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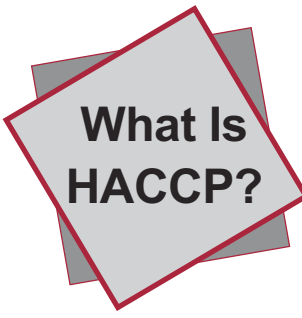
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What Is HACCP?

HACCP stands for Hazard Analysis and Critical Control Points. HACCP is an industry-wide effort approved by the scientific community as well as regulatory and industry practitioners. This effort is designed to focus specifically on food safety, including food safety in retail establishments.

This training manual has been designed to provide a simple and logical approach for introducing a HACCP-based food-safety training program for employees of retail establishments. The manual provides the necessary information and references for developing a HACCP plan. Such a plan is intended to produce a system having a step-by-step analysis and resulting in procedures to be followed, including the much-needed documentation of those procedures.

The first five chapters introduce basic information about HACCP and its relationship and applications to retail food operations. An important aspect of these chapters is the information related to prerequisites to HACCP and the Sanitation Standard Operating Procedures (SSOP) in retail stores. These first chapters will help first-tier managers understand the importance of, and responsibility associated with, such a program. Managers will find the information they need to form executive decisions that promote food safety.

Chapters six and seven deal specifically with aspects related to understanding the HACCP

principles and creating HACCP plans. In these chapters, the biological, physical, and chemical hazards of the different food categories are identified. The seven HACCP principles are presented and discussed. This information leads to the creation and the implementation of a HACCP plan, including the requirements of the plan, the HACCP team, products and categories, employee training records, and recall procedures.

Preparing the HACCP plan is the initial step. Once the plan has been prepared, it is necessary to validate and verify that the plan works after it is implemented. Chapters 8 and 9 discuss the implementation of the plan and maintaining the plan. Chapter 10 provides sources of regulations pertaining to HACCP.

Chapter 11, the last chapter, consists of the appendices that support the HACCP program. Included are examples of the tasks that are to be performed and supporting information on the technical and regulatory aspects of the HACCP plan. These appendices are provided to give examples to help the retail store in how to prepare, implement, and practice the HACCP concept.

Having a HACCP plan in place and following it will result in practices that will aid in further ensuring safe food for consumers as well as providing proof of those safe practices through documentation.

Introduction to Hazard Analysis and Critical Control Points (HACCP) Systems

Americans have become increasingly concerned about food safety. Incidences of food-borne illness are receiving more attention as consumers have become more aware of new pathogens that threaten all of us.

The Hazard Analysis and Critical Control Points system (HACCP) was developed to focus specifically on food safety. A major focus of the new HACCP system is “from farm to table.” In short, everyone is responsible for safe food products.

The primary factor in the implementation of HACCP is a shift toward reliance on systems rather than individual defect. Taking a systems approach involves looking at all parts of the food handling and preparation process, step by logical step. It is a preventive maintenance plan rather than a fix-it-when-it-breaks attitude.

HACCP is a concept as well as a method of operation. When it comes to pathogens, “sight, smell, and taste” just do not get it done. We must have control over the process, the raw materials, the environment, and the people, beginning as early in the food production system as possible. A very important component of the HACCP

system is the change between past and future regulatory oversight. Having a HACCP plan will:

- Improve your operation from the regulatory standpoint and provide for the safety of your food products.
- Reduce the chance for food-borne illness.
- Identify and document where corrections need to be made.
- Have you thoroughly review your operation specifically for food safety and place controls on those areas of concern.

See *Appendix 5: HACCP: Origins* — how the regulatory agencies are starting to focus on the benefits of HACCP. See page 54.

Finally, since we all want to provide safe food of acceptable quality to the public, it should be the retail stores’ responsibility to design and implement the means by which such responsibility can be met to the satisfaction of regulatory agencies, or more importantly, the consuming public.

HACCP and Retail Food Operations

HACCP plans and operating procedures are adaptable to any food production, processing, or distribution activity. The food industry began realizing a number of years ago that the lack of



proper food-handling procedures could lead to very drastic situations concerning food-borne microorganisms, toxic chemicals, and physical contaminants. The national Centers for Disease Control and

Prevention (CDC) report that we in the United States experience between 4 to 7 million cases of food-borne illness resulting in 5,000 deaths and \$3 billion to \$6 billion in costs annually. The U.S. food distribution and marketing system is a potential source for these causative agents.

Federal, state, and local food regulatory agencies, along with other food educational and organizational groups, are working to implement the HACCP Food Safety Program in the entire food chain — from producers and growers to processors, and on to the marketing and distribution channels.

