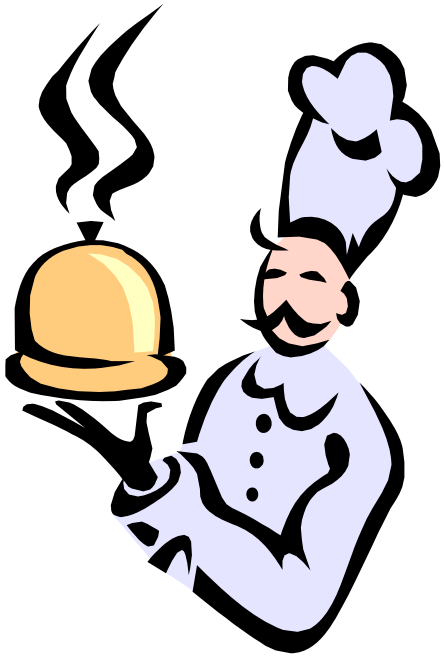

Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

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See additional PRA statement in Annex 5 of this manual

Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

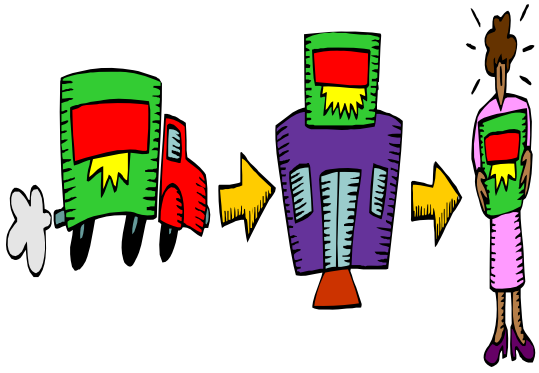
Chapter 1 – Introduction

PURPOSE AND SCOPE

> *"Foodborne illness in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. Mead et al. (1999) estimated that foodborne diseases cause 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year…The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs is estimated to be $10-83 billion."*
>
> 2001 *Food Code*
> Public Health Service - Food & Drug Administration
> U.S. Department of Health and Human Services

The statistics on foodborne illness speak for themselves. Regulatory officials and the retail and food service industries they regulate must partner with each other if we are to prevent or reduce foodborne illness. This Manual was prepared by the United States Food and Drug Administration (FDA), in partnership with federal, state, and local regulators, industry, academia, and consumers, to assist you, the operators of retail and food service establishments, in your efforts to produce safe food.

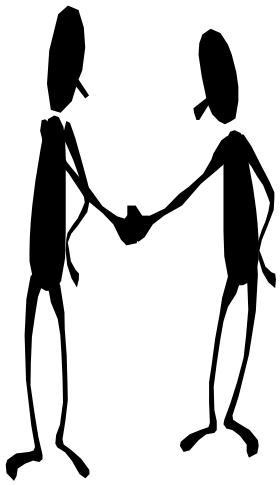
Who has the responsibility for ensuring safe food?



"Delivering safe food to the dinner table is the culmination of the work of many people. Producers, shippers, processors, distributors, handlers, and numerous others perform actions every day that may affect the safety of our food. Everyone's challenge is to perform these individual actions as well as possible, so that the food Americans eat is free from physical hazards and dangerous levels of pathogenic microorganisms and hazardous chemicals."

2001 Food Safety Strategic Plan
GOAL 2 - RISK MANAGEMENT
The President's Council on Food Safety
http://www.foodsafety.gov/~fsg/cstrpl-4.html#chap2

While every player in the flow of food from farm to table has some degree of responsibility for food safety, you are usually the last line of defense before food reaches the consumer. Because of this, you have a significant share of the responsibility for ensuring safe food. By voluntarily developing a food safety management system, you can better ensure that the foods served or sold in your establishment are safe.



What is my health inspector's role in helping me to prevent foodborne illness in my establishment?

Regulatory food inspection programs provide you with feedback on how well you are controlling certain conditions in your establishment that can lead to foodborne illness. Although your inspector can offer suggestions for how you can improve conditions in your establishment, he or she cannot possibly oversee every activity or function in your day-to-day operation. Given this limitation, you clearly have the greatest impact on food safety.

How can this manual help me to prevent foodborne illness?

> *"Voluntary approaches can complement regulatory programs, particularly where government actions enhance existing incentives for individuals to adopt practices that increase food safety. Other approaches rely on the power of information to influence behavior. Such voluntary, prevention-oriented approaches will have a greater chance of success if they are promoted in partnership with the affected stakeholders"*
>
> 2001 Food Safety Strategic Plan
> The President's Council on Food Safety

This Manual provides you with a "roadmap" for writing and voluntarily implementing a food safety management system based on Hazard Analysis and Critical Control Point (HACCP) principles. By voluntarily developing and implementing a food safety management system like the one suggested in this Manual, you can take a proactive role in ensuring that the food served or sold in your establishment is safe. Rather than responding to a foodborne illness when it occurs, you can prevent it by taking active steps to eliminate, prevent, or reduce to an acceptable level food safety hazards that cause someone to be sick or injured.

