) Ensure the CCP is under control after the corrective action is taken; (3) Ensure measures are established to prevent recurrence; and (4) Ensure no product affected by the deviation is shipped. Corrective actions may also include a determination of the disposition of the non-compliant product

Corrective actions must be developed for each CCP to be implemented when there is a deviation from a critical limit and included in the HACCP plan. The HACCP plan must 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. Experts may be consulted as needed to review the information available and to assist in determining the disposition of non-compliant product.

Establish Verification Procedures - Principle 6

The establishment of verification procedures is required to ensure the HACCP plan is working correctly. 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. Validation asks the question, “Is the correct thing being done?” Verification asks, “Is the correct thing continuing to be done?”

Three primary processes are involved in the verification of the HACCP system: (1) Initial Validation; (2) Ongoing Verification; and (3) Reassessment.

Initial Validation

The first process of verification is the initial validation of the HACCP plan, which is the scientific and technical process to determine that all hazards have been properly identified and the CCPs and associated critical limits are adequate and sufficient to control the hazards. The HACCP plan is tested and reviewed to verify proper implementation of the plan will result in the hazards being effectively controlled.

Information required to validate the HACCP plan includes expert advice and scientific studies, as well as observations, measurements, and evaluations within the facility. For example, validation of the pasteurization process for cashew kernels should include the scientific justification of the heating times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms (such as enteric pathogens) and studies to confirm that the conditions of pasteurization will deliver the required time and temperature to each kernel.

Ongoing Verification

The second primary process of verification is the ongoing verification which is conducted to ensure that the HACCP plan is working effectively on a day to day basis after initial validation is completed. This type of verification includes activities such as instrument calibration, observing monitoring activities and corrective actions, auditing of CCP's and critical limits, product testing, and reviewing HACCP records to confirm they are being made and kept according to the plan.

An important 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. Therefore, rather than relying on end-product testing, facilities should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, and review of CCP monitoring and corrective action records.

Reassessment

The third primary process of verification consists of documented, periodic, reassessment and verification of the HACCP plan conducted by an unbiased, independent authority. Such authorities can be internal or external to the food operation.

Reassessment is a periodic comprehensive verification and overall review of the HACCP plan that must be performed at least annually. A reassessment is also performed whenever any changes occur that could affect the hazard analysis or alter the HACCP plan and in response to a deviation not covered by a specific corrective action (unforeseen hazard). Reassessment is similar to validation in that it considers, in general, whether the plan is adequate, rather than focusing on the plan's daily operations.

A reassessment should include a technical evaluation of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from operation of the plan. A comprehensive verification is independent of other verification procedures and must be performed to ensure the HACCP plan is resulting in the control of the hazards. The HACCP team must modify the HACCP plan as necessary if the results of the comprehensive verification identifies deficiencies.

Subsequent validations are performed and documented by the HACCP team or an independent expert as needed. These validations are conducted when there are deficiencies, unexplained system failures; a significant product, process or packaging change occurs; or new hazards are recognized. Verification activities are carried out by individuals within the company and third party experts. It is important that individuals doing verification have appropriate technical expertise to perform this function.

An example of a verification schedule is given in Figure 2. Additionally, examples of verification activities are included as Appendix G.

Figure 2. Example of a Company Established HACCP Verification Schedule

Activity	**Frequency**	**Responsibility**	**Reviewer**
Verification Activities Scheduling	Yearly or Upon HACCP System Change	HACCP Coordinator	Plant Manager
Initial Validation of HACCP Plan	Prior to and During Initial Implementation of Plan	Independent Expert(s)[(a)]	HACCP Team
Subsequent validation of HACCP Plan	When Critical Limits Changed, Significant Changes in Process, Equipment Changed, After System Failure, etc.	Independent Expert(s)[(a)]	HACCP Team
Verification of CCP Monitoring as Described in the Plan (e.g., monitoring of pasteurization temperature)	According to HACCP Plan (e.g., once per shift)	According to HACCP Plan (e.g., Line Supervisor)	According to HACCP Plan (e.g., Quality Control)
Review of Monitoring, Corrective Action Records to Show Compliance with the Plan	Monthly	Quality Assurance	HACCP Team
Comprehensive HACCP System Verification	Yearly	Independent Expert(s)[(a)]	Plant Manager
[(a)] Done by others than the team writing and implementing the plan. May require additional technical expertise as well as laboratory and plant test studies.			

