

Hazard Analysis Critical Control Point



HACCP

Student Workbook

**Food Service Courses, Marine Corps
Detachment, Fort Lee Virginia**

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U. S. Food and Drug Administration
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Foods
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**HAZARD ANALYSIS AND CRITICAL CONTROL
POINT PRINCIPLES AND APPLICATION
GUIDELINES**

**NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS**

EXECUTIVE SUMMARY

The National Advisory Committee on Microbiological Criteria for Foods (Committee) reconvened a Hazard Analysis and Critical Control Point (HACCP) Working Group in 1995. The primary goal was to review the Committee's November 1992 HACCP document, comparing it to current HACCP guidance prepared by the Codex Committee on Food Hygiene. Based upon its review, the Committee made the HACCP principles more concise; revised and added definitions; included sections on prerequisite programs, education and training, and implementation and maintenance of the HACCP plan; revised and provided a more detailed explanation of the application of HACCP principles; and provided an additional decision tree for identifying critical control points (CCPs).

The Committee again endorses HACCP as an effective and rational means of assuring food safety from harvest to consumption. 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 the application of HACCP, the use of microbiological testing is seldom an effective means of monitoring CCPs because of the time required to obtain results. In most instances, monitoring of CCPs can best be accomplished through the use of physical and chemical tests, and through visual observations. Microbiological criteria do, however, play a role in verifying that the overall HACCP system is working.

The Committee believes that the HACCP principles should be standardized to provide uniformity in training and applying the HACCP system by industry and government. In accordance with the National Academy of Sciences recommendation, the HACCP system must be developed by each food establishment and tailored to its individual product, processing and distribution conditions.

In keeping with the Committee's charge to provide recommendations to its sponsoring agencies regarding microbiological food safety issues, this document focuses on this area. The Committee recognizes that in order to assure food safety, properly designed HACCP systems must also consider chemical and physical hazards in addition to other biological hazards.

For a successful HACCP program to be properly implemented, management must be committed to a HACCP approach. A commitment by management will indicate an awareness of the benefits and costs of HACCP and include education and training of employees. Benefits, in addition to enhanced assurance of food safety, are better use of resources and timely response to problems.

The Committee designed this document to guide the food industry and advise its sponsoring agencies in the implementation of HACCP systems.

DEFINITIONS

CCP Decision Tree:

A sequence of questions to assist in determining whether a control point is a CCP.

Control:

- (a) To manage the conditions of an operation to maintain compliance with established criteria.
- (b) The state where correct procedures are being followed and criteria are being met.

Control Measure:

Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Control Point:

Any step at which biological, chemical, or physical factors can be controlled.

Corrective Action:

Procedures followed when a deviation occurs.

Criterion:

A requirement on which a judgment or decision can be based.

Critical Control Point:

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.

Critical Limit:

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.

Deviation:

Failure to meet a critical limit.

HACCP:

A systematic approach to the identification, evaluation, and control of food safety hazards.

HACCP Plan:

The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

HACCP System:

The result of the implementation of the HACCP Plan.

HACCP Team:

The group of people who are responsible for developing, implementing and maintaining the HACCP system.

Hazard:

A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis:

The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Monitor:

To conduct 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.

Prerequisite Programs:

Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.

Severity:

The seriousness of the effect(s) of a hazard.

Step:

A point, procedure, operation or stage in the food system from primary production to final consumption.

Validation:

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.

Verification:

Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

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.

GUIDELINES FOR APPLICATION OF HACCP PRINCIPLES

Introduction

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. Prerequisite programs such as current Good Manufacturing Practices (cGMPs) are an essential foundation for the development and implementation of successful HACCP plans. Food safety systems based on the HACCP principles have been successfully applied in food processing plants, retail food stores, and food service operations. The seven principles of HACCP have been universally accepted by government agencies, trade associations and the food industry around the world.

The 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. Examples of common prerequisite programs are listed in [Appendix A](#). 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. Many of the conditions and practices are specified in federal, state and local regulations and guidelines (e.g., cGMPs and Food Code). The Codex Alimentarius General Principles of Food Hygiene describe the basic conditions and practices expected for foods intended for international trade. In addition to the requirements specified in regulations, industry often adopts policies and procedures that are specific to their operations. Many of these are proprietary. 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 ([Appendix A](#)). 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. Certain aspects, however, of a prerequisite program may be incorporated into a HACCP plan. For example, many establishments 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 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.

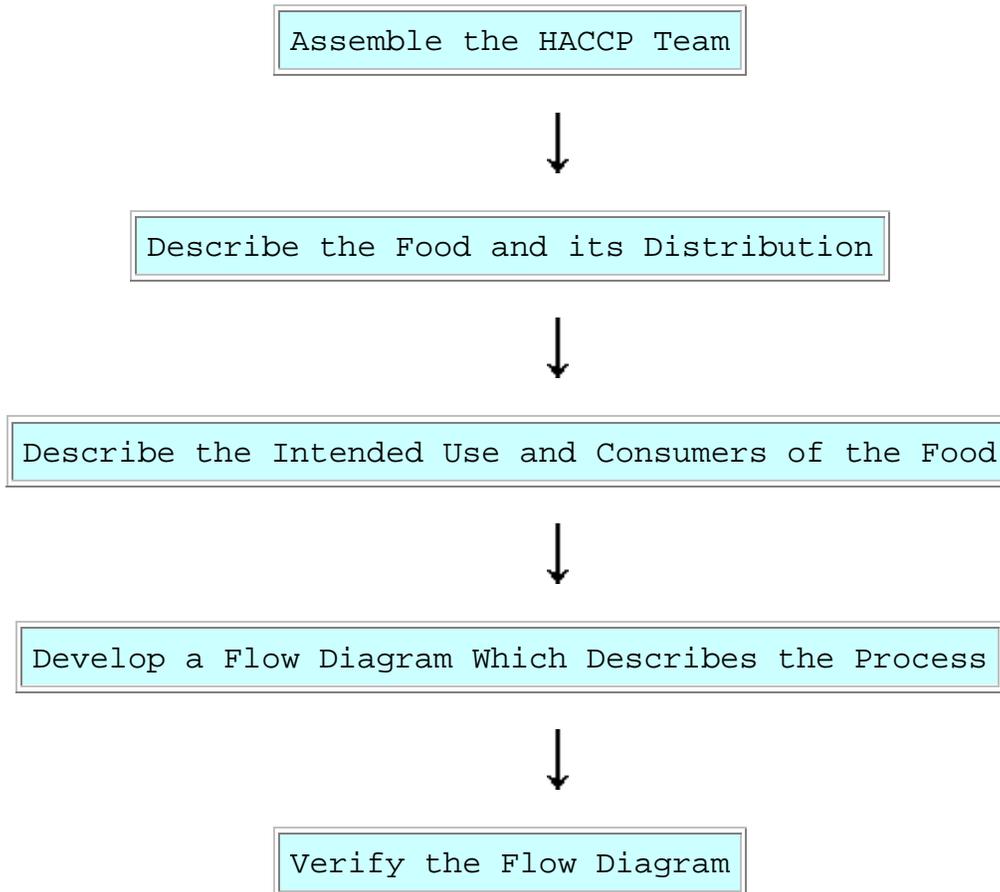
Management must provide adequate time for thorough education and training. Personnel must be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP plan.