If you already have an existing food safety management system, you may use the concepts in this Manual to upgrade the system you have in place. Whether you are developing a new food safety management system or merely upgrading the one you currently have, this Manual encourages operators and regulators of retail and food service to partner together to make the greatest impact on food safety.

How was this manual prepared?

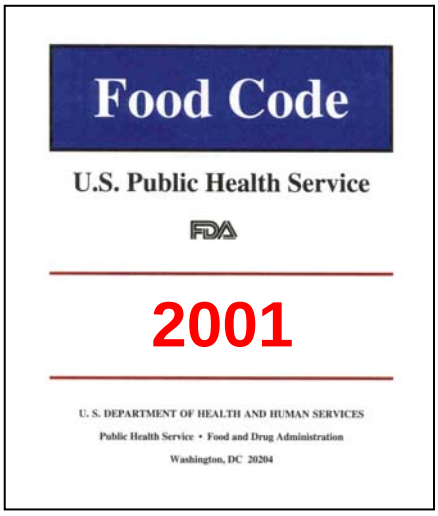
The procedures and information presented in this manual were prepared with feedback received from regional FDA food safety seminars and Food Safety Initiative grassroots meetings. In addition, the Conference for Food Protection (CFP) has reviewed and endorsed this manual and has provided FDA with comments and suggestions on two separate occasions (in December 2001 and again in November 2002). Comments received from these reviews were incorporated into this document by the FDA.

Who regulates me?

Although this document was written by FDA, your respective state, local, or tribal government directly regulates your operation. Understand that the requirements of your regulatory authority may not be the same as what is recommended in the model FDA *Food Code.* The 2001 FDA *Food Code* is used as the basis of this document, but it is neither federal law nor federal regulation. It also does not supercede the requirements of your state, local, or tribal government. However, most states have adopted the *Food Code* to regulate retail and food service establishments under their jurisdiction since it represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. With this in mind, you should compare the requirements of your state, local, or tribal government with any *Food Code* requirements mentioned in this Manual to make sure they are consistent with one another.

Is it a requirement that I implement a food safety management system based on HACCP principles?

The *Food Code* clearly establishes that the implementation of HACCP at retail should be a voluntary effort by industry. If, however, you plan on conducting certain specialized processes that carry considerably high risk, you should consult your regulatory authority to see if you are required to have a HACCP plan. Examples of specialized processes covered in Chapter 3 of the *Food Code* include formulating a food so that it is not potentially hazardous or using performance standards to control food safety.
Federal performance standards define public food safety



expectations for a product usually in terms of the number of disease-causing microorganisms that need to be destroyed through a process. For example, instead of cooking chicken to 165 ºF for 15 seconds as dictated in the *Food Code*, performance standards allow you to use a different combination of time and temperature as long as the same level of public safety is achieved. Use of performance standards allows you to use innovative approaches in producing safe products.

When using performance standards or when conducting other specialized processes, the FDA *Food Code* requires an establishment to obtain a variance, or exemption from the requirements of the Code, and to implement a more comprehensive HACCP plan than is outlined in this Manual. The regulatory authority must not only approve this HACCP plan, but records generated in support of the plan must be made available for review when requested.

Jurisdictions that have not adopted the *Food Code*, but otherwise allow the use of performance standards or other specialized processing methods, may also require you to obtain a variance. In such cases, the regulatory authority may also require that you develop a more comprehensive HACCP plan than is outlined in this Manual. In some jurisdictions around the country, the implementation of HACCP programs is a requirement regardless of the processing methods used. You should consult your regulatory authority if you are unsure of your requirements, if you plan on deviating from the requirements, or if you plan on conducting specialized processes.

What do I need to assist me in using this manual?

This Manual should be used in consultation with your federal, state, local, or tribal regulatory authority or other food safety professionals. Your regulatory authority can be an important resource in the development of your food safety management system. Regulatory food safety professionals can provide important information about the public health rationale for controlling a particular food safety hazard.

It is recommended that you use the latest version of the FDA *Food Code*, if applicable, or a copy of your local or state regulations as a reference. Many of the requirements in the *Food Code* or your local or state regulations provide fundamental prerequisites to implementing a food safety management system based on HACCP principles. If you do not have a copy of the *Food Code*, you can refer to Annex 1 of this Manual for information on how to obtain a copy. It is also available on the FDA/Center for Food Safety and Applied Nutrition website at: http://www.cfsan.fda.gov/~dms/foodcode.html.