Establish Record Keeping and Documentation Procedures - Principle 7

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

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.

Generally, the records maintained specifically for the HACCP Plan should include the following:

1. Listing of the HACCP team and assigned responsibilities
2. Description of the food, its distribution, intended use, and consumer
3. Verified flow diagram
4. HACCP Plan Summary Table that includes information for:
    a) Steps in the process that are CCPs
    b) The hazard(s) of concern.
    c) Critical limits
    d) Monitoring*
    e) Corrective actions*
    f) Verification procedures and schedule*
    g) Record-keeping procedures*

* A brief summary of position responsible for the activity, 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

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.

Examples of HACCP records are given in Appendix H

Implementation and Maintenance of the HACCP Plan

The successful implementation of a HACCP plan is facilitated by commitment from top management. The next step is to establish a plan that describes the individuals responsible for developing, implementing and maintaining the HACCP system. Initially, the HACCP coordinator and team are selected and trained as necessary. The HACCP team is then responsible for developing the initial plan and coordinating its implementation. Product teams can be appointed to develop HACCP plans for specific products.

An important aspect in developing these teams is to assure they have appropriate training. The workers who will be responsible for monitoring need to be adequately trained. Upon completion of the HACCP plan, operator procedures, forms and procedures for monitoring and corrective actions are developed. A timeline should be developed for the activities involved in the initial implementation of the HACCP plan. Implementation of the HACCP system involves the continual application of the monitoring, record-keeping, corrective action procedures and other activities as described in the HACCP plan.

Maintaining an effective HACCP system depends largely on regularly scheduled verification activities. The HACCP plan should be updated and revised as needed. An important aspect of maintaining the HACCP system is to assure all individuals involved are properly trained to ensure they understand their role and can effectively fulfill their responsibilities.

The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan. The HACCP plan shall be dated and signed: (1) Upon initial acceptance; (2) Upon any modification; and (3) At least annually, upon reassessment.

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.