Developing a HACCP Plan

The format of HACCP plans will vary. In many cases the plans will be product and process specific. However, some plans may use a unit operations approach. 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.

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 in Figure 1.

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. In addition, this fosters 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 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, immunocompromised 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 (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)

After addressing the preliminary tasks discussed above, the HACCP team conducts a hazard analysis and identifies appropriate control measures. 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. 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. Thus, the word hazard as used in this document is limited to safety.

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 objectives: Those hazards and associated control measures are identified. The analysis may identify needed

modifications to a process or product so that product safety is further assured or improved. The analysis provides a basis for determining CCPs in Principle 2.

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 C lists examples of questions that may be helpful to consider when identifying potential hazards. Hazard identification focuses on developing a list of potential hazards associated with each process step under direct control of the food operation. Knowledge of any adverse health-related events historically associated with the product will be of value in this exercise.

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. 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. Such considerations do not include common dietary choices, which lie outside of HACCP. 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 might 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. 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.

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.

Appendix D gives three examples of using a logic sequence in conducting a hazard analysis. While these examples relate to biological hazards, chemical and physical hazards are equally important to consider. Appendix D is for illustration purposes to further explain the stages of hazard analysis for identifying hazards. Hazard identification and evaluation as outlined in Appendix D may eventually be assisted by biological risk assessments as they become available. While the process and output of a risk assessment (NACMCF, 1997)⁽¹⁾ is significantly different from a hazard analysis, the identification of hazards of concern and the hazard evaluation may be facilitated by information from risk assessments. Thus, 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 of milk).

For example, if a HACCP team were to conduct a hazard analysis for the production of frozen cooked beef patties (Appendices B and D), enteric pathogens (e.g., *Salmonella* and verotoxin-producing *Escherichia coli*) in the raw meat would be identified as hazards. Cooking 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)
5. Cooking	Enteric pathogens: e.g., <i>Salmonella</i> , verotoxigenic- <i>E. coli</i>	enteric pathogens have been associated with outbreaks of foodborne illness from undercooked ground beef	Y	Cooking

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)

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 of decision trees are given in Appendices E and F). 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.

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. 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 (Appendix B). 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 155° F 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 155° F for 16 seconds. In another facility, the HACCP team may conclude that the best approach is to use the internal patty temperature of 155° F 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: ___° F Time; rate of heating and cooling (belt speed in ft/min): ___ft/min Patty thickness: ___in. Patty composition: e.g. all beef 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.

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.

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. The NAS (1985) ⁽²⁾ 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 Figure 2.

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. The role of regulatory and industry in HACCP was further described by the NACMCF (1994) ⁽³⁾.

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 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.

**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 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 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 that 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 action are developed. Often it is a good idea to develop a timeline 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 that all individuals involved are properly trained so they understand their role and can effectively fulfill their responsibilities.

(1) National Advisory Committee on Microbiological Criteria for Foods. 1997. The principles of risk assessment for illness caused by foodborne biological agents. Adopted April 4, 1997.

(2) An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients. 1985. National Academy of Sciences, National Academy Press, Washington, DC.

(3) National Advisory Committee on Microbiological Criteria for Foods. 1994. The role of regulatory agencies and industry in HACCP. Int. J. Food Microbiol. 21:187-195.

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.

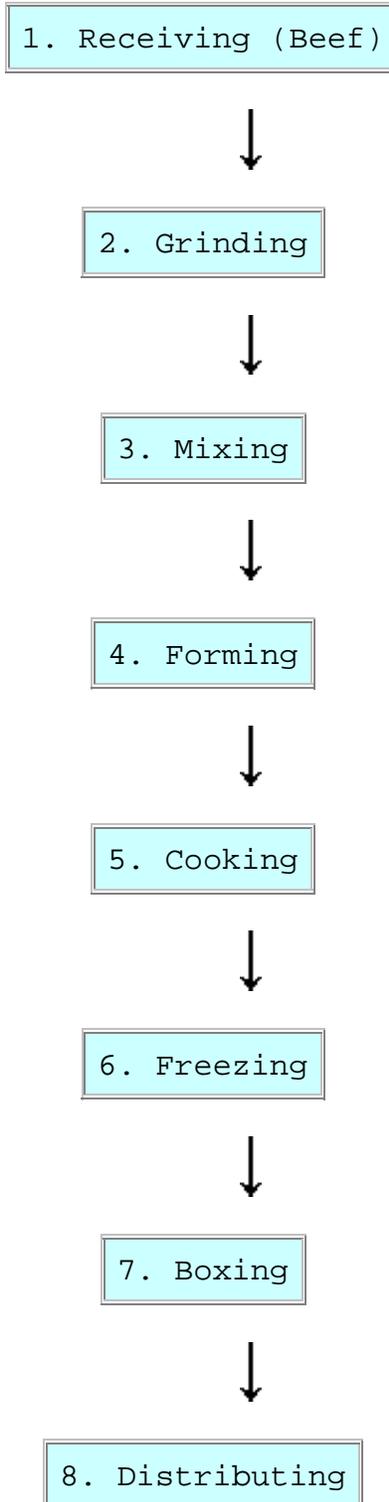
Pest Control.