BACKGROUND

What are the retail and food service industries?

Unlike many food processing operations, the retail and food service industries are not easily defined by specific commodities or conditions. These establishments share the following characteristics:

- These industries have a wide range of employee resources, from highly trained executive chefs to entry-level front line employees. Employees may have a broad range of education levels and communication skills. It may be difficult to conduct in-house training and maintain a trained staff because employees may speak different languages or there may be high employee turnover.

- Many are start-up businesses operating without the benefit of a large corporate support structure. Having a relatively low profit margin means they may have less money to work with than other segments of the food industry.

- There is an almost endless number of production techniques, products, menu items, and ingredients used. Suppliers, ingredients, menu items, and specifications may change frequently.

The following is a <u>partial</u> listing of the types of businesses that are usually considered part of the retail and food service industries:

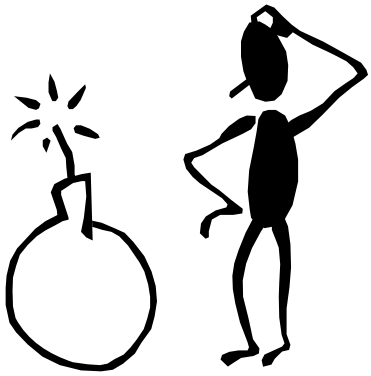
Back-country guided trips for groups
Bakeries
Bed and breakfast operations
Cafeterias
Camps - recreational, children's, etc.
Casinos, bares, and taverns
Child and adult day care
Church kitchens
Commissaries
Community fund raisers
Convenience stores
Fairs
Food banks
Grocery stores with specialized departments
    deli
    in-store prepared foods
    produce
    meat and seafood
Health care facilities
Interstate conveyances
Markets
Meal services for home-bound persons
Mobile food carts
Penal institutions
Restaurants
    chains
    international specialties
    fast food
    full service
    independent operations
    road-side stands
    schools
Snack bars
Temporary outdoor events
Vending machines

What are food safety hazards?

Hazards are biological, physical, or chemical properties that may cause food to be unsafe for human consumption. The goal of a food safety management system is to control certain factors that lead to out-of-control hazards.

Because many foods are agricultural products and have started their journey to your door as animals and plants raised in the environment, they may contain microscopic organisms. Some of these organisms are pathogens which means that under the right conditions and in the right numbers, they can make someone who eats them sick. Raw animal foods such as meat, poultry, fish, shellfish, and eggs often carry bacteria, viruses, or parasites that can be harmful to humans.

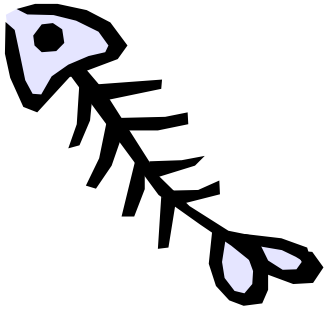
Food can become contaminated by toxic chemicals or toxins in your establishment or in the environment. Physical objects may also contaminate food and cause injury. Food may become naturally contaminated from the soil in which it is grown or from harvest, storage, or transportation practices. Some foods undergo further processing and at times, despite best efforts, become contaminated. These inherent hazards, along with the hazards that may be introduced in your establishment such as metal fragments from grinding can lead to injury, illness, or death. Hazards are a huge threat to your business. Think of hazards as ticking bombs in your establishment. Unless they are kept under control, they could result in financial ruin for your business.



Hazards include –

- Biological agents
  - Bacteria and their toxins
  - Parasites
  - Viruses

- Physical Objects
  - Bandages
  - Jewelry
  - Stones
  - Glass
  - Bone and metal fragments
  - Packaging materials



- Chemical Contamination
  - Natural plant and animal toxins
  - Unlabeled allergens (allergen-causing protein)
  - Nonfood-grade lubricants
  - Cleaning compounds
  - Food additives
  - Insecticides

What are foodborne illness risk factors?

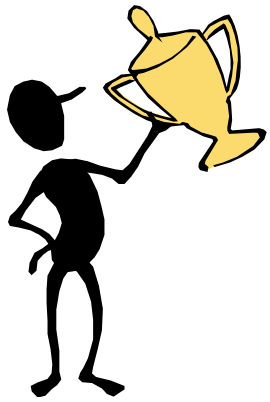
The Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne-Disease Outbreaks – United States," identifies the most significant contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the FDA as "foodborne illness risk factors." These five broad categories are:

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene

No national baseline on the occurrence of foodborne illness risk factors was available until 2000 when FDA released the *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors.* The report, commonly referred to as the "FDA Baseline Report," is provided to regulators and industry with the expectation that it will be used to focus greater attention and increased resources on the control of foodborne illness risk factors. A copy of the report is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/retrsk.html.