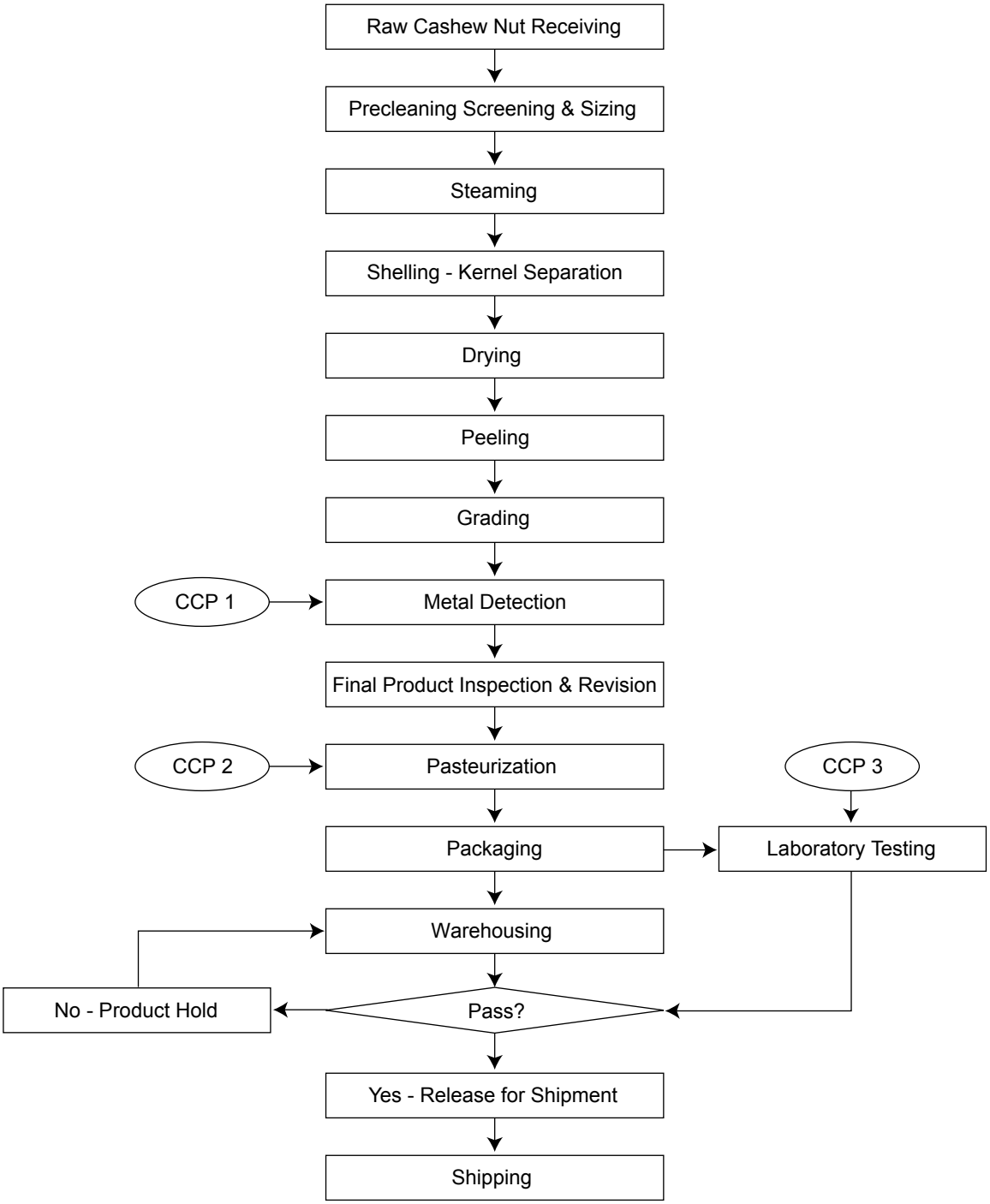
Pest Control: Effective pest control programs should be in place.

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

EXAMPLE OF A FLOW DIAGRAM FOR THE PRODUCTION OF CASHEW KERNELS

PROCESS FLOW DIAGRAM



APPENDIX C

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, free fatty acid, 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, metal?

7. What product safety devices are used to enhance consumer safety?
    - metal detectors
    - magnets
    - sifters
    - filters
    - screens
    - thermometers
    - 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 D

Examples of How the Stages of Hazard Analysis are used to Identify and Evaluate Hazards*

Hazard Analysis Stage		Raw cashew nut processed in a processing facility	Cashew kernels processed in a processing facility	Cashew kernels prepared for foodservice
Stage 1 Hazard Identification ***Determine potential hazards associated with product***		Enteric pathogens (E. coli, Salmonella, and Staphylococcus aureus)	Salmonella in finished product.	Staphylococcus aureus in finished product.
Stage 2 Hazard Evaluation	*Assess severity of health consequences if potential hazard is not properly controlled.*	Epidemiological evidence indicates these pathogens cause severe health effects including death among children and elderly. Unpasteurized cashews have been linked to disease from these pathogens.	Salmonellosis is a food borne infection causing a moderate to severe illness that can be caused by ingestion of only a few cells of Salmonella.	Certain strains of S. aureus produce an enterotoxin which can cause a moderate foodborne illness.
	Determine likelihood of occurrence of potential hazard if not properly controlled.	E. coli, Salmonella, and Staphylococcus aureus is of moderate probability in raw cashew nuts.	E. coli, Salmonella, and Staphylococcus aureus is of moderate probability in cashew kernels. If not effectively controlled, some consumers are likely to be exposed to these pathogens from this food.	Product may be contaminated with S. aureus and Salmonella due to human handling during processing. If not effectively controlled, some consumers are likely to be exposed to these pathogens from this food.
	Using information above, determine if this potential hazard is to be addressed in the HACCP plan.	The HACCP team decides that enteric pathogens are hazards for this product. **Hazards must be addressed in the plan.**	The HACCP team determines that if the potential hazard is not properly controlled, consumption of product is likely to result in an unacceptable health risk. **Hazard must be addressed in the plan.**	HACCP team determines that if the potential hazard is not properly controlled, consumption of product is likely to result in an unacceptable health risk. **Hazard must be addressed in the plan.**

