# CHAPTER 7
# Developing the HACCP Plan

## 7 .1 Documentation of HACCP Plan

The HACCP plan shall be documented and shall include the following information for each identified critical control point (CCP):
a) food safety hazard(s) to be controlled at the CCP;
b) control measure(s)
c) critical limit(s);
d) monitoring procedure(s;
e) corrections and corrective action(s) to be taken if critical limits are exceeded;
f) responsibilities and authorities;
g) record(s) of monitoring.

This principle focuses on the records and documentation needed to show that all activities have been performed according to approved procedures.

Documentation provides clear instruction on the approved processes so that each person knows how to perform the process in the approved manner.

Records show that the work performed was done in compliance with these procedures. The standards require specific procedures and documents as well as requiring the organization to identify documentation that it needs to develop, implement and update the FSMS. Your documentation must include:

**Food Safety Policy and Objectives**

- Documents needed for the effective development, implementation and updating of the FSMS
- A documented PRP program
- Documentation of raw materials, ingredients and product contact materials
- Characteristics of end products
- Intended use of end products
- Flow diagrams for products or process categories
- Description of process steps and control measures
- Methodology and parameters used for selection of control measures
- HACCP Plan
- Procedure for Corrections
- Procedure for Corrective Action
- Procedure for Control of Nonconforming Product
- Procedure for Withdrawals
- Procedure for Internal Audits
- Procedure for Document Control
- Procedure for Records Control

**Records:**

- The standard calls out specific records that are required. These are in addition to any records required by statutory, regulator or customer requirements. They include:
- Records of communication
- Records of management review
- Records of contracts with external experts

- Records of training
- Records of preliminary steps for hazard analysis
- Records of verification of PRPs
- Records of the food safety team members qualifications
- Verified flow diagrams
- Results of hazard identification and assessment
- Records of operational PRP monitoring
- Verification results
- Traceability records
- Records of HACCP monitoring
- Records of internal audits and verification activities
- Records of review of product manufactured when operational PRPs were not within conformance limits
- Records of corrective action
- Records of withdrawal
- Records of calibration
- System updating activities

The documentation and records are a critical element of the food safety management system. They will help control your processes and ensure that they are done in a consistent and approved manner

**7.2 Identification of Critical Control Points (CCP's)**

For each hazard that is to be controlled by the HACCP plan, CCP(s) shall be identified for the control measures identified

Critical control point is a step in the process of manufacturing or preparing food in which the right procedure can minimize or remove a potential health hazard such as a food-borne illness. By correctly identifying critical control points, food manufacturers and restaurant owners can reduce the risk of harm to the public.

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. 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 1 & 2 of decision trees are given in the end of the chapter**). 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 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. 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, processes employed, etc.

**Preventive Measures**

The identification of a critical control point is based on the CCP decision tree. The first step in the CCP decision tree is to determine whether any preventive measures exist for this particular hazard. For example, one possible hazard at a restaurant is food-borne illness from undercooked pork. In this case, cooking the meal at a particular temperature for an appropriate length of time should control the potential hazard, so the answer is yes. When the answer is no, this step in the process is not a critical control point unless this step is the only step at which the hazard could be controlled. In this case, the process must be redesigned so that the hazard can be controlled at this step.

**Elimination or Reduction of Risk**

The second step in the CCP decision tree is to determine whether the proposed control is sufficient to either eliminate the risk completely or at least reduce it to a minimal risk. Cooking fresh pork at a high enough temperature for a long enough time will reduce the risk of food-borne illness to a minimal level, so in this case, the answer is yes. When the answer to question two is yes, the step under consideration is a critical control point. When the answer is no, move on to step three.

**Level of Risk**

Step three of the CCP decision tree is to determine whether the hazard could realistically occur. For example, it might be a hazard if a meal became contaminated with a particular pathogen, but the pathogen might normally be present only at non-hazardous levels. In this case, the question is whether the pathogen could realistically increase to the level where it would be dangerous. In some situations, the answer to this question depends on the context. Ground beef cooked rare is considered an acceptable hazard for healthy adults, but not for children or elderly people. If the hazard turns out to be unrealistic on closer analysis, this step in the process is not a critical control point. If the hazard can realistically occur, move on to step four.

**Control**

Step four in the CCP decision tree is to determine whether the hazard could be controlled at some later stage in the process. For example, one hazard in beef production is that fragments of metal from the grinder can contaminate the beef. By using a metal detector at the end of the production process, the manufacturing facility can control the hazard. If the hazard cannot be controlled at a later stage, the step in question is a critical control point. The process must be redesigned to make it possible to control the hazard at the critical point. For instance, if the hazard is a potential pathogen that cannot be controlled either at the current stage or a later stage, the company might need to use a different piece of equipment that is less vulnerable to contamination or easier to clean.