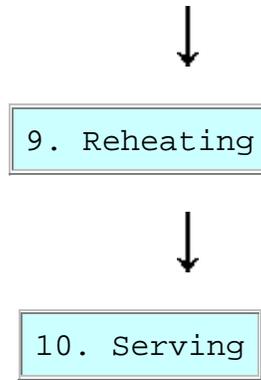
Effective pest control programs should be in place.

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 Frozen Cooked Beef Patties





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, 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. 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. K. Intended use
1. Will the food be heated by the consumer?
 2. Will there likely be leftovers?
- L. 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	Frozen cooked beef patties produced in a manufacturing plant	Product containing eggs prepared for foodservice	Commercial frozen pre-cooked, boned chicken for further processing
Stage 1 Determine	Enteric	Salmonella in	Staphylococcus

<i>potential Hazard hazards associated</i>		pathogens (i.e., E. coli O157:H7 and Salmonella)	finished product.	aureus in finished product.
Identification with product				
Stage 2 Hazard Evaluation	<i>Assess severity of health consequences if potential hazard is not properly controlled.</i>	Epidemiological evidence indicates that these pathogens cause severe health effects including death among children and elderly. Undercooked beef patties 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.
	<i>Determine likelihood of occurrence of potential hazard if not properly controlled.</i>	E. coli O157:H7 is of very low probability and salmonellae is of moderate probability in raw meat.	Product is made with liquid eggs which have been associated with past outbreaks of salmonellosis. Recent problems with Salmonella serotype Enteritidis in eggs cause increased concern. Probability of Salmonella in raw eggs cannot be ruled out. If not effectively controlled, some consumers are likely to be exposed to Salmonella from this food.	Product may be contaminated with S. aureus due to human handling during boning of cooked chicken. Enterotoxin capable of causing illness will only occur as S. aureus multiplies to about 1,000,000/g. Operating procedures during boning and subsequent freezing prevent growth of S. aureus, thus the potential for enterotoxin formation is very low.

	<p><i>Using information above, determine if this potential hazard is to be addressed in the HACCP plan.</i></p>	<p>The HACCP team decides that enteric pathogens are hazards for this product.</p> <p>Hazards must be addressed in the plan.</p>	<p>HACCP team determines that if the potential hazard is not properly controlled, consumption of product is likely to result in an unacceptable health risk.</p> <p>Hazard must be addressed in the plan.</p>	<p>The HACCP team determines that the potential for enterotoxin formation is very low. However, it is still desirable to keep the initial number of <i>S. aureus</i> organisms low. Employee practices that minimize contamination, rapid carbon dioxide freezing and handling instructions have been adequate to control this potential hazard.</p> <p>Potential hazard does not need to be addressed in plan.</p>
<p>* 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 establishments.</p>				