Based on the measurable trends identified in CDC's 1993-1997 Surveillance Report and in FDA's Baseline Report, FDA recommends that your food safety management system focus on establishing active managerial control of the five CDC-identified risk factors.

What is meant by active managerial control?



The term “active managerial control” is used extensively throughout this document to describe your role for developing and implementing a food safety management system to reduce the occurrence of risk factors. Although the term “active managerial control” may be new to some, the basic management principles are probably already being used in your day-to-day operations.

Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of your business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety. Having active managerial control includes having procedures in place for controlling identified foodborne illness risk factors through a continuous system of monitoring and verification.

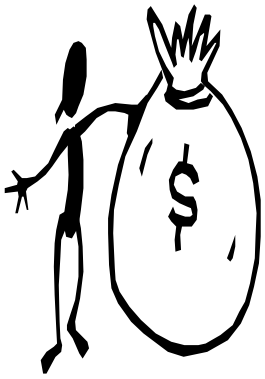
FDA recognizes that there are many management systems that you can voluntarily implement to achieve active managerial control of risk factors. This Manual focuses only on the voluntary implementation of HACCP principles in your food safety management system. Regardless of the system you use, effective elements of a food safety management system may include –

- Certified food protection managers who have shown a proficiency of required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for performing critical operational steps in a food preparation process such as cooling
- Recipe cards that contain the specific steps for preparing a food item and the food safety critical limits such as final cooking temperatures that need to be monitored and verified
- Purchase specifications
- Equipment and facility design and maintenance
- Monitoring procedures
- Record keeping
- Employee health policy for restricting or excluding ill employees
- Manager and employee training
- On-going quality control and assurance
- Specific goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling specific foodborne illness risk factors

THE USE OF HACCP AS A FOOD SAFETY MANAGEMENT SYSTEM

Since the 1960's, food safety professionals have recognized the importance of HACCP principles for controlling risk factors that directly contribute to foodborne illness. The principles of HACCP embody the concept of active managerial control by encouraging participation in a system that ensures foodborne illness risk factors are controlled.

HACCP is not a stand-alone program, but is built upon a foundation of operational practices called prerequisite programs (discussed in Chapter 3). The success of a HACCP program (or plan) is dependent upon both facilities and people. The facilities and equipment should be designed to facilitate safe food preparation and handling practices by employees. Furthermore, FDA recommends that managers and employees be properly motivated and trained if a HACCP program is to successfully reduce the occurrence of foodborne illness risk factors. Instilling food worker and management commitment and dealing with problems like high employee turnover and communication barriers should be considered when designing a food safety management system based on HACCP principles.



Properly implemented, a food safety management system based on HACCP principles may offer you the following other advantages:

- Reduction in product loss
- Increase in product quality
- Better control of product inventory
- Consistency in product preparation
- Increase in profit
- Increase in employee awareness and participation in food safety

What are the seven HACCP principles?

The 1997 National Advisory Committee for the Microbiological Criteria for Foods (NACMCF) recommendations updated the seven HACCP principles to include the following:

1. **Perform a Hazard Analysis.** The first principle is about understanding the operation and determining what food safety hazards are likely to occur. The manager needs to understand how the people, equipment, methods, and foods all affect each other. The processes and procedures used to prepare the food are also considered. This usually involves defining the operational steps (receiving, storage, preparation, cooking, etc.) that occur as food enters and moves through the operation. Additionally, this step involves determining the control measures that can be used to eliminate, prevent, or reduce food safety hazards. Control measures include such activities as implementation of employee health policies to restrict or exclude ill employees and proper handwashing.

2. **Decide on the Critical Control Points (CCPs).** Once the control measures in principle #1 are determined, it is necessary to identify which of the control measures are absolutely essential to ensuring safe food. An operational step where control can be applied and is essential for ensuring that a food safety hazard is eliminated, prevented or reduced to an acceptable level is a critical control point (CCP). When determining whether a certain step is a CCP, if there is a later step that will prevent, reduce, or eliminate a hazard to an acceptable level, then the former step is not a CCP. It is important to know that not all steps are CCPs. Generally, there are only a few CCPs in each food preparation process because CCPs involve only those steps that are absolutely essential to food safety.

3. **Determine the Critical Limits.** Each CCP must have boundaries that define safety. Critical limits are the parameters that must be achieved to control a food safety hazard. For example, when cooking pork chops, the *Food Code* sets the critical limit at 145 ºF for 15 seconds. When critical limits are not met, the food may not be safe. Critical limits are measurable and observable.