The operating principles of HACCP systems are applicable to any of the food chain activities and to any size of business. The critical areas within supermarkets and other food sales and marketing areas that have a potential to cause consumer harm are essentially the same whether the operation is a large, multifunctional store or a small mom-and-pop grocery and/or deli.

The entire concept of the HACCP program is to provide the consumer with a safe consumable product. The responsibility for producing and marketing these safe products rests with the food industry. Workers in retail food establishments must understand the hazards that are present and the effects these hazards might have on anyone consuming your products.

People in the United States do not go to the supermarket with any fear concerning the safety of the food that they purchase and take home. The majority of food-borne illnesses related to retail food operations are not created in the food store. They are created at home or in a restaurant.

Nevertheless, because of the large complex distribution system that we use to deliver our food from the supplier to the consumer, any situation that arises concerning the safety of the food product can result in literally hundreds of people becoming ill. The Critical Control Points (CCP) can range from the bacteria spread on the knife or slicer in the meat department to an improper chemical sanitizer used in the deli to a light bulb that inadvertently falls into the mixer in the bakery.

The HACCP program is designed so that we are aware of the Critical Control Points that we have within our establishment, and that

we ensure that these critical factors are monitored in such a way as to produce a safe food supply.



In order to implement any sort of a food-safety program, retailers must first understand why it is necessary. Scientists and technicians at universities and food-related trade associations have long known the basics of food safety and what might be involved in producing products that are not safe for consumption.

However, the retail food industry has done a poor job of informing workers of what the problem areas are. It is understood that bacteria can cause food-borne illnesses, but what can be done to minimize the growth of bacteria and protect the food?

Workers must understand the basic way organisms multiply, survive, and are killed. This is essential information for us to do a good job in controlling these organisms in the food distribution chain. This information must be made available to workers prior to initiation of HACCP programs.

The same goes for metal pieces, splinters of wood, or undesirable caustic chemicals in foods. These, too, can be serious to consumers in regard to breaking off a tooth, lacerating the esophagus, lacerating a hole in the intestines, or poisoning due to the strong chemical.

Second, we must know what hazards to control in order to determine where the Critical Control Points (CCP) are within our operation. Are the products that we handle susceptible to the growth of microorganisms, particularly ones that are associated with food poisoning? Or are our products particularly prone to contamination

with small rocks because of the harvesting conditions and the automatic harvesters that are used for our products at the farm? Or, are our products susceptible to chemical contamination because of their processing, fumigation, or sterilization? In all cases, we have to know what we have to control before we can establish programs to actually control it.

Third, it is necessary to know the limits that are needed to control the hazards. If something undesirable happens at every one millionth container, is that a level that we need to control? If we find metal shavings from our machinery at least once a day, is that at a level we need to be controlling?

In order to determine the limits necessary to control the hazards, standards are needed by which we compare our operation to industry-accepted conditions. Many regulatory agencies — the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), state inspection services, local departments of health, industry associations, and others — have developed many guidelines against which your operation can be measured. Good Manufacturing Practices (GMP) affect many industry situations and give recommendations concerning equipment type, construction, and operation.

Sanitation Standard Operating Procedures (SSOP) develop the basics for maintaining a food facility that has a clean, sanitary environment that is free from food hazards. In addition to these two regulatory programs, a company should establish its own Standard Operating

Procedures (SSOP) where the company establishes how things are to be done, when they are to be done, who will do them, and at what levels of operation a procedure is out of control and needs to be properly adjusted.

An example is a cooler where fresh meat is stored. It might be your SSOP to completely scrub and sanitize your cooler weekly and to maintain a temperature no higher than 40°F,

with the temperature to be checked every four hours. During one of your regular temperature monitoring checks, it is found that the temperature is up to 45°F. Your SSOP should indicate what you should do under these conditions and how you should do it in order to correct the problem. You should also indicate whether any action must be taken regarding the product that has been in the cooler where the temperature has risen.

Chapter 4

Identification and Control of Hazards

To help us understand the hazards of food safety and their control, see *Appendix 6: Common Hazards Found in Retail Food Establishments*. See page 55.

The identification and control of these hazards may require help from outside resources, one resource being part of the Hazard Analysis and Critical Control Points (HACCP) program. But

once this is done, the main responsibility for providing a safe food product rests on the employees of the retail establishment, with strong support and training from their management.

Providing a safe and nutritious product is an everyday activity. Maybe the most important factor is educating the employee about why something is done and the consequences to safe food if it is not.



When dealing with foods, hazards associated with physical contamination, such as nuts, bolts, and metal shavings, and foods containing hazardous chemicals, such as pesticides or strong cleaning compounds, can certainly be very serious. However, the most serious hazard associated with food products is contamination with microorganisms that can lead to food-borne illnesses and poisonings.