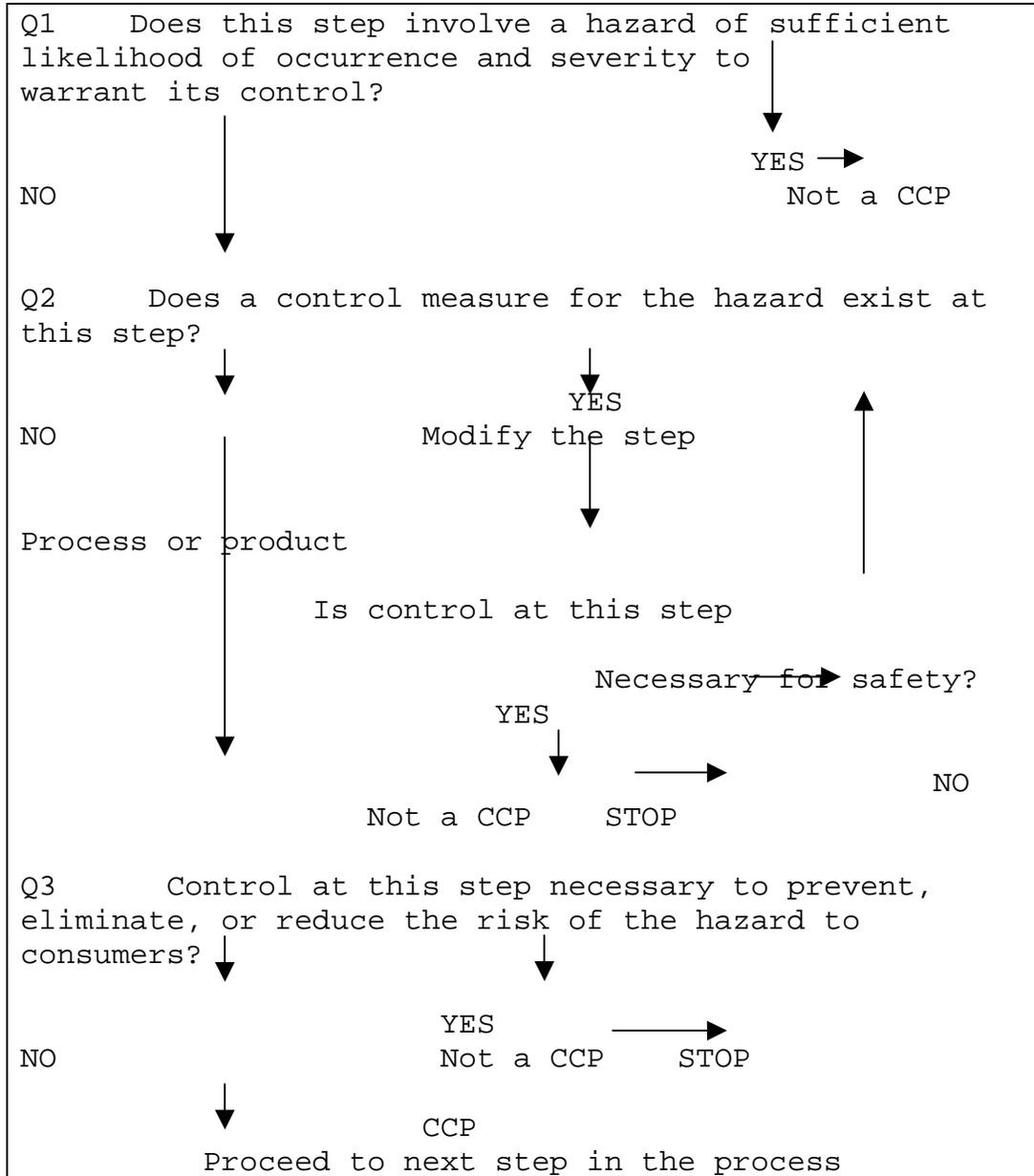
APPENDIX E

Example I of a CCP Decision Tree

Important considerations when using the decision tree:

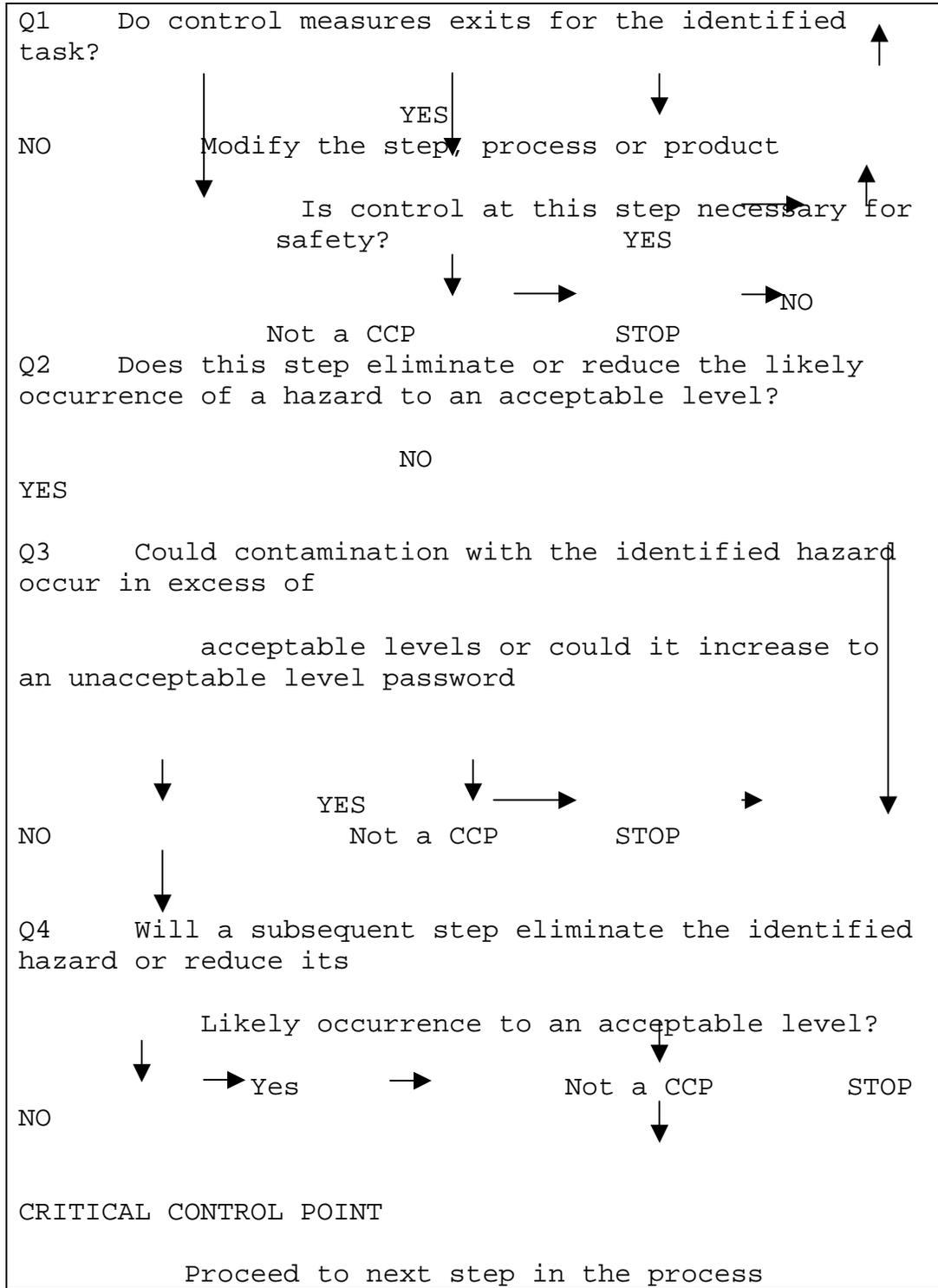
- The decision tree is used after the hazard analysis.
- The decision tree then is used at the steps where a hazard that must be addressed in the HACCP plan has been identified.
- A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP.

- 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.



APPENDIX F

Example II of a CCP Decision Tree



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 food borne 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 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.

