

HACCP SEVEN PRINCIPLES

Objectives

To demonstrate mastery of this module, the Inspection Program Personnel (IPP) will

1. Identify the HACCP Seven Principles
2. Define HACCP
3. Define the following terms:
 - a. Hazard Analysis
 - b. Prerequisite Program
 - c. Critical Control Point
 - d. Critical Limit
 - e. Monitoring
 - f. Verification
4. Explain the purpose of monitoring

Resources

Hazard Analysis and Critical Control Point Principles and Application Guidelines, The National Advisory Committee on Microbiological Criteria for Food (NACMCF), *Journal of Food Protection*, Vol. 61, No 9, 1998.

<http://www.fsis.usda.gov/wps/wcm/connect/dccfe894-36bb-4bd9-b27a-a7f5275a22cd/JFP0998.pdf?MOD=AJPERES>

Federal Register, Vol. 61, No. 144, July 25, 1996, Final Rule, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems. 9 CFR Parts 304, 308, 310, 320, 327, 381, 416, and 417 [Docket No. 93-016F]

<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf>

HACCP Seven Principles

FSIS has the overall authority and oversight to regulate meat and poultry products intended for distribution into commerce. The official establishment's responsibility is to produce safe wholesome meat and poultry products. FSIS requires all establishments that produce federally inspected meat and poultry products to design and operate HACCP (**Hazard Analysis and Critical Control Point**) systems. HACCP provides a framework for establishments to conduct science-based process controls that can be validated as effective in eliminating, preventing, or reducing to an acceptable level the food safety hazards that are reasonably likely to occur in an official establishment's

particular production processes. Under the HACCP regulatory system, establishments assume full responsibility for producing products that are safe for consumers.

What is HACCP?

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) working group created guidelines and redefined the seven basic principles of HACCP as an effective and rational means of assuring food safety from harvest to consumption. The working group published the HACCP principles and application guideline document in August 1997. This paper is not a regulatory document. However, it was used by FSIS when the HACCP regulation was developed and then published in the Federal Register. As regulators, you will be responsible for verifying compliance with the HACCP regulation. The HACCP guideline with the seven principles is not an enforceable document; however, it is helpful for inspection personnel to be familiar with the basis for the development of the HACCP plan is under Title 9 Code of Federal Regulation (CFR) Part 417. Later sections in this training will cover your regulatory responsibilities.

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures

Principle 1: Conduct a Hazard Analysis.

A thorough hazard analysis is the key to preparing an effectively designed HACCP plan. The NACMCF identified the purpose of the hazard analysis in the guidance document as a process used to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns.

A hazard is defined by NACMCF as a biological, chemical or physical agent that is **reasonably likely to occur**, and will **cause illness or injury in the absence of its control**. Establishments must consider all **three types of hazards – biological, chemical, and physical** – at each step of the production process. A "step" is a point or activity in an operation within the production process that is essential to the proper production of the finished product. A food safety hazard that is reasonably likely to occur

is one for which a prudent establishment would establish controls because the hazard has historically occurred in the product/process or because there is a reasonable probability that the hazard would occur in the absence of these controls.

The hazard analysis and identification of associated control measures accomplish three objectives:

1. hazards and associated control measures are identified,
2. the analysis may identify needed modifications (also known as interventions) to the initial process or product so that product safety is assured, and
3. the analysis provides a basis for determining Critical Control Points (CCP) in Principle 2.

A summary of the HACCP design decisions and the rationale developed during the hazard analysis should be kept for future reference. 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.

Federally inspected establishments must conduct hazard analyses for their processes. The establishment can either conduct the hazard analysis itself or have an outside source conduct it. The hazard analysis is the heart of the successful food safety system. The identification of the food safety hazards in the hazard analysis must be thorough in order to ensure that the HACCP plan when executed will result in an adequate food safety system. When the hazard analysis is not well thought out, it results in a design flaw, and products that pose a food safety hazard to the consumer may be produced and shipped.

Every hazard analysis is unique, because each establishment is responsible for identifying the hazards reasonably likely to occur in its particular process, and for determining how it will control those hazards to prevent, eliminate, or reduce them to an acceptable level. Hazards identified in one facility may not be significant in another operation producing the same product. Different establishments may have identified different hazards as reasonably likely to occur and different control measures for them, even though their processes may appear to be similar. For example, differences may exist in the type of equipment, incoming product, employee training, or production practices.