Generally, the physical and chemical hazards are detectable and identifiable as soon as the problem is evident. However, food-borne illnesses associated with microbiological activity may not become evident for some time, with people becoming ill hours or even days after the contaminated food product was consumed. It is also quite possible that tracking down the contaminant is difficult because of the wide variety of people who may have consumed the product out of a tainted batch and also because of the time required for positive microbiological testing and confirmation.

Thus, it is not inconceivable that a period of several days up to several weeks may lapse between the time a person consumes a contaminated product and positive identification has been made as to the source and type of microbiological contamination causing the problem.

Exemplary sanitation programs are imperative in the food industry. The development of such programs is vital in the prevention of microbiological buildup that can contaminate food products and transmit illnesses to those consuming the product. The importance of these sanitation programs becomes clear when one considers the difficulty associated with detecting microbiological contamination in foods, the time and difficulty involved in specifically identifying the cause of invasion, and the severity of food-borne illness or poisoning that may result.

Standard sanitary practices should be developed for each retail food establishment. A specific food-safety program may be developed by a large supermarket organization that will deal with most sanitation problems. However, specifics about the sanitation program should be developed for and adhered to by each individual store operation. Specifics as to store design, size, products handled, employees, construction materials, ventilation systems, and many more items point out the necessity to individualize any proper sanitation program.



It is imperative that anyone designing a sanitation program for a retail food establishment be aware that there is no single magic cleaning equipment, detergent, sanitizing system, or equipment construction

material that will make all sanitation problems disappear. Wherever food products are handled and come in contact with equipment, packaging material, or people, the food product leaves a residue. Bacteria are sure to congregate, grow, and multiply in this residue.

Any food product that is of value to humans or animals will also be of value for microorganisms. If we provide the food supply and also the environmental conditions, bacteria can multiply at the rate of doubling every 20 minutes. This means if you have a cutting board on which you are cutting red meat and it has 50,000 bacteria on it, 20 minutes later there can be 100,000 bacteria, and 20 minutes after that, there can be 200,000 bacteria.

Because in our marketing location we have so many areas where we provide the appropriate food supply and environmental conditions, we must maintain a strict sanitation policy to clean and sanitize our equipment on a regular basis. Rolling the deli slicer into the cooler at six in the evening without washing it does not prevent the possibility of severe problems from a microbiological standpoint. The only thing the cooler will do is reduce the multiplication of the bacteria, not control it. This provides an opportunity for continual contamination and microbiological buildup the next morning when the unit is taken from the cooler.

Microbiological contamination is a certainty if good sanitation cleaning procedures are not followed in areas involving any fresh food product, such as meats, produce, dairy products, bakery products, and others where the product is eaten without further processing. These cleaning procedures include the utilization of recommended detergents and appropriate agitation, whether that is from high-pressure cleaners or good old elbow grease, to remove the physical soil and bacterial numbers.

Even though we reduce the number of microorganisms a substantial amount by cleaning, we must further sanitize our produce cases, deli tables, and meat-cutting blocks so that we reduce potential contamination to the very lowest numbers. These sanitation procedures must be followed on a routine schedule every day and every week.

Skipping these procedures for even one day can mean the difference between having a piece of equipment that is cleaned and sanitized or having one that will spread bacteria to the consuming public.

See Appendix 7: Growth Rate of Microorganisms at Different Temperatures. See page 57.

See Appendix 3: Sanitation Standard Operating Procedures (SSOP.) See page 48.

The Seven HACCP Principles

Having an effective food-safety program in place means knowing, understanding, and following the seven HACCP Principles. They are:

1. **Conduct a Hazard Analysis.**
2. **Identify Critical Control Points.**
3. **Establish Critical Limits.**
4. **Establish Monitoring Procedures.**
5. **Establish Corrective Actions.**
6. **Establish Verification Procedures.**
7. **Establish Record-Keeping Procedures.**



Principle 1

Conduct a Hazard Analysis

HACCP Principle No. 1 States:

Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.

The regulation defines a food safety hazard as “any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.”

The hazard analysis shall include ONLY food safety hazards.

Principle 2



Identify Critical Control Points

HACCP Principle No. 2 States:

Identify the Critical Control Points (CCP) in the process.

- A Critical Control Point (CCP) 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.”
- For every significant hazard identified, there must be at least one corresponding CCP to control the hazard, although more than one hazard may be controlled at a CCP.
- Is this step a Critical Control Point (CCP)? The Critical Control Point may be at the point where the hazard occurs or at a later step.