CHAPTER 2

Study Questions

1. A sequence of questions to assist in determining whether a control point is a CCP.
Control.
 - A. CCP Decision Tree
 - B. Corrective Action

2. To manage the conditions of an operation to maintain compliance with established criteria. The step where correct procedures are being followed and criteria are being met.
 - A. Control
 - B. Corrective Action

3. Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.
 - A. Control Measure
 - B. Criterion

4. Any step at which biological, chemical, or physical factors can be controlled.
 - A. Control Point
 - B. Corrective Action:

5. Procedures followed when a deviation occurs.
 - A. Decision Tree
 - B. Corrective Action

6. A requirement on which a judgment or decision can be based.
 - A. Criterion
 - B. Control Point

7. 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.
 - A. Deviation
 - B. Critical Control Point

8. 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
 - B. Severity

9. Failure to meet a critical limit.
 - A. Deviation
 - B. HACCP

10. A systematic approach to the identification, evaluation, and control of food safety hazards.
 - A. HACCP
 - B. Monitor

11. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.
 - A. Step
 - B. HACCP PLAN

12. The result of the implementation of the HACCP Plan.
 - A. HACCP System
 - B. Validation

13. The group of people who are responsible for developing, implementing and maintaining the HACCP system.
 - A. Mentors
 - B. HACCP Team

14. A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
 - A. Hazard
 - B. Severity

15. The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.
 - A. Hazard Analysis
 - B. Monitor:

16. To conduct 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.
- A. Monitor
 - B. Prerequisite Programs
17. Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.
- A. Prerequisite Programs
 - B. Severity:
18. The seriousness of the effect(s) of a hazard.
- A. Severity
 - B. Step:
19. A point, procedure, operation or stage in the food system from primary production to final consumption.
- A. Validation
 - B. Step
20. 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.
- A. Validation
 - B. Verification
21. Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.
- A. Verification
 - B. Validation
22. _____ is a systematic approach to the identification, evaluation, and control of food safety hazards based on _____ (number) principles.

23. The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Identify a prerequisite program.

Note: there is more than one.

- A. Facilities
- B. Supplier Control
- C. Specifications
- D. Equipment
- E. Personal Hygiene
- F. HACCP
- G. Control Point
- H. Training
- I. Chemical Control
- J. Pest Control

24. Often found in contaminated water or through shellfish. Purchase food from approved vendors and cook thoroughly. Who am I? _____

25. Its common name is _____ and can be found in cattle and contaminated water. Undercooking ground beef, non-pasteurized dairy products and fruit and vegetables washed in contaminated water are frequent sources

26. _____ is often found in the feces of animals. It is linked to poultry, eggs and meat products, and many high protein foods. To control _____ we must cook food properly, use pasteurized products, and avoid cross contamination.

27. _____ aureus is common bacteria found in the nose, mouth, and skin. At all times many of us have _____ present on those areas. Proper hand washing and controlling employee eating, drinking and smoking are good control methods.

28. Living bacteria on food cause food borne infection. We control food borne infection by _____. Such as the storage, cooling and cooking.

29. Food Borne intoxication occurs when the food or bacteria on the food produce a poison or toxin in the food. Any food that has intoxication must be discarded. True or False.

30. Biological contamination is caused when microorganisms come into contact with food. The majority of food borne illness occurs with biological contamination. Most biological hazards are attributed to improper poor _____ and cross _____.

31. V_____: Found on living hosts, such as employees & customers. Controlled by personal hygiene.

32. P_____: Microorganisms that enter our body. Controlled by cooking internal temperature.

33. B_____: Most common, ancient form of life that have been very successful.

34. A_____: Is the worm commonly found in fish and some marine mammals.

35. T_____: Is the parasitical disease found in pork products or game animals?

36. _____ Contamination is caused when _____ substances come in contact with food. _____ Hazards are found in manmade subsistence's such as cleaning agents, sanitizers, solvents, pesticides, or lubricants. (Hint - same word)

37. _____ Hazards are common type and can be controlled by employees simply removing objects. Packaging accounts for many of our _____ hazards. (Hint - same word)

38. An infection of the intestinal tract also found in contaminated water and facilities with bad sanitation. Processed meats, dairy products and vegetables are also contaminated. Proper sanitation and avoiding cross contamination is necessary for control. Who am I?

39. The food operation should assure that the appropriate product specific knowledge and expertise for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Who am I? _____

40. A full description of the product should be drawn up, including relevant safety information such as: composition, physical structure, packaging, durability, and storage conditions and method of distribution. Who am I? D_____ the P_____

41. The intended use should be based upon the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population may have to be considered. Who am I? Id_____ intended U__

42. The _____ diagram will be constructed by the HACCP team. The _____ should cover all steps in the operation. Consideration should be given to steps preceding and following the specified operation. (Hint - same word)

43. The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram. (Who am I? Hint I am the third principle) O_ S___ Confirmation of F_____ D_____

44. List all hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution. Identify which hazards are of such nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. Which step is this called? Hazard A_____

45. M_____ is the scheduled measurement or observation of a CCP relative to its critical limits. M_____ procedures must be able to detect loss of control at the CCP.

46. C_____ a_____ must be developed for each CCP in order to deal with deviations as they occur. A_____ must also include proper disposition of affected products, and must be documented.

47. V_____ and auditing methods, procedures and tests, including random sampling and analysis. The frequency of v_____ should be sufficient to confirm the system is effective.

48. Accurate r_____ keeping is essential to the application of the HACCP system.

49. C_____ limits must be specified and validated for each Critical Control Point. Criteria used include measurements of temperature, time, moisture level, pH, Aw, available chlorine, and sensory parameters such as visual appearance and texture.