The hazard analysis is the foundation of the food safety system. A thorough hazard analysis is the key to preparing an effectively designed HACCP plan. Federally inspected establishments must conduct hazard analyses for each process. During the development and design of the hazard analysis, establishments must consider all three types of hazards – biological, chemical, and physical – at each step they identify in the production process. Once the establishment has identified potential hazards, these hazards are evaluated to determine if each one is **reasonably likely to occur (RLTO)**,

or **not reasonably likely to occur (NRLTO)**. If the establishment determines that the hazard is reasonably likely to occur, a preventive measure must be identified and a critical control point must be developed to address the hazard, either at that step or later in the process. If the establishment determines the hazard is not reasonably likely to occur, they must provide justification for this decision. Establishments may use scientific or technical support, or they may have a variety of supporting programs as the basis for the decision that a hazard is not likely to occur.

A **Prerequisite Program** is a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. The programs provide a **foundation for the development and implementation of an effective HACCP system**. Some programs are managed as facility-wide programs and others are specific to a certain process. An establishment may determine that a hazard is not reasonably likely to occur, using the justification that a properly designed and implemented prerequisite program is preventing the hazard from occurring.

Some establishments may use **Good Manufacturing Practices (GMP)** to reduce the likelihood of certain hazards. GMPs are minimum sanitary and processing requirements. GMPs are fairly broad and general, for example, "*Training: All employees should receive training in personal hygiene.*" GMPs are usually not designed to control specific hazards, but are intended to provide guidelines to help establishments produce safe and wholesome products.

Standard Operating Procedures (SOP) are step-by-step directions for completing important procedures and are usually very specific. SOP may be used to address a specific hazard, for instance, an establishment may have specific preventive maintenance procedures for its processing equipment, which prevent the hazard of metal fragments. **Sanitation SOP (SSOP)** may be considered by establishments to reduce the likelihood of occurrence of some food safety hazards. For example, the SSOP may address washing and sanitizing of knife and hands between carcasses to reduce potential contamination with pathogens.

Some examples of prerequisite programs include:

Process Step	Potential hazard	Example Prerequisite Program
Receiving live cattle	SRM	Dentition program for age verification
Cooler	Pathogen growth	Temperature control program
Receiving raw beef	<i>E. coli</i> O157:H7 and other STEC	Supplier purchase specifications
Receiving	Foreign objects	Incoming product inspection

When establishments perform their hazard analysis, they identify any potential biological, physical, or chemical hazards. Then for each hazard, they ask "**Is this**

hazard reasonably likely to occur? If **no**, then the establishment must have support for that decision. If **yes**, the establishment must address the hazard with a CCP. A record of the hazard analysis must be kept for future verification. When completed, the hazard analysis should have

- Identified hazards reasonably likely to occur before, during and after entry into the establishment, and
- Identified the associated preventive measures that can be applied to control these hazards, which provides a basis for determining the critical control points (CCPs).

Principle 2: Determine Critical Control Points

The hazards that were identified in the hazard analysis must be addressed in the HACCP plan. A hazard is controlled by one or more critical control points (CCPs).

A **critical control point** is defined as a point, step, or procedure in a food process at which control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Critical control points are locations in a process at which some aspect of control can be applied to control food safety hazards that have been determined reasonably likely to occur.

Examples of CCPs include product temperature, certification of incoming product, microbiological testing, testing for foreign objects such as metal contamination, the chemical concentration of a carcass rinse or spray, and other such parameters.

The step of the process at which the critical control point is located does not necessarily have to be at the point where the hazard is introduced. They may be placed at any location deemed adequate to prevent, eliminate, or effectively control the hazard in the product produced. The control point for a hazard may be later in the process than the point at which the hazard occurs. For example, the cooking step is a common control for biological hazards that have been introduced into the product at previous steps.

Control may actually be achieved as a cumulative effect, also known as multiple hurdles. There may be several steps in the process that together attain sufficient control, but individually do so only partially. For example, an official establishment that slaughters cattle may have a pre-evisceration organic acid rinse, a post evisceration organic acid rinse, and a wash step followed by steam pasteurization.

For **each** hazard that is determined to be reasonably likely to occur, the establishment must identify critical control points and corresponding critical limits that are measurable or observable. Establishments must have documentation supporting all of these decisions, and they must be able to demonstrate that their plan designs are valid and effective in operation.