Principle 3



Establish Critical Limits

HACCP Principle No. 3 States:

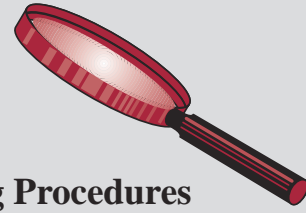
Establish critical limits for preventive measures associated with each identified CCP.

The regulation defines critical limit as “the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a Critical Control Point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.”

Critical limits are expressed as numbers or specific parameters based on visual observation, such as:

- Temperature — 155°F
- Time — 20 minutes

Principle 4



Establish Monitoring Procedures

HACCP Principle No. 4 States:

Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

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 will go much more smoothly if management:

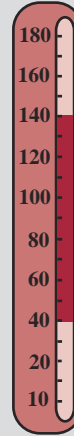
- Monitors Critical Limits Values for What, How, Frequency, and Who.
- Identifies clearly the employee positions responsible for monitoring.
- Trains employees monitoring the CCP in the testing procedures, the critical limits established, the methods of recording test results, and the actions to be taken when critical limits are exceeded.
- Ensures that the employees understand the purpose and the importance of monitoring.

Principle 5

Establish Corrective Actions

HACCP Principle No. 5 States:

Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.



The regulation defines corrective action as “procedures to be followed when a deviation occurs.” A deviation is a failure to meet a critical limit.

HACCP is a preventive system to correct problems before they affect the safety of the food.

The corrective actions are to ensure that:

- The cause of the deviation is identified and eliminated.
- The CCP will be under control after the corrective action is taken.
- Measures to prevent recurrence are established.
- No product that is injurious to health or otherwise adulterated as a result of the deviation is distributed for human consumption.

The Corrective Actions may be included in forms that are created to address:

- The cause of the deviation so that it can be identified and eliminated.
- The CCP so it will be under control after the corrective action is taken.
- The establishment of appropriate measures so that a recurrence may be avoided.
- The affected food so that no product that would be injurious to health or otherwise adulterated as a result of the deviation is allowed to enter commerce.

Principle 6



Establish Verification Procedures

HACCP Principle No. 6 States:

Establish procedures to verify that the HACCP system is working correctly.

- Simply stated, the HACCP team needs to verify that the HACCP system is working the way it is expected to work.
- By doing these verifications, the establishment will initially evaluate the operation of the HACCP system and then maintain an updated and effective HACCP system.
- Verification may be broken down into three categories:
 1. Validation
 2. Verification
 3. Reassessment

Validation — Test that the process with the Critical Limits prevent, eliminate, or reduce the hazard to an acceptable level. If a hot deli serving table is to maintain food above 140°F, then validate that it does.

Verification — Assure that all required information is written down and documented. If cleaning of equipment is stated in the Hazard Analysis, then check that cleaning is done. *Do what you say and say what you do.* Verify the written statements.

Reassessment —

- Do at least annually.
- Consider potential new hazards.
- Examine changes in the preparation, raw materials or raw ingredients, personnel, packaging of the finished product, or any other changes that could affect the hazard analysis.

Principle 7

Establish Record-Keeping Procedures

HACCP Principle No. 7 States:

Establish effective record-keeping procedures that document the HACCP system.



Maintaining proper HACCP records is an essential part of the HACCP system. Good HACCP records — meaning that the records are accurate and complete — can be very helpful because:

- Records serve as written documentation of the establishment's compliance with its HACCP plan.
- Records allow the retail facility to trace the history of an ingredient, in-process operations, or a finished product should problems arise.
- Records help identify trends in a particular operation that could result in a deviation if not corrected.
- Records could help identify and narrow the scope of a recall in the event a product recall becomes necessary.
- Records that are well-maintained are good evidence in potential legal actions against an establishment.
- There may be new HACCP team members and the rationale for certain decisions is forgotten.

Records

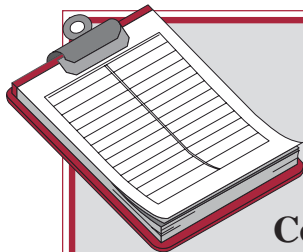
Three Types of Records

1. In the Hazard Analysis, records of practices that keep hazards from likely occurring, i.e.:
 - Cleaning procedures
 - Employee training
2. HACCP plan and reassessments:
 - Validations
 - Verifications
3. Operating records (such as):
 - Operating Records of Critical Limits
 - Calibrations

Creating a HACCP Plan

The seven HACCP Principles:

1. Conduct a Hazard Analysis.
2. Identify Critical Control Points.
3. Establish Critical Limits.
4. Establish Monitoring Procedures.
5. Establish Corrective Actions.
6. Establish Verification Procedures.
7. Establish Record-Keeping Procedures.