4. **Establish Procedures to Monitor CCPs.** Once CCPs and critical limits have been determined, someone needs to keep track of the CCPs as the food flows through the operation. Monitoring involves making direct observations or measurements to see that the CCPs are kept under control by adhering to the established critical limits.

5. **Establish Corrective Actions.** While monitoring CCPs, occasionally the process or procedure will fail to meet the established critical limits. This step establishes a plan for what happens when a critical limit has not been met at a CCP. The operator decides what the actions will be, communicates those actions to the employees, and trains them in making the right decisions. This preventive approach is the heart of HACCP. Problems will arise, but you need to find them and correct them before they cause illness or injury.

6. **Establish Verification Procedures.** This principle is about making sure that the system is scientifically-sound to effectively control the hazards. In addition, this step ensures that the system is operating according to what is specified in the plan. Designated individuals like the manager periodically make observations of employees' monitoring activities, calibrate equipment and temperature measuring devices, review records/actions, and discuss procedures with the employees. All of these activities are for the purpose of ensuring that the HACCP plan is addressing the food safety concerns and, if not, checking to see if it needs to be modified or improved.

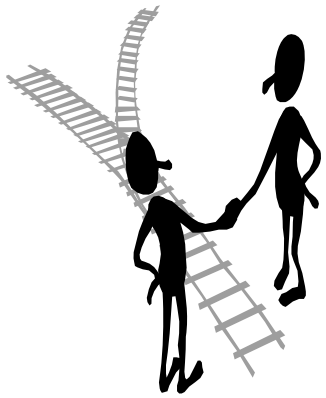
7. **Establish a Record Keeping System.** There are certain written records or kinds of documentation that are needed in order to verify that the system is working. These records will normally involve the HACCP plan itself and any monitoring, corrective action, or calibration records produced in the operation of a the HACCP system. Verification records may also be included. Records maintained in a HACCP system serve to document that an ongoing, effective system is in place. Record keeping should be as simple as possible in order to make it more likely that employees will have the time to keep the records.

How can HACCP principles be used in retail and food service operations?

Within the retail and food service industries, the implementation of HACCP principles varies as much as the products produced. The resources available to help you identify and control risk factors common to your operation may also be limited. Due to this diversity, implementation of "textbook" HACCP is impractical in most retail and food service establishments.

Like many other quality assurance programs, the principles of HACCP provide a common-sense approach to identifying and controlling risk factors. Consequently, many food safety management systems at the retail level incorporate some, if not all, of the principles of HACCP. While a complete HACCP system is ideal, many different types of food safety management systems may be implemented to control risk factors. It is also important to recognize that HACCP has no single correct application. Variations in the procedures presented in this Manual are appropriate as long as they are based on sound public health judgment. In addition to the material presented in the text of this Manual, several references have been provided in Annex 1 to assist you in developing a food safety management system specific to your operation.

SUMMARY



FDA endorses the voluntary implementation of food safety management systems in retail and food service establishments. Combined with good basic sanitation, a solid employee training program, and other prerequisite programs, HACCP can provide you and your employees a complete food safety management system.

The goal in applying HACCP principles in retail and food service is to have you, the operator, take purposeful actions to ensure safe food. You and your regulatory authority have a common objective in mind – providing safe, quality food to consumers. Your health inspector can help you achieve this common objective, but remember that the ultimate responsibility for food safety at the retail level lies with you and your ability to develop and maintain an effective food safety management system.

Managing food safety should be as fully integrated into your operation as those actions that you might take to open in the morning, ensure a profit, or manage cash flow. By putting in place an active, ongoing system, made up of actions intended to create the desired outcome, you can achieve your goal of improving food safety. The application of the HACCP principles provides one system that can help you accomplish that goal.

This Manual will provide details on how to organize your products so that you can voluntarily develop your own food safety management system using HACCP principles. The HACCP plans that you will develop using this Manual, in combination with prerequisite programs (discussed in Chapter 3), will constitute a complete food safety management system. Partnering with your regulatory authority or other food safety professional is recommended, but the design, implementation, and success of your system rests with you.