50. The determination of a C_____ _____ point in the HACCP system can be aided by the use of a d_____ tree.

ANSWERS TO QUESTIONS:

1 A	11 B	21 A	31 VIRUSES	41 IDENTIFY USER
2 A	12 A	22 HACCP 7	32 PARASITES	42 FLOW
3 A	13 B	23 ABCDE HIJ	33 BACTERIA	43 ON SITE FLOW DIAGRAM
4 A	14 A	24 NORWALK VIRUS	34 ANISAKIS	44 ANALYSIS
5 B	15 A	25 E-Coli	35 TRICHINOSIS	45 MONITORING
6 A	16 A	26 SALMONELLOSIS	36 CHEMICAL	46 CORRECTIVE ACTION
7 B	17 A	27 STAPHYLOCOCCUS STAPH	37 PHYSICAL	47 VERIFICATION
8 A	18 A	28 TEMPERATURE	38 LISTERIOSIS	48 RECORDS
9 A	19 B	29 TRUE	39 HACCP TEAM	49 CRITICAL
10 A	20 A	30 PERSONAL HYGIENE CONTAMINATION	40 DESCRIBE THE PRODUCT	50 CRITICAL CONTROL DECISION

Practice Questions

1. When cooking a stuffed turkey the internal temperature should reach
 - a. 155 ° F
 - b. 145 ° C
 - c. 165 ° F
 - d. 165 ° C

2. A workstation sanitation solution using iodine should contain:
 - a. 100 PPM
 - b. 50 PPM
 - c. 12.5 - 25 PPM
 - d. 25 - 50 PPM

3. A shell fish tag must be keep on premise for:
 - a. 120 days
 - b. Until inspected by the local regulatory agency
 - c. A period of ninety days
 - d. 7 days

4. Record Keeping is required for:
 - a. Hand washing
 - b. HACCP Plan
 - c. All activities in the kitchen
 - d. By the FDA Food code

5. Fresh meats should be stored at:
 - a. 32 ° F
 - b. 45 ° F
 - c. 41 ° F
 - d. 0 ° F

6. E-coli is a:
 - a. Food borne infection
 - b. Food borne intoxication
 - c. Parasite
 - d. Virus

7. The most effective method of controlling food contamination is:
 - a. Cooking all foods to 165 ° F
 - b. Hand washing
 - c. Freezing all foods
 - d. Proper storage

8. Containers should have:
 - a. Identification numbers
 - b. Wheels
 - c. Tight fitting covers
 - d. Holes for air circulation

9. HACCP is a:
 - a. A food Safety plan
 - b. A safety plan dealing with slips, falls and injuries
 - c. An example of food borne illness
 - d. An example of food borne intoxication

10. Anisakis (ana-sackis) is found in:
 - a. Stuffed poultry
 - b. Cooked meats
 - c. Pork products
 - d. Fish

11. A Critical limit is part of a:
 - a. Hazard analysis
 - b. HACCP plan
 - c. OSHA plan
 - d. MSDS program

12. Cast iron can only be used in food service if it is:
 - a. Washed
 - b. Sanitized
 - c. Heated
 - d. A storage container

13. Trichinosis is a:
 - a. Food borne intoxication
 - b. Parasite
 - c. Food borne infection
 - d. Virus

14. The proper procedure for cleaning utensils in a manual dishwashing station:
 - a. Wash, rinse, sanitize
 - b. Wash, rinse, dry, store
 - c. Wash, dry, sanitize, store
 - d. Wash, rinse, sanitize, air dry

15. The most effective control of the spread of viruses:
 - a. Proper cooking temperature
 - b. Personal hygiene
 - c. Proper storage
 - d. Cleaning all work surfaces

16. What type of system prevents back flow:
 - a. Personal hygiene
 - b. Equipment maintenance
 - c. Air-gaps
 - d. Cleaning schedule

17. A chef makes a salad at home for his/her restaurant.
 - a. He / she must tell the customers he made it at home
 - b. He /she must price it accordingly
 - c. He / she cannot sell products made at home
 - d. He / she must put proper labeling on the container

18. The chef leaves cooked chicken to cool for 6 hours at room temperature.
 - a. Reheat the chicken to 165°F
 - b. Sell the chick as soon as possible
 - c. Cool the chicken in shallow containers
 - d. Discard the chicken after 4 hours at room temperature

19. When cooling hot foods they should be placed in a:
 - a. Sink with hot running water
 - b. Steam table
 - c. A shallow container
 - d. A porous plastic container

20. A waterproof bandage falls into a pot of gravy; describe the problem.
 - a. Physical hazard
 - b. Chemical hazard
 - c. CCP's
 - d. Monitoring

21. Proper hair restraints should be worn:
 - a. By cooks only
 - b. By cooks and servers
 - c. Anyone in the kitchen or serving food
 - d. Only by cooks and servers with long hair

22. Staphylococcal intoxication can be controlled by:
 - a. Eliminating employees touching their nose, mouth
 - b. Proper sanitizing
 - c. Storage of fresh foods
 - d. Food specifications

23. Food should be thawed:
 - a. At room temperature
 - b. Under refrigeration
 - c. Under hot running water
 - d. In a sink

24. Thermometers should be calibrated:
 - a. Every week
 - b. Daily
 - c. When necessary
 - d. In ice water to a temperature of 32°F

25. Thermometers should be made of:
 - a. Glass
 - b. Bimetallic material
 - c. Iron
 - d. Plastic

26. Food in a steam table should be kept at:
 - a. 165°F
 - b. 140°F
 - c. 145°F
 - d. 155°F

27. Bacteria grow most rapidly at:
 - a. 165°F to 210°F
 - b. 32°F to 41°F
 - c. 140°F to 165°F
 - d. 41°F to 140°F

28. A potentially hazardous food would most likely be:
 - a. Bread
 - b. Salty crackers
 - c. Lemon juice
 - d. Baked potatoes

29. We find botulism in:
 - a. Fresh meats
 - b. Frozen foods
 - c. Swollen cans
 - d. Washed produce

30. Corrective action plans are part of:
 - a. Hazard analysis
 - b. SSOP's
 - c. Preliminary steps
 - d. HACCP plan

31. Foods should be stored above:
 - a. All cooked foods
 - b. Cooked poultry only
 - c. Produce
 - d. Other raw foods in leak proof containers

32. Raw foods with mold should:
 - a. Have the moldy section removed
 - b. Have the moldy section cooked to 165°F
 - c. Be refrigerated immediately
 - d. Be discarded

33. What is the minimum concentration of chlorine sanitizer?
 - a. 12.5 to 25 ppm
 - b. 50 ppm
 - c. 100 ppm
 - d. 200 ppm