### 7.3 Determination of Critical Limits for Critical Control Points

Critical limits shall be determined for the monitoring established for each CCP.

Critical limits shall be established to ensure that the identified acceptable level of the food safety hazard in the end product is not exceeded.

Critical limits shall be measurable.

The rationale for the chosen critical limits shall be documented.

Critical limits based on subjective data (such as visual inspection of product, process, handling, etc.) shall be supported by instructions or specifications and/or education and training.

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. 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 cooking of beef patties (Refer flow diagram of earlier chapter). The process should be designed to ensure the production of a safe product. The hazard analysis for cooked meat patties identified enteric pathogens (e.g., verotoxigenic *E. coli* such as *E. coli* O157:H7, and salmonellae) as significant biological hazards. Furthermore, cooking 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 raw patties, their heat resistance, the factors that influence the heating of the patties, and the area of the patty which heats the slowest. 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 68.3°C for 16 seconds would be necessary to assure the safety of this product. To ensure that this time and temperature are attained, the HACCP team for one facility determined that it would be necessary to establish critical limits for the oven temperature and humidity, belt speed (time in oven), patty thickness and composition (e.g., all beef, beef and other ingredients). Control of these factors enables the facility to produce a wide variety of cooked patties, all of which will be processed to a minimum internal temperature of 68.3° C for 16 seconds. In another facility, the HACCP team may conclude that the best approach is to use the internal patty temperature of 68.3° C and hold for 16 seconds as critical limits. In this second facility the internal temperature and hold time of the patties are monitored at a frequency to ensure that the critical limits are constantly met as they exit the oven. The example given below applies to the first facility.

| Process Step | CCP | Critical Limits |
|---|---|---|
| 5. Cooking | YES | Oven temperature:___° C<br>Time; rate of heating and cooling (belt speed in C/min): ____ C/min<br>Patty thickness: ____in.<br>Patty composition: e.g. all beef<br>Oven humidity: ____% RH |

### 7.4 System for the Monitoring of Critical Control Points

A monitoring system shall be established for each CCP to demonstrate that the CCP is in control. The system shall include all scheduled measurements or observations relative to the critical limit(s).

The monitoring system shall consist of relevant procedures, instructions and records that cover the following:
a) measurements or observations that provide results within an adequate time frame;
b) monitoring devices used;
c) applicable calibration methods;
d) monitoring frequency;
e) responsibility and authority related to monitoring and evaluation of monitoring results;
f) record requirements and methods.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

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.

An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical limit deviation, monitoring procedures must be effective. 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 low-acid canned foods 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 product from the retort is retained and the disposition determined as in Principle 5. Likewise, pH measurement may be performed continually in fluids or by testing each batch before processing. There are many ways to monitor critical limits on a continuous or batch basis and record the data on charts. Continuous monitoring is always preferred when feasible. Monitoring equipment must be carefully calibrated for accuracy.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs and control measures and the complexity of monitoring. Personnel who monitor CCPs are often associated with production (e.g., line supervisors, selected line workers and maintenance personnel) and, as required, quality control personnel. 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. In addition, 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 that the process remains under control. The person responsible for monitoring must also 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.

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. Statistically designed data collection or sampling systems lend themselves to this purpose. Most monitoring procedures need to be rapid because they relate to on-line, "real-time" processes and there will not be time for lengthy analytical testing. Examples of monitoring activities include: visual observations and measurement of temperature, time, pH, and moisture level.

Microbiological tests are seldom effective for monitoring due to their time-consuming nature and problems with assuring detection of contaminants. Physical and chemical measurements are often preferred because they are rapid and usually more effective for assuring control of microbiological hazards. For example, the safety of pasteurized milk is based upon measurements of time and temperature of heating rather than testing the heated milk to assure the absence of surviving pathogens.

With certain foods, processes, ingredients, or imports, there may be no alternative to microbiological testing. However, it is important to recognize that a sampling protocol that is adequate to reliably detect low levels of pathogens is seldom possible because of the large number of samples needed. This sampling limitation could result in a false sense of security by those who use an inadequate sampling protocol. In addition, there are technical limitations in many laboratory procedures for detecting and quantitating pathogens and/or their toxins.

### 7.5 Actions to be Taken When Results Exceed Critical Limits

Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the HACCP plan. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented (refer Corrective actions & Handling of potentially unsafe products in further chapter).

Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated.

**Actions:** 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.

### 7.6 Continual Updating of Information and Documents

Following the establishment of operational PRP(s) and/or the HACCP plan, the organization shall update the following information, if necessary:

a) product characteristics;
b) intended use;
c) flow diagrams;
d) process steps;
e) control measures.

If necessary, the HACCP plan and the procedures and instructions specifying the PRP(s) shall be amended.