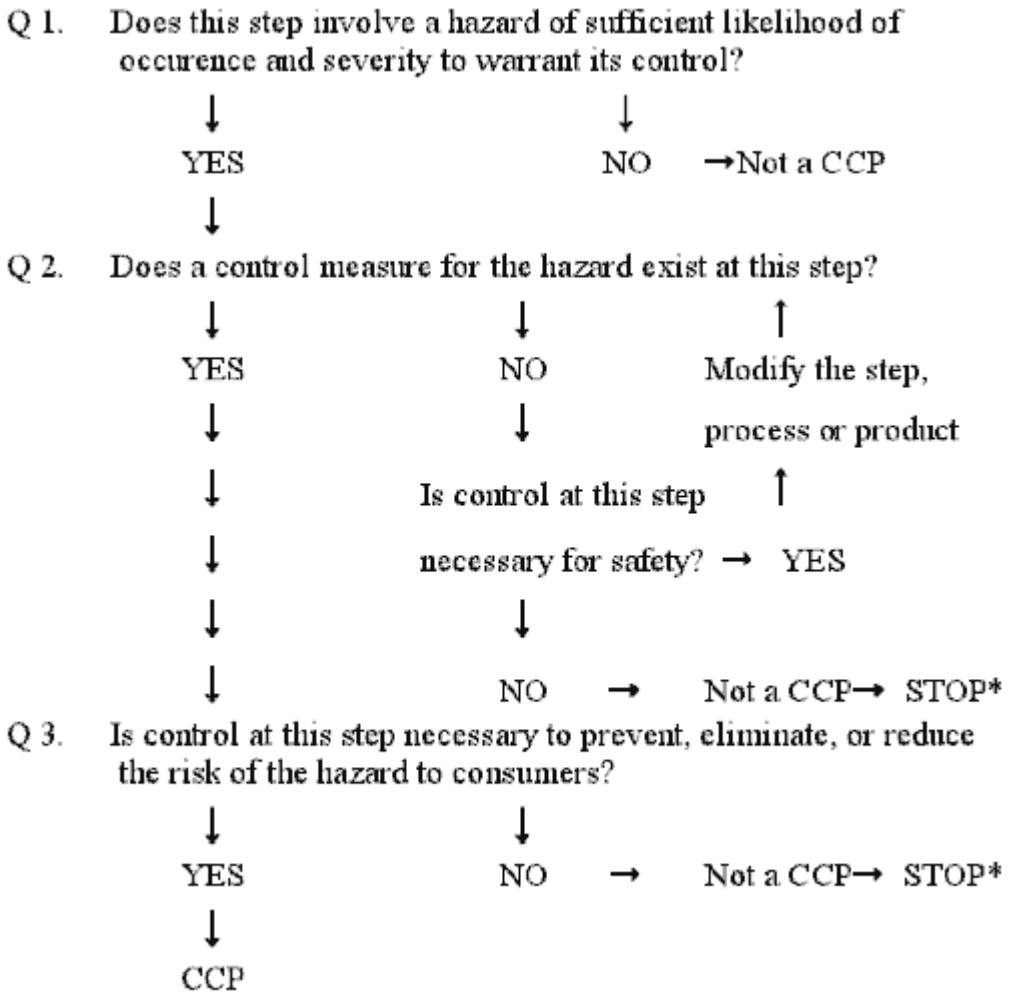
* For illustrative purposes only. The potential hazards identified may not be the only hazards associated with the products listed. The responses may be different for different facilities.