Principle 1

Conduct a Hazard Analysis

HACCP Principle No. 1 States:

Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.

The *2001 Food Code* defines a potentially hazardous food as “a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infections or toxigenic microorganisms.” Further, “hazard” means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

The hazard analysis shall include ONLY food safety hazards.

Step 1

1. **Create the Process Flow Diagram.** (See page 21 for a blank form and see the Appendix 8: HACCP Plans—Process Flow Diagram for samples of completed Process Flow Diagrams. Your Process Flow Diagrams must be created for and tailored to your specific process.)
2. **Verify the Process Flow Diagram.**

See Appendix 8: HACCP Plans — Process Flow Diagram. See pages 60 and 61-69.

Step 2

Add each **Process Step** from the **Process Flow Diagram** (see page 21) onto the **Hazard Analysis and CCP** form (see page 22).

See Appendix 8: HACCP Plans — Hazard Analysis and CCP. See pages 60 and 70-92.

Step 3

For each **Process Step** and each **Potential Hazard** (Biological, Chemical, and Physical), complete the **Hazard Analysis and CCP** form shown on page 22 for:

- a. Potential Hazards introduced, controlled, or enhanced at this step.
- b. Does this potential hazard need to be addressed in the HACCP plan?
- c. Why? (Justification for the decision made in the previous column.)
- d. What measures can be applied to prevent, eliminate, or reduce the hazards being addressed in the HACCP plan?

See Appendix 8: HACCP Plans — Hazard Analysis and CCP. See pages 60 and 70-92.

Process Flow Diagram

Product:

Indicate areas over which you have control.

Approved By: _____

Date: _____

Hazard Analysis and CCP

Product:

Ingredient/ Process Step	Potential Hazards: Introduced, controlled, or enhanced at this step. ¹	Is this hazard likely to occur?	Why? (Justification for decision made in previous column) ²	What measures can be applied to prevent, eliminate, or reduce the hazards being addressed in HACCP plan? ³	Is this step a Critical Control Point (CCP)? ⁴
	B				
	C				
	P				
	B				
	C				
	P				
	B				
	C				
	P				
	B				
	C				
	P				

- ¹ Hazards are classified as: B — Biological, C — Chemical, P — Physical.
- ² List the justification for your decision based upon the severity and the likely occurrence of the hazard.
- ³ List control measures within your operation that occur at this or a later step.
- ⁴ Note CCP number and hazards controlled (e.g., CCP 1 (B-1) for biological hazard).

Approved By: _____ Date: _____

Principle 2



Identify Critical Control Points

HACCP Principle No. 2 States:

Identify the Critical Control Points (CCP) in the process.

- A Critical Control Point (CCP) is defined by the National Restaurant Association as “the last 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.”
- For every significant hazard identified, there must be at least one corresponding CCP to control the hazard, although more than one hazard may be controlled at a CCP.
- The Critical Control Point (CCP) for a Hazard may occur at or later in the Process Step.

Step 4

For each **Process Step** and each **Potential Hazard** (Biological, Chemical, and Physical), complete the **Hazard Analysis and CCP** form shown on page 22 for:

- Is this step a Critical Control Point (CCP) based on the following questions?
 1. Is the identified hazard likely to occur?
 2. Are there preventive measures for each hazard?
 3. Is this the last point in which control can be applied to prevent, reduce or eliminate hazards?

Each CCP is to be separately identified as CCP 1, CCP 2, and so forth.

See *Appendix 8: HACCP Plans — Hazard Analysis and CCP*.
See *pages 60 and 70-92*.

Principle 3



Establish Critical Limits

HACCP Principle No. 3 States:

Establish critical limits for preventive measures associated with each identified CCP.

The regulation defines critical limit as “the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a Critical Control Point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.”

Critical limits are expressed as numbers or specific parameters based on visual observation, such as:

- Temperature — 155°F
- Time — 20 minutes

Step 5

For each **Process Step/CCP** identified from the **Hazard Analysis and CCP** form as a Critical Control Point, enter the Process Step/CCP on the **Critical Limits, Monitoring, and Corrective Actions** form on page 25.

For each **Process Step/CCP** on the **Critical Limits, Monitoring, and Corrective Actions** form, enter the Critical Limits. Scientific review may be necessary for this input. Remember, the Critical Limit entered must be a measurable value.

See *Appendix 8: HACCP Plans — Critical Limits, Monitoring, and Corrective Actions. See pages 60 and 93-101.*

Critical Limits, Monitoring, and Corrective Actions

Product:

Process Step/ CCP	Critical Limits	What	Monitoring Procedures		Who	Corrective Actions
			How	Frequency		

Approved By: _____ Date: _____

FDA Food Code Time and Temperature Regulations

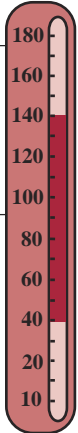
The Time and Temperature Regulations presented here should be used to establish critical limits for processing foods.