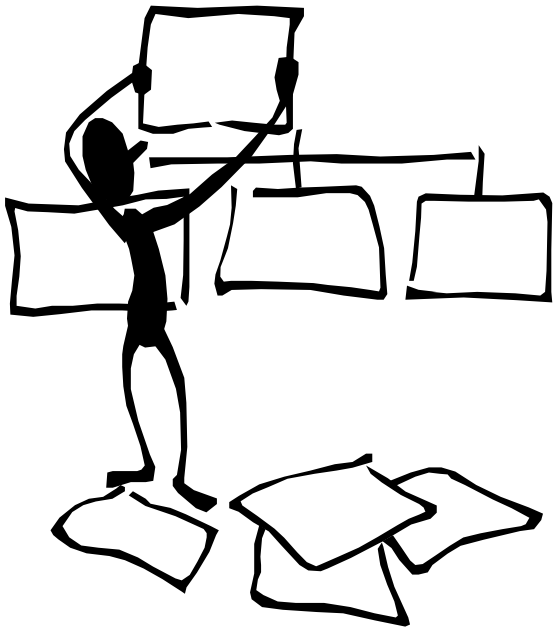
Chapter 2 - The Process Approach

APPLYING HACCP PRINCIPLES TO RETAIL AND FOOD SERVICE

What is the process approach?

Since the early 1980's, retail and food service operators and regulators have been exploring the use of HACCP in restaurants, grocery stores, and other retail food establishments. Most of this exploration has centered on the question of how to stay true to the definitions of HACCP yet still make the principles useful to an industry that encompasses a very broad range of conditions. Through this exploration, HACCP principles have been slightly modified to apply to the varied operations found at retail.

When conducting the hazard analysis, food manufacturers usually use food commodities as an organizational tool and follow the flow of one product. This is a very useful approach for producers or processors since they are usually handling one product at a time. By contrast, in retail and food service operations, foods of all types are worked together to produce the final product. This makes a different approach to the hazard analysis necessary. Conducting the hazard analysis by using the food preparation processes common to a specific operation is often more efficient and useful for retail and food service operators. This is called the "Process Approach" to HACCP.



The process approach can best be described as dividing the many food flows in an establishment into broad categories based on activities or stages in the flow of food through your establishment, then analyzing the hazards, and placing managerial controls on each grouping.

What is the flow of food?

The flow of food in a retail or food service establishment is the path that food follows from receiving through service or sale to the consumer. Several activities or stages make up the flow of food and are called operational steps. Examples of operational steps include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling, packaging, serving, and selling. Keep in mind that the terminology used for operational steps may differ between food service and retail food store operations.

What are the three food preparation processes most often used in retail and food service establishments?

Most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41 ºF to 135 ºF:

- **Process 1: Food Preparation with No Cook Step**

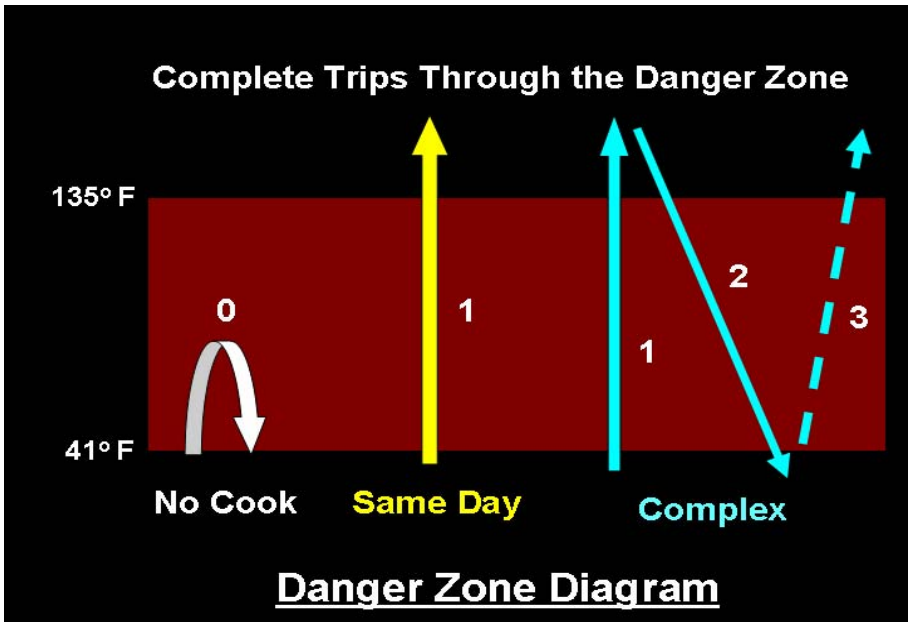
Example flow: Receive – Store – Prepare – Hold – Serve
(other food flows are included in this process, but there is no cook step to destroy pathogens)

- **Process 2: Preparation for Same Day Service**

Example flow: Receive – Store – Prepare – Cook – Hold – Serve
(other food flows are included in this process, but there is only one trip through the temperature danger zone)

- **Process 3: Complex Food Preparation**

Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve
(other food flows are included in this process, but there are always two or more complete trips through the temperature danger zone)



A summary of the three food preparation processes in terms of number of times through the temperature danger zone can be depicted in a Danger Zone diagram. Note that while foods produced using process 1 may *enter* the danger zone, they are neither cooked to destroy pathogens, nor are they hot held. Foods that go through the danger zone only once are classified as Same Day Service, while foods that go through more than once are classified as Complex food preparation.