Principle 3: Establish Critical Limits

The next step in the development of a HACCP plan is to establish critical limits for each critical control point. **Critical limits** (CL) are the parameters that indicate whether the control measure at the CCP is in or out of control. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) states that a CL is **a maximum or minimum value** to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The establishment must consider the food safety standard that must be met at each CCP. Critical limits are designed to ensure applicable targets or performance standards pertaining to the specific process or product. Critical limit design should be based on applicable FSIS **regulations** or compliance guidelines, FDA tolerances, scientific and technical literature, experimental studies, or the recommendations of recognized experts in the industry, academia, or processing authorities. Critical limits should not be confused with operational limits which are established for reasons other than food safety.

Critical limits are most often based on process parameters such as temperature, time, physical dimensions, or presence of target pathogens. Critical limits must be actual values that can be **measured or quantified**. Regardless of the parameter used, the critical limit must be sufficient to prevent, eliminate, or reduce to an acceptable level the occurrence of the food safety hazard it is designed to control. The establishment must be able to provide the basis for their decision documents regarding the selection and development of the critical limits. The CLs must also be designed to work effectively given the capabilities and limitations of the establishment's processes.

Principle 4: Establish Monitoring Procedures

Once critical limits are set for each CCP during the HACCP plan development, procedures must be established to monitor the CCPs to determine whether the critical limits are being met. **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. Every CCP that is in the HACCP plan must be monitored to ensure that the critical limits are consistently met and that the process is producing safe product. Establishments are responsible for determining the procedure used to monitor each CCP. Monitoring procedures usually involve either a measurement or an observation. If the critical limit is a numerical value, then monitoring usually involves a measurement. If the critical limit is defined as the presence or absence of an attribute, then the monitoring procedure may involve observation. Monitoring procedures should be designed to determine when deviations from the critical limit occur so that appropriate corrective actions can be initiated.

Establishments must determine how often they need to monitor CCPs. Ideally, the monitoring frequency would be continuous whenever possible. An example is the

continual recording of cooking temperatures on temperature recording charts. The advantage of continuous monitoring is that it allows an establishment to see what is occurring at a CCP throughout the production process at any given time.

When it is not possible to monitor a CCP on a continuous basis then it is monitored intermittently and the frequency must be determined. The frequency selected should be adequate to determine that the CCP is under control. Statistically designed data collection systems are used to establish the frequency when monitoring is not on a continuous basis. Establishments can select any employee to conduct monitoring activities. Assigning monitoring responsibilities is an important consideration for establishment management. HACCP monitors are often production employees or quality control personnel. Employees selected to be HACCP monitors should be adequately trained and should understand the purpose of monitoring. They should also be trained to immediately report unusual occurrences to the individual responsible for initiating corrective actions. The HACCP plan does not have to specify *who* will do the monitoring.

Monitoring has three objectives:

- ***To track control of the process.***
Monitoring the process allows the establishment to identify situations in which a trend is developing that may lead to loss of process control. If monitoring detects such a trend, establishments can take appropriate measures to restore process control **before** a deviation occurs.
- ***To determine when there is a loss of control and a deviation occurs.***
Monitoring serves to determine when the process has deviated from the critical limit. This information lets the establishment know appropriate corrective actions must be taken to restore process control and to effectively address all affected product.
- ***To provide a written document to be used in verification.***
Monitoring results must be recorded on official HACCP records, and such records serve as the basis for verification activities.

Principle 5: Establish Corrective Actions

The corrective actions must be determined for each CCP in cases where the CL is not met. The specific corrective actions depend upon the process used and type of food produced.

When there is a deviation from the critical limit, corrective actions are required to prevent potentially hazardous foods from reaching consumers. The HACCP plan must include corrective actions to be taken when a deviation from the critical limit occurs at a critical control point. The corrective actions consist of:

- Identifying and eliminating the cause of the deviation,
- Ensuring that the CCP is under control after the corrective action is taken,
- Ensuring that measures are established to prevent recurrence, and
- Ensuring that no product affected by the deviation is shipped.