Processing Step	Type of Food	Temperature
Cooking	Poultry, stuffed poultry/meat/fish/pasta, stuffing containing poultry, meat, or fish, wild game, reheated foods, products that contain one or more previously cooked foods.	165°F for 15 seconds
	Ground, chopped, or tenderized meats/fish, ratites.	155°F for 15 seconds
	All other potentially hazardous food including: Beef, veal, lamb, pork, fish, eggs, dairy. Heat-treated foods such as cooked pasta, cooked rice.	145°F for 15 seconds
	Fruits and vegetables.	140°F
Microwave Cooking	Foods must be stirred during cooking, covered, and allowed to stand covered for 2 minutes after cooking to obtain even temperature throughout the food.	165°F in all parts of the food
Hot Holding/Service	All potentially hazardous foods intended to be served hot.	140°F or above
Reheating	All potentially hazardous foods intended to be served hot.	165°F for 15 seconds within 2 hours
Cooling	Cooked potentially hazardous foods.	From 140°F to 70°F within 2 hours, and from 70°F to 41°F within additional 4 hours.
	Potentially hazardous foods at room temperature.	To 41°F within 4 hours.

2001 FDA Food Code

FDA Food Code Time and Temperature Regulations, Continued

Processing Step	Type of Food	Temperature
Cold Holding/ Service	All potentially hazardous foods intended to be served cold.	41°F or below
Receiving	Frozen foods.	Must be frozen
	Refrigerated foods.	41°F or below
Storage	Frozen foods.	Must be frozen
	Refrigerated foods.	41°F or below for 7 calendar days after opening
Thawing in Refrigerator	All potentially hazardous foods.	41°F or below



Note the 41°F to 140°F danger zone.

2001 FDA Food Code



Cold Deli



Hot Deli



Meat Preparation — Ground Beef



Bakery



Fresh Produce



Eggs



Seafood



Vaccum-Packaged Ham

Principle 4



Establish Monitoring Procedures

HACCP Principle No. 4 States:

Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

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.

Step 6

For each *Critical Limit*, enter on the *Critical Limits, Monitoring, and Corrective Actions* form:

- **What** — Identifying the Critical Limit(s) to be monitored.
- **How** — The monitoring instrument(s) to be used.
- **Frequency** — Although continuous recording is best, it may not be practical. When creating the frequency between non-continuous readings, remember that if a **Critical Limit Value** does not meet specification, all product from the last acceptable reading to the next acceptable reading must be considered for **Corrective Action**.
- **Who** — Identify the position responsible for recording the **Critical Limit Value(s)**.

Critical Limit Values need to be developed for each Critical Limit. These *Critical Limit Values* are to be reviewed and approved and will prove valuable in documenting your food safety record-keeping.

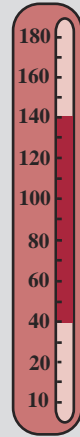
See *Appendix 8: HACCP Plans — Critical Limits, Monitoring, and Corrective Actions*. See page 60 and 93-101.

Principle 5

Establish Corrective Actions

HACCP Principle No. 5 States:

Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.



The regulation defines corrective action as “procedures to be followed when a deviation occurs.” A deviation is a failure to meet a Critical Limit Value.

HACCP is a preventive system to correct problems before they affect the safety of the food.

Step 7

For each **Critical Limit**, enter the corrective actions on the **Critical Limits, Monitoring, and Corrective Actions** form (see page 25).

Since all failures for Critical Limits cannot be anticipated, enter under Corrective Actions:

1. CCP under control.
2. Disposition of noncomplying product determined.
3. Cause corrected to prevent recurrence.
4. Maintain records.



Corrective Actions forms (see page 31) may be created to address:

- a. Identification and elimination of the cause of the deviation.
- b. Assurance that the CCP will be under control after the corrective action is taken.
- c. Establishment of measures to prevent recurrence.
- d. Procedures to prevent the introduction into commerce of any product that is injurious to health or otherwise adulterated as a result of the deviation.

Corrective Actions

**CCP/Process
Step**

Product Name

Lot Number

Date

Deviation No.

Time (Began)

Time (Ended)

Deviation No.

Corrective Action

Enter number

1. The cause of the deviation.

**Critical Limit
Value
(Specification)**

2. The corrective action taken.

Enter number

3. Measures to prevent recurrence.

**Critical Limit
Value
(Actual)**

4. Disposition of the product.

Enter number

Performed By: _____ Date: _____

Approved By: _____ Date: _____

- e. Provisions for the signature of the person approving the Corrective Action. Each Corrective Action should be entered onto a separate form to be available for review by management and any regulatory agency.