APPENDIX E

Example 1 of a CCP Decision Tree

Important considerations when using the decision tree:

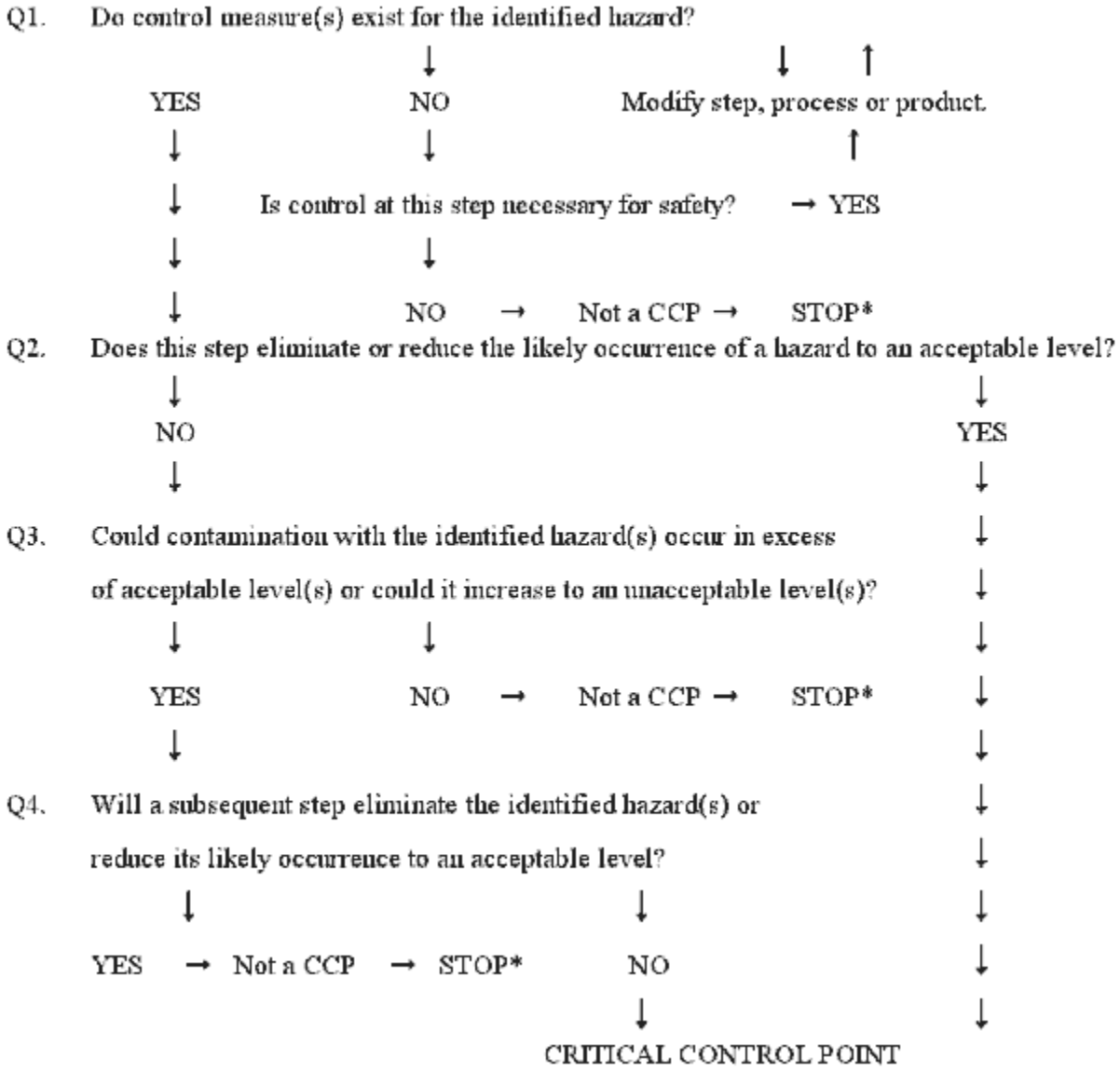
1. The decision tree is used after the hazard analysis.
2. The decision tree then is used at the steps where a hazard that must be addressed in the HACCP plan has been identified.
3. A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP.
4. More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



* Proceed to next step in the process.

APPENDIX F

Example II of a CCP Decision Tree



*Proceed to next step in the described process

APPENDIX G

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 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 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 H

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.