HACCP plans should specify what is to take place when a deviation occurs, who is responsible for implementing corrective actions, and that corrective actions will be documented as part of the HACCP records. When designing their HACCP plans, establishments can either specify particular corrective actions they will take when a deviation occurs, or can simply state that they will address the regulatory requirements in 9 CFR Part 417.3, Corrective Action. Experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

Principle 6: Establish Recordkeeping and Documentation Procedures

When developing the HACCP plan, the establishment must ensure that the HACCP system has an effective recordkeeping system. **Records** are written evidence documenting the operation of the HACCP system. All measurements taken at a CCP, and any corrective actions taken, should be documented and kept on file. These records can be used to trace the production history of a finished product. If any questions arise about the product, a review of records may be the only way to determine whether the product was produced in a safe manner according to the HACCP plan.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) recommends that the establishment maintain four types of records. *These recommendations are also regulatory requirements as outlined in 9 CFR Part 417.*

- Summary of the hazard analysis including the rationale
- HACCP plan
- Support documentation such as validation records
- Daily operational records generated during the operation of the HACCP plan

The **summary of the hazard analysis** covers the basis and justification for an establishment's HACCP plan. This includes information about decisions the establishment made during the hazard analysis process. It contains all the information about the hazard analysis, including justification for CCPs and critical limits.

The **HACCP plan** outlines the formal procedures the establishment will follow to meet the seven principles. The NACMCF recommends that HACCP plan records should contain the following.

- List of the HACCP team and assigned responsibilities.
- Description of the food, its distribution, intended use, and consumer.
- Verified flow chart for the entire manufacturing process
- HACCP Plan Summary Table that lists the following for each hazard of concern—the CCP, critical limit, the monitoring procedures and frequencies, the corrective actions, the verification procedures and frequencies, and the recordkeeping system.

The **supporting documentation** includes the rationale used to establish CCPs, critical limits, monitoring procedures and frequencies, corrective action procedures, and verification procedures and frequencies. This includes all scientific references, regulatory resources, and materials from other sources (for example, extension services, academic experts, consultants) that have been used in the development of the HACCP plan.

The **daily operational records** are what most of us think of when we think of HACCP records. These include the actual records from the implementation of the HACCP plan (monitoring, corrective actions, and verification).

The HACCP records should:

- Contain the date and time of the activity reflected on the record.
- Contain the signature or initials of the employee making the entry.
- Have the information entered on the record at the time it is being observed.
- Contain actual observations or data values obtained.

Principle 7: Establish Verification Procedures

HACCP systems must be systematically verified. In the NACMCF explanation of the verification principle, four processes are involved in the verification of the establishment's HACCP system. The establishment is responsible for the first three; FSIS is responsible for the fourth.

- The first is the scientific and technical process, known as **validation** for determining that the CCP and associated critical limits are adequate and sufficient to control likely hazards.

- The second process is to ensure, initially and on an **ongoing** basis, that the entire HACCP system functions properly.
- The third process consists of documented, periodic, **reassessment** of the HACCP plan.
- The fourth process defines FSIS's responsibility for certain actions (**government verification**) to ensure that the establishment's HACCP system is functioning adequately.

Verification ensures that the HACCP plan is being implemented as written. Verification confirms the accurate monitoring of the critical control points. The verification procedures demonstrate that the HACCP system is adequately controlling food safety hazards. After initial validation the system must be verified periodically. Periodic verification involves the use of methods, procedures, or tests in addition to those used for monitoring, to determine whether the HACCP system is in compliance with the HACCP plan, or whether the HACCP plan needs modification and revalidation to achieve its food safety objective. Establishments must also be able to provide supporting documentation for the verification procedures and frequencies specified in the HACCP plan.

Ongoing verification activities consist at a minimum of calibration procedures (if there are instruments that require calibration), direct observations of monitoring and corrective actions, and records review. They should be described in the HACCP plan.

The goal of **calibration procedures** is to ensure that all measurements taken with process-monitoring equipment are accurate. If the findings from the procedures show that the measuring device is incorrect, then the device must be recalibrated or replaced.

The **direct observation** procedures and frequency for involve observing the monitor to determine that monitoring is being done correctly.

The purpose of **records review** is to ensure that the records were prepared correctly, that all activities were performed as required by the HACCP plan, that no activity was missed, and that all results were within the critical limits.

Not all CCPs require the calibration of process-monitoring equipment. Establishments are not limited to only these three types of verification activities. Other types of verification procedures that establishments may use include independent checks or measurements to verify the accuracy of monitoring and microbiological testing.

Summary Chart

The following chart illustrates the seven principles as a process that the establishment must accomplish when developing their HACCP system.

Seven Principles of HACCP

Develop a Flow chart – a prerequisite for the 7 HACCP principles that documents the steps in the process