### 7.7 Verification Activities

Verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities. The verification activities shall confirm that:

a) the PRP(s) are implemented,
b) input to the hazard analysis is continually updated,
c) the operational PRP(s) and the elements within the HACCP plan are implemented and effective,
d) hazard levels are within identified acceptable levels, and
e) other procedures required by the organization are implemented and effective.

The output of this planning shall be in a form suitable for the organization's method of operations.

Verification results shall be recorded and shall be communicated to the food safety team.

Verification results shall be provided to enable the analysis of the results of the verification activities.

If system verification is based on testing of end product samples, and where such test samples show nonconformity with the acceptable level of the food safety hazard, the affected lots of product shall be handled as potentially unsafe in accordance with clause called handling of potentially unsafe products.

**Importance:** 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. The National Academy of Sciences (1985) pointed out that the major infusion of science in a HACCP system centers on proper identification of the hazards, critical control points, critical limits, and instituting proper verification procedures. These processes should take place during the development and implementation of the HACCP plans and maintenance of the HACCP system. An example of a verification schedule is given in **Example 3 at the end of the chapter**

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. Therefore, rather than relying on end-product testing, firms 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.

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.

For example, validation of the cooking process for beef patties should include the scientific justification of the heating times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms (i.e., enteric pathogens) and studies to confirm that the conditions of cooking will deliver the required time and temperature to each beef patty.

Subsequent validations are performed and documented by a HACCP team or an independent expert as needed. For example, validations are conducted when there is an unexplained system failure; a significant product, process or packaging change occurs; or new hazards are recognized.

In addition, a periodic comprehensive verification of the HACCP system should be conducted by an unbiased, independent authority. Such authorities can be internal or external to the food operation. This 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 that the HACCP plan is resulting in the control of the hazards. If the results of the comprehensive verification identifies deficiencies, the HACCP team modifies the HACCP plan as necessary.

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 in **Example 4 at the end of the chapter.**

### 7.8 Establishing a traceability System

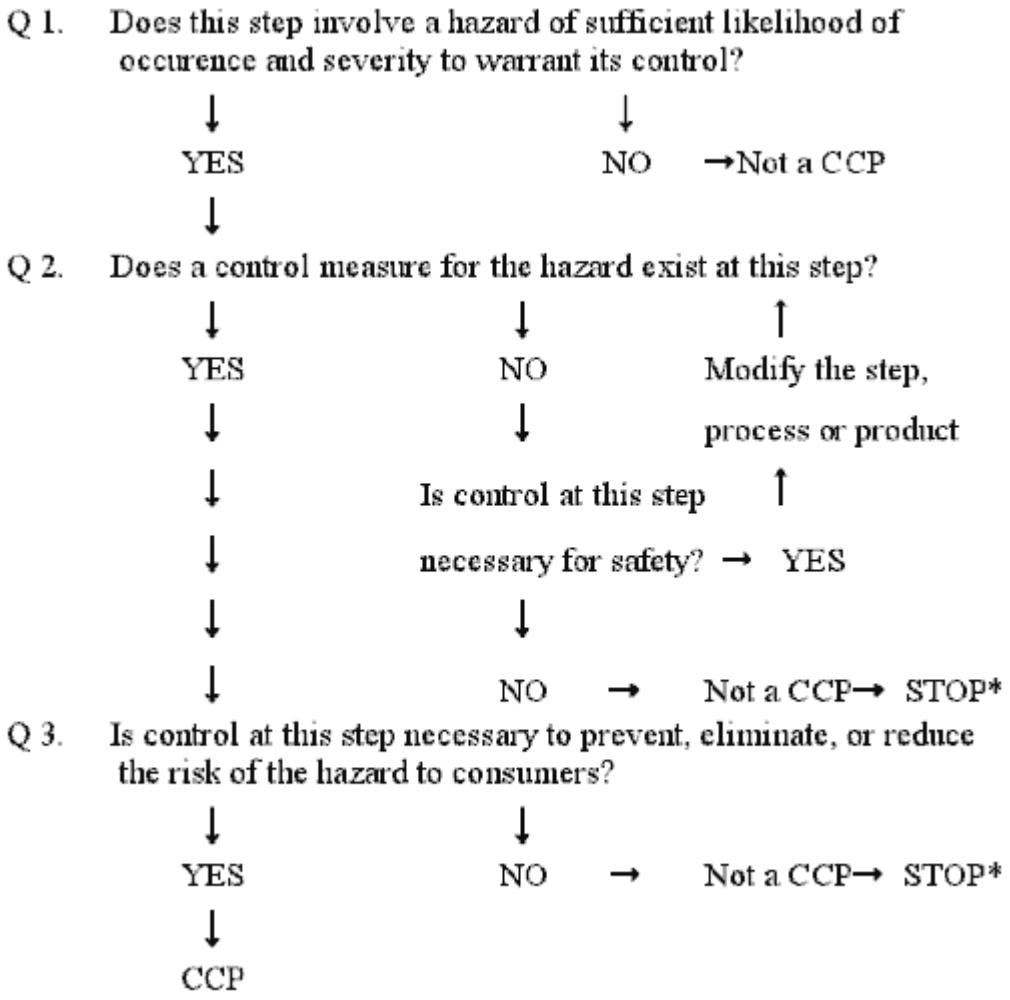
The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.