The three food preparation processes conducted in retail and food service establishments are not intended to be all-inclusive. For instance, quick service facilities may have "cook and serve" processes specific to their operation. These processes are likely to be different from the "Same Day Service" preparation processes in full service restaurants since many of their foods are generally cooked and hot held before service. In addition, in retail food stores, operational steps such as packaging and assembly may be included in all of the food preparation processes prior to being sold to the consumer.

It is also very common for a retail or food service operator to have a single menu item (i.e. chicken salad sandwich) that is created by combining several components produced using more than one kind of food preparation process. It is important for you to remember that even though variations of the three food preparation process flows are common, the control measures – actions or activities that can be used to prevent, eliminate, or reduce food safety hazards – to be implemented in each process will generally be the same based on the number of times the food goes through the temperature danger zone.

THE HAZARD ANALYSIS

In the "process approach" to HACCP, conducting a hazard analysis on individual food items is time and labor intensive and is generally unnecessary. Identifying and controlling the hazards in each food preparation process listed above achieves the same control of risk factors as preparing a HACCP plan for each individual product. Example: An establishment has dozens of food items (including baked chicken and meatloaf) in the "Preparation for Same Day Service" category. Each of the food items may have unique hazards (See Annex 3, Table 1), but regardless of their individual hazards, control via proper cooking and holding will generally ensure the safety of all of the foods in this category. An illustration of this concept follows:

- Even though they have unique hazards, baked chicken and meatloaf are items frequently grouped in the "Same Day Service" category (Process 2).

- *Salmonella* and *Campylobacter,* as well as spore-formers, such as *Bacillus cereus* and *Clostridium perfringens*, are significant biological hazards in chicken.

- Significant biological hazards in meatloaf include *Salmonella*, *E. coli* O157:H7, *Bacillus cereus,* and *Clostridium perfringens.*

- Despite their different hazards, the control measure used to kill pathogens in both these products should be cooking to the proper temperature.

- Additionally, if the products are held after cooking, then proper hot holding or time control is also recommended to prevent the outgrowth of spore-formers that are not destroyed by cooking.

As with product-specific HACCP, critical limits for cooking remain specific to each food item in the process. In the scenario described above, the cooking step for chicken requires a final internal temperature of 165 ºF for 15 seconds to control the pathogen load for *Salmonella.* Meatloaf, on the other hand, is a ground beef product and requires a final internal temperature of 155 ºF for 15 seconds to control the pathogen load for both *Salmonella* and *E. coli* O157:H7. Note that there are some operational steps, such as refrigerated storage or hot holding, that have critical limits that apply to all foods.

The following table further illustrates this concept. Note that the only unique control measure applies to the critical limit of the cooking step for each of the products. Other food safety hazards and control measures may exist:

Process 2: Preparation for Same Day Service		
Example Products	**Meatloaf**	**Chicken**
Example Biological Hazards	*Salmonella*	*Salmonella*
	E. coli O157:H7	*Campylobacter*
	Clostridium perfringens	*Clostridium perfringens*
	Bacillus cereus	*Bacillus cereus*
	Various fecal-oral route pathogens	Various fecal-oral route pathogens
Example Control Measures (there may be others)	**Cooking at 155 °F for 15 seconds**	**Cooking at 165 °F for 15 seconds**
	Refrigeration 41 °F or below	Refrigeration 41 °F or below
	Hot Holding at 135 °F or above OR Time Control for 4 hours or less	Hot Holding at 135 °F or above OR Time Control for 4 hours or less
	No bare hand contact with RTE food, proper handwashing, exclusion/restriction of ill employees	No bare hand contact with RTE food, proper handwashing, exclusion/restriction of ill employees

DETERMINING RISK FACTORS IN PROCESS FLOWS

Several of the most common risk factors associated with each food preparation process are discussed below. Remember that while you should generally focus your food safety management system on these risk factors, there may be other risk factors unique to your operation or process that are not listed here. You should evaluate your operation and the food preparation processes you use independently.

In developing your food safety management system, keep in mind that active managerial control of risk factors common to each process can be achieved by either designating certain operational steps as critical control points (CCPs) or by implementing prerequisite programs. This will be explained in more detail in Chapter 3. The HACCP plans that you will develop using this Manual, in combination with prerequisite programs, will constitute a complete food safety management system.