These *Corrective Actions* forms will prove valuable in documenting your food safety actions.

See *Appendix 8: HACCP Plans — Critical Limits, Monitoring, and Corrective Actions. See pages 60 and 93-101.*

Principle 6



Establish Verification Procedures

HACCP Principle No. 6 States:

Establish procedures to verify that the HACCP system is working correctly.

- Simply stated, the HACCP team needs to verify that the HACCP system is working the way it is expected to work.
- By doing these verifications, the establishment will initially evaluate the operation of the HACCP system and then maintain an updated and effective HACCP system.



- Verification may be broken down into three categories:
 1. Validation
 2. Verification
 3. Reassessment

Validation — Test that the process with the Critical Limits eliminates the hazard.

If a hot deli serving table is to maintain food above 140°F, then validate that it does.

Verification — Assure that all required information is written down and documented.

If cleaning of equipment is stated in the Hazard Analysis, then check that cleaning is done. *Do what you say and say what you do.* Verify the written statements.

Reassessment —

- Do at least annually.
- Consider potential new hazards.
- Examine changes in the process, raw materials or raw ingredients, formulation production volume, personnel, packaging of the finished product, distribution, or any other changes that could affect the hazard analysis.

Step 8

For each **Process Step** identified from the **Hazard Analysis and CCP** form (see page 22), enter that **Process Step** on the **Verification and Record-Keeping** form shown on page 34.

For each *Process Step*, enter all the *Validation and Verification* activities. This is part of the needed documentation.

Whenever a Reassessment occurs, fully document the reason for the reassessment and the results.

See *Appendix 8: HACCP Plans — Verification and Record Keeping*. See pages 60 and 102-108.

Verification and Record Keeping

Product:

**Process Step/
CCP**

Verification Activities

Record-Keeping Procedures

Approved By: _____

Date: _____

Principle 7

Establish Record-Keeping Procedures

HACCP Principle No. 7 States:

Establish effective record-keeping procedures that document the HACCP system.



Maintaining proper HACCP records is an essential part of the HACCP system. Good HACCP records — meaning that the records are accurate and complete — can be very helpful because:

- Records serve as written documentation of the establishment's compliance with its HACCP plan.
- Records allow the retail facility to trace the history of a product, should problems arise.
- Records help identify trends in a particular operation that could result in a deviation if not corrected.
- Records could help identify and narrow the scope of a recall in the event a product recall becomes necessary.
- Records that are well-maintained are good evidence in potential legal actions against an establishment.
- There may be new HACCP team members and the rationale for certain decisions is forgotten.

Records

Three Types of Records

1. In the Hazard Analysis, records of practices that keep hazards from likely occurring, i.e.:
 - Cleaning procedures
 - Employee training
2. HACCP plan and reassessments:
 - Validations
 - Verifications
3. Operating records (such as):
 - Records of Critical Limits
 - Calibrations

Step 9

On each *Process Step/CCP*, enter all the Record-Keeping Procedures on the *Verification and Record Keeping* form (*see page 34*). This is part of the needed documentation.

See *Appendix 8: HACCP Plans — Verification and Record Keeping*.
See *pages 60 and 102-108*.

Step 10

For each *Process Step/CCP* identified from the *Critical Limits, Monitoring, and Corrective Action* form, enter the information listed here on the *HACCP Plan Summary* form on page 38:

- Hazard
- Critical Limit
- Monitoring Instrument
- Corrective Action
- Verification
- Record Keeping

See *Appendix 8: HACCP Plans — HACCP Plan Summary*.
See *pages 60 and 109-118*.

Step 11

All forms are to be reviewed for correctness, signed, and dated.

HAACP Plan Summary

Product:

Include every Process Step and indicate those with their CCP numbers. But don't break each process into biological, chemical, and physical.

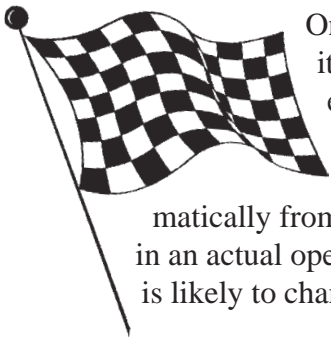
Process Step/ CCP	Hazard	Critical Limit	Monitoring	Corrective Action	Verification	Record Keeping

Approved By: _____ Date: _____

Chapter 8

Implementation of a HACCP Plan

It is important to communicate early and often with the regulatory personnel who will be overseeing a HACCP plan. What the HACCP committee might have learned about HACCP plan writing and HACCP implementation in a HACCP training course may or may not apply to your specific regulatory situation. It is important to acquaint your inspector(s) with your plan early and not surprise anyone with challenges at the eleventh hour.