34. Leftovers should be rapidly reheated to an internal temperature of:
 - a. 145°F
 - b. 155°F
 - c. 165°F
 - d. 140°F

35. What leads to pest infestation?
 - a. Use of pesticides
 - b. Improper hand washing
 - c. Food not stored properly
 - d. Improper cooking temperatures

36. Foods should be stored in:
 - a. Copper pans
 - b. Aluminum pans
 - c. Tightly covered containers
 - d. Galvanized pans

37. Hot water sanitizing requires what temperature?
 - a. 171°F
 - b. 75°F
 - c. 140°F
 - d. 165°F

38. Listeria:
 - a. Is found in all baked products
 - b. Can be controlled by freezing
 - c. Cannot be controlled by freezing
 - d. Grows under refrigeration

39. Smoking is allowed in:
 - a. Outside areas only
 - b. Designated areas
 - c. Only in locker rooms
 - d. Only in parking structures

40. Workers with AIDS are allowed in:
 - a. Non food areas only
 - b. Have no restrictions in the kitchen
 - c. Cannot work in kitchen
 - d. Only hot food areas

41. FIFO Storage system refers to:
 - a. Federally funded food programs
 - b. Accounting based inventory
 - c. Par level
 - d. Using old foods first

42. All cold buffet items must be held at:
 - a. 145°F
 - b. 31°F
 - c. 41°F
 - d. 45°F

43. Salmonella is found in:
 - a. All cooked foods
 - b. All raw foods
 - c. Poultry and eggs
 - d. Fish and shellfish

44. Clean sanitized glasses should be stored:
 - a. Stacked bottom down
 - b. Individually bottom down
 - c. Hanging from a rack
 - d. Bottom up individually

45. Foods with dirt should be:
 - a. Rejected at the receiving dock
 - b. Cleaned at the receiving dock
 - c. Immediately cooked
 - d. Placed in shallow containers

46. The most important procedure the employees do is:
 - a. Collect a paycheck
 - b. Clean their uniforms
 - c. Practice good personal hygiene
 - d. Smoke only in designated areas

47. An employee suffers a minor burn. The first thing to do is:
 - a. Wrap it in a bandage
 - b. Seek medical attention
 - c. Rinse it with cool water
 - d. Send the employee home

48. Potable water is acceptable for:
 - a. Drinking
 - b. Fire prevention
 - c. Irrigation
 - d. Waste water

49. What method is used to prove the HACCP Plan is effective?
 - a. Hazard analysis
 - b. Prerequisite programs
 - c. Critical limits
 - d. Verification

50. When receiving dairy products we should check the:
 - a. Weight
 - b. Volume
 - c. Expiration date
 - d. Name of the producer

Answers to questions:

1	C	11	B	21	C	31	D	41	D
2	C	12	C	22	A	32	D	42	C
3	C	13	B	23	B	33	B	43	C
4	B	14	D	24	D	34	C	44	D
5	C	15	B	25	B	35	C	45	A
6	A	16	C	26	B	36	C	46	C
7	B	17	C	27	D	37	A	47	C
8	C	18	D	28	D	38	D	48	A
9	A	19	C	29	C	39	B	49	D
10	D	29	A	30	D	40	B	50	C

More Questions

1. Monitoring is an example of:
 - a. A system to indicate loss of control
 - b. Corrective Actions that must be implemented
 - c. Descriptions of critical limits
 - d. An action to assure the CCP is under control

2. The first preliminary step is:
 - a. Documenting the flow of food safety
 - b. Describing the product and its intended use
 - c. Forming the HACCP Team
 - d. Identifying the market

3. Prerequisite programs would include:
 - a. Include all information regarding packaging
 - b. Describe the flow diagram
 - c. Conduct in-plant testing
 - d. Consider the activities of the third shift

4. In describing the product the HACCP Team should:
 - a. Include all information regarding packaging
 - b. Describe the flow diagram
 - c. Conduct in-plant testing
 - d. Consider the activities of the third shift

5. Confirmation of the flow diagram is a component of:
 - a. Prerequisite programs
 - b. MSDS
 - c. Preliminary steps
 - d. Hazard Analysis

6. Control Trichinosis with the following procedure:
 - a. Double washing
 - b. Rapid Cooling
 - c. Freezing
 - d. Thawing

7. Hazard Analysis Critical Control Point
 - a. Is based on the flow of food through a facility and the effects of hazards
 - b. Was founded on regulatory mandates
 - c. Indicates the required preparation techniques
 - d. Must include all quality standards

8. Corrective Action should include records of product:
 - a. Validation
 - b. Hazard Analysis
 - c. Critical Control Points
 - d. Disposition

9. Record keeping requires records to b maintained for:
 - a. 5 years
 - b. 6 months
 - c. Up to 2 years
 - d. 3 years

10. HACCP is based on:
 - a. Local health regulations
 - b. Council for Food Protection
 - c. Serv Safe
 - d. Science

11. Validation is required to ensure the effectiveness of:
 - a. Record Keeping
 - b. Hazard Analysis
 - c. Intended audience
 - d. Control Procedures

12. When changes occur in the menu items the HACCP Team must:
 - a. Dispose of all inventory not meeting specifications of new product
 - b. Eliminate all calibration activities until new procedures are implemented
 - c. Utilize the receive-prepare-serve process
 - d. Validate all new control procedures

13. The HACCP Team should be comprised of:
 - a. The Executive Chef and the General Manager
 - b. Corporate trainers and the kitchen staff
 - c. All supervisory and management staff
 - d. Representatives from all groups who handle food

14. Vulnerable groups are usually identified in the:
 - a. Prerequisite programs
 - b. Preliminary steps
 - c. Hazard Analysis
 - d. Critical Limits