Facility-wide Considerations

In order to have active managerial control over personal hygiene and cross-contamination, you must implement certain control measures in all phases of your operation. All of the following control measures should be implemented regardless of the food preparation process used:

- **No bare hand contact with ready-to-eat foods (or use of an approved, alternative procedure)** to help prevent the transfer of viruses, bacteria, or parasites from hands
- **Proper handwashing** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Restriction or exclusion of ill employees** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Prevention of cross-contamination** of ready-to-eat food or clean and sanitized food-contact surfaces with soiled cutting boards, utensils, aprons, etc. or raw animal foods

Food Preparation Process 1 – Food Preparation with No Cook Step

Example Flow: RECEIVE – STORE – PREPARE – HOLD – SERVE

Several food flows are represented by this particular process. Many of these food flows are common to both retail food stores and food service facilities, while others only apply to retail operations. Raw, ready-to-eat food like sashimi, raw oysters, and salads are grouped in this category. Components of these foods are received raw and will not be cooked prior to consumption.

Foods cooked at the processing level but that undergo no further cooking at the retail level before being consumed are also represented in this category. Examples of these kinds of foods are deli meats, cheeses, and other pasteurized products. In addition, foods that are received and sold raw but are to be cooked by the consumer after purchase, i.e. hamburger meat, chicken, and steaks, are also included in this category.

All the foods in this category lack a kill (cook) step *while at the retail or food service establishment*. In other words, there is no complete trip made through the danger zone for the purpose of destroying pathogens. You can ensure that the food received in your establishment is as safe as possible by requiring purchase specifications. Without a kill step to destroy pathogens, your primary responsibility will be to prevent further contamination by ensuring that your employees follow good hygienic practices.

Cross-contamination must be prevented by properly storing your products away from raw animal foods and soiled equipment and utensils. Foodborne illness may result from ready-to-eat food being held at unsafe temperatures for long periods of time due to the outgrowth of bacteria.

In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring that you have active managerial control over the following:

- **Cold holding or using time alone** to inhibit bacterial growth and toxin production
- **Food source** (especially for shellfish due to concerns with viruses, natural toxins, and *Vibrio* and for certain marine finfish intended for raw consumption due to concerns with ciguatera toxin) (See Annex 2, Table 1)
- **Receiving temperatures** (especially certain species of marine finfish due to concerns with scombrotoxin) (See Annex 2, Table 2)
- **Date marking** of ready-to-eat PHF held for more than 24 hours to control the growth of *Listeria monocytogenes*
- **Freezing** certain species of fish intended for raw consumption due to parasite concerns (See Annex 2, Table 3)
- **Cooling** from ambient temperature to prevent the outgrowth of spore-forming or toxin-forming bacteria

Food Preparation Process 2 – Preparation for Same Day Service

Example Flow: RECEIVE – STORE – PREPARE – COOK – HOLD – SERVE

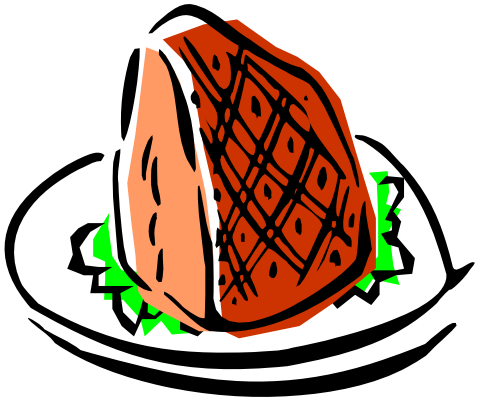
In this food preparation process, food passes through the danger zone only once in the retail or food service establishment before it is served or sold to the consumer. Food is usually cooked and held hot until served, i.e. fried chicken, but can also be cooked and served immediately. In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring that you have active managerial control over the following:

- **Cooking** to destroy bacteria and parasites
- **Hot holding or using time alone** to prevent the outgrowth of spore-forming bacteria

Approved food source, proper receiving temperatures, and proper cold holding prior to cooking are also important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrotoxin. Consult Annex 2 of this Manual for special considerations related to seafood.

Food Preparation Process 3 – Complex Food Preparation

Example Flow: RECEIVE – STORE – PREPARE – COOK – COOL – REHEAT – HOT HOLD – SERVE



Foods prepared in large volumes or in advance for next day service usually follow an extended process flow. These foods pass through the temperature danger zone more than one time; thus, the potential for the growth of spore-forming or toxigenic bacteria is greater in this process. Failure to adequately control food product temperatures is one of the most frequently encountered risk factors contributing to foodborne illness. In addition, foods in this category have the potential to be recontaminated with *L. monocytogenes*, which could grow during refrigerated storage. FDA recommends that food handlers minimize the time foods are at unsafe temperatures.