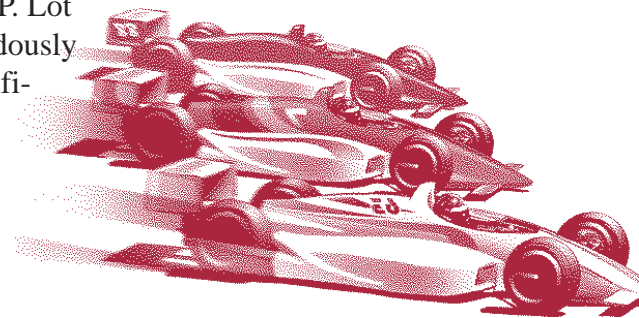
Once Critical Control Points (CCP) have been identified, it is important to introduce the HACCP plan to existing employees and to do a mock implementation as far ahead of an implementation deadline as possible. Most companies find that their HACCP plan changes dramatically from what was originally on paper to what is feasible to do in an actual operation. Everything from CCP to monitoring procedures is likely to change in a HACCP plan during a mock implementation.

As with any major change, expect that some employees may be resistant to the HACCP process, and that some of the planned monitoring and verification procedures may be difficult to accomplish with the time that employees have available. Mock implementation will likely lead to even more changes, but it is wise to work through these rough spots before you are expected to comply with a regulatory deadline.

Employee training will be very necessary when implementing a HACCP plan. Employees may have only been told to go do something in the past, without knowing exactly why. With HACCP, employees need to understand how their performance (both processing and CCP monitoring) impacts the safety of the food product that they are working with, and the importance of accuracy and honesty in monitoring CCP.

If you don't already have a lot identification system established, you may need to develop one before you can operate under HACCP. Lot identification is another process that will likely evolve tremendously during a mock implementation. The requirements for lot identification/coding may be found in *Appendix 9 (see page 119)*.

See *Appendix 10: Final HACCP Plan* — which contains an outline of the material to be included in a completed HACCP Plan manual. See page 120.

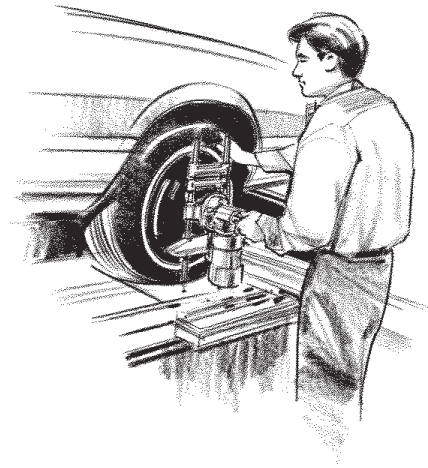


Maintaining the HACCP Plan

Once implemented, it is important to maintain a HACCP plan properly. Verification of the plan will help to determine if employees are properly monitoring a CCP (see Chapter 6). A HACCP plan should also be regularly reassessed, particularly as changes are made in processing methods and in intended users of the final product (again, see Chapter 6).

These verification activities should be maintained as continuous additions to the HACCP plan. They should also go through the same review and approval process as the original plan.

It is very important that operations keep up-to-date with their record keeping (monitoring, corrective actions, etc.), as even the best-intentioned operation will be in trouble if it gets behind in its records.



The *2001 Food Code* is not federal regulation. However, it does represent the Food and Drug Administration's best advice for a uniform system of regulation to ensure that food is safe, properly protected, and properly presented. It is the responsibility of both the government and retail food operations to ensure that food presented to the customer is safe.

The *2001 Food Code* provides the most recent and best scientifically based advice regarding prevention of food-borne illness. The emphasis of HACCP is a continuation of this concept by focusing on the prevention, rather than on detection, of problems in the final product.

The U.S. Food and Drug Administration's web site at <http://vm.cfsan.fda.gov/~comm/nacmcfp.html> is detailed in presenting *Hazard Analysis and Critical Control Point Principles and Application Guidelines*.

The guidelines are presented by the:
U.S. Food and Drug Administration
U.S. Department of Agriculture
National Advisory Committee on Microbiological Criteria for Foods
Adopted August 14, 1997.

Hazard Analysis and Critical Control Point Principles and Application Guidelines

Adopted August 14, 1997

National Advisory Committee on Microbiological Criteria for Foods

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and comprised of participants from the USDA (Food Safety and Inspection Service), Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry, and state employees. NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.