15. A critical control point is a point, location or process where:
- Critical limits are defined
 - Monitoring activities are eliminated
 - Hazards are reduced or eliminated
 - Prerequisite programs are validated
16. The decision tree determines:
- The flow of food
 - Vulnerable groups
 - Critical limits
 - Critical Control Points
17. Critical limits may be:
- Determined only by quantitative criteria
 - Altered due to business volume
 - Critical Control Points
 - Water activity level in foods
18. Monitoring will determine:
- The activation of Corrective Actions
 - Target levels for Critical limits
 - Hazard Analysis requirements
 - Sampling procedures
19. When conducting the Hazard Analysis:
- Biological hazards are eliminated
 - Physical hazards are identified
 - Chemical hazards are validated
 - Hazards are reduce to acceptable levels
20. Corrective Actions include:
- Authorization to imitate action
 - Decision tree analysis for deviations
 - Severity of the hazards
 - Requirements for monitoring
- Answers to questions:

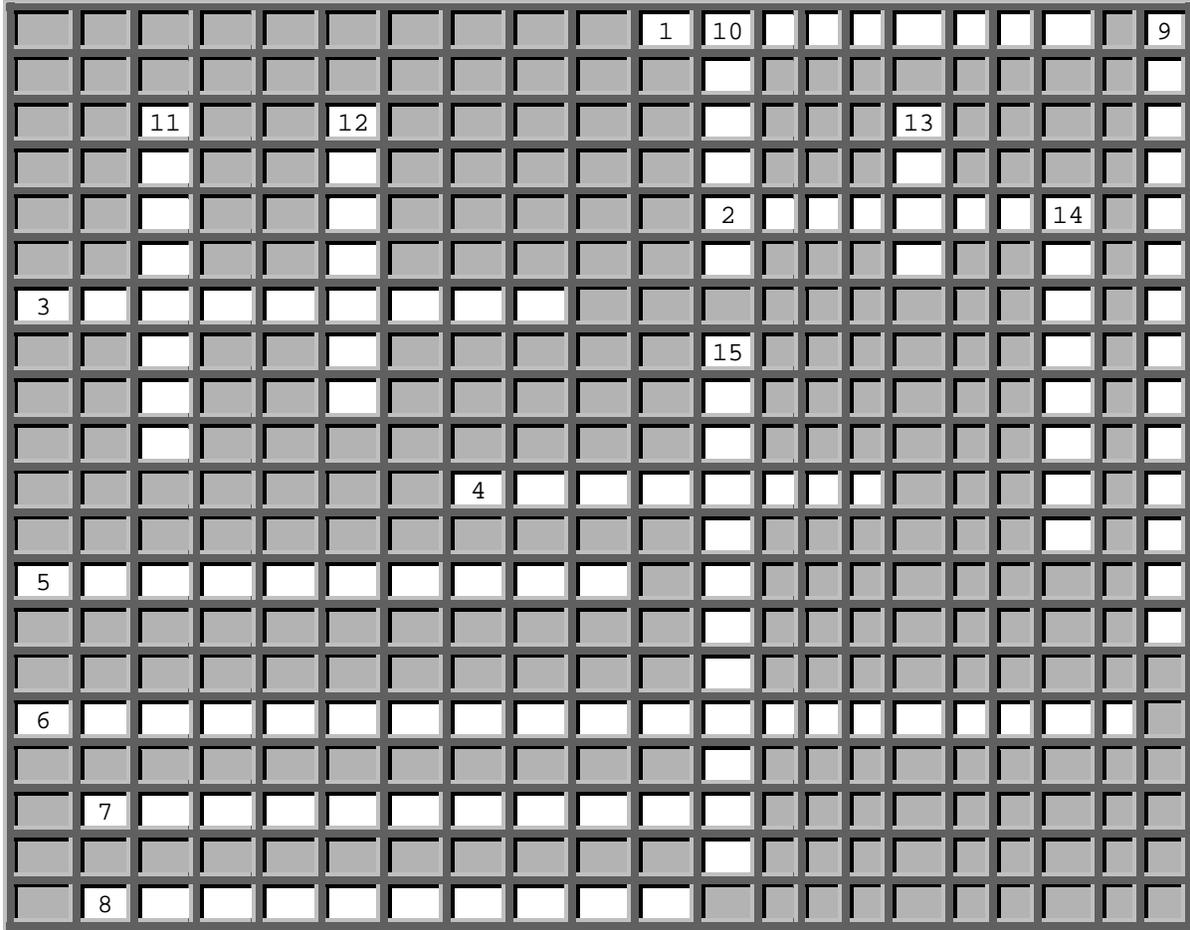
1	D	6	C	11	D	16	D
2	C	7	A	12	D	17	D
3	C	8	D	13	D	18	A
4	A	9	C	14	B	19	B
5	C	10	D	15	C	20	A

Answers to questions:

Note: By knowing, and understanding these sample questions, and the Workbook material will effectively increase your chances of successfully passing the NSF HACCP EXAM.

All the material in the questions is NOT covered in class. It is expected that you know some of the material by attending/completing basic sanitation and ServSafe course.

Chapter 3 CROSSWORD



Across

1. Failure to meet a critical limit
2. Infection of the intestinal tract can be found in process meats and dairy products.
3. Requirement on which a judgment or a decision can be made.
4. Found in sanitizers, solvent, and pesticides.
5. 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.
6. A step critical to prevent or eliminate a hazard or reduce it to an acceptable level.
7. We control food borne infection by such as storage, cooking, and cooling.
8. Bacteria commonly associated with poultry and poultry products.

Down

9. Is common bacteria found in nose, mouth, and on he skin?
10. Found in feces of animals and undercooking of ground beef.
11. Packaging accounts for many of our _____ hazards.
12. A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
13. A point, procedure, operation or stage in the food system from primary production to final consumption.
14. Is the worm commonly found in fish and some marine mammals?
15. The determination of a CCP in the HACCP system can be aided by the use of a _____ .

Words used in crossword:

1. Salmonella
2. Temperature
3. Critical control point
4. Validation
5. Chemical
6. Criterion
7. Listeria
8. Deviation
9. Physical
10. Hazards
11. E-coli
12. Step
13. Anisakis
14. Decision tree
15. Staphylococcus