The traceability system shall be able to identify incoming material from the immediate suppliers and the initial distribution route of the end product.
Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements and customer requirements and may, for example, be based on the end product lot identification.

**Example I: CCP Decision Tree**

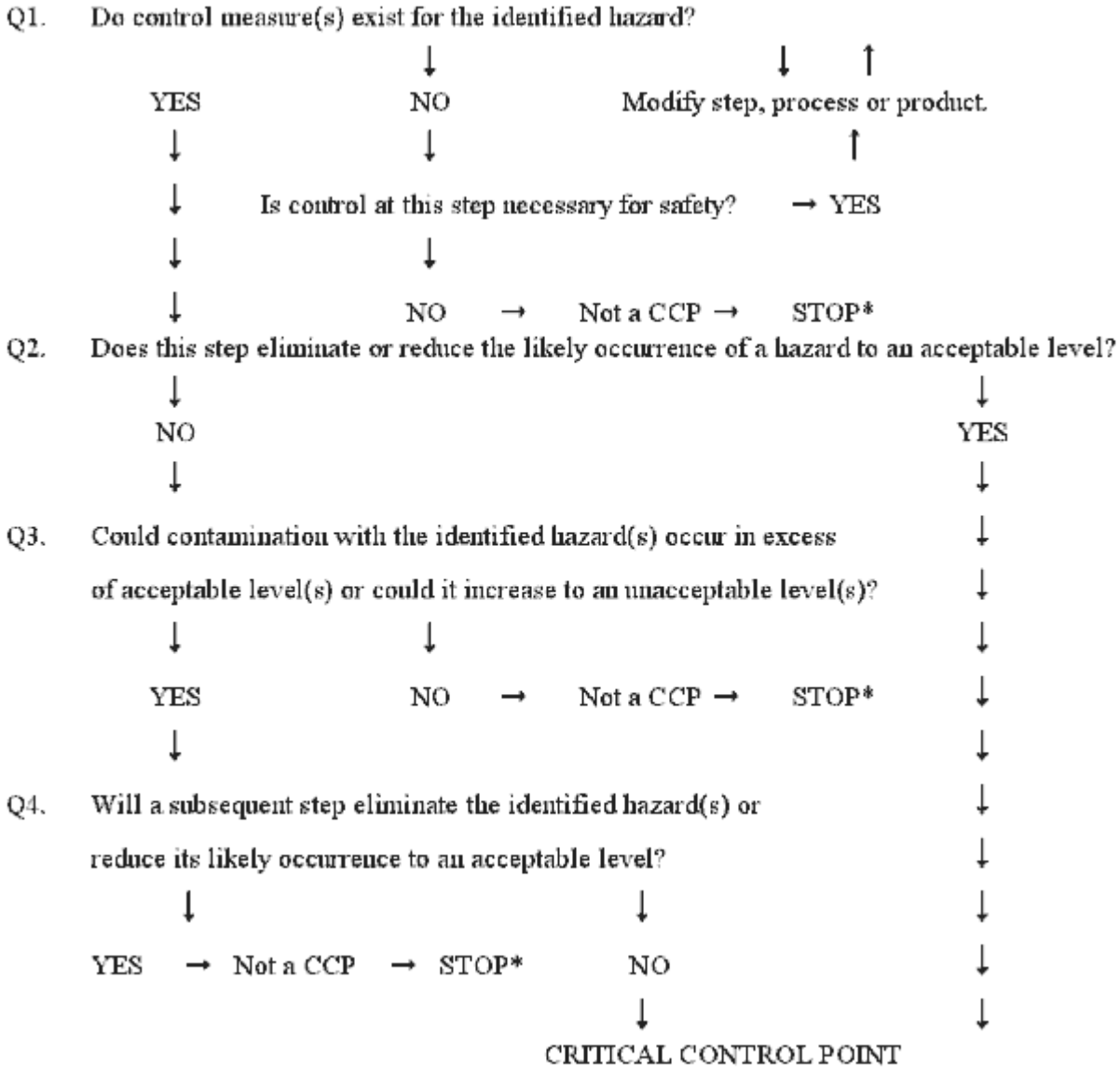
Important considerations when using the decision tree:

- 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.

**Example II: CCP Decision Tree**




*Proceed to next step in the described process

**Example 3:** 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 patty cooking 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. | | | |

**Example 4: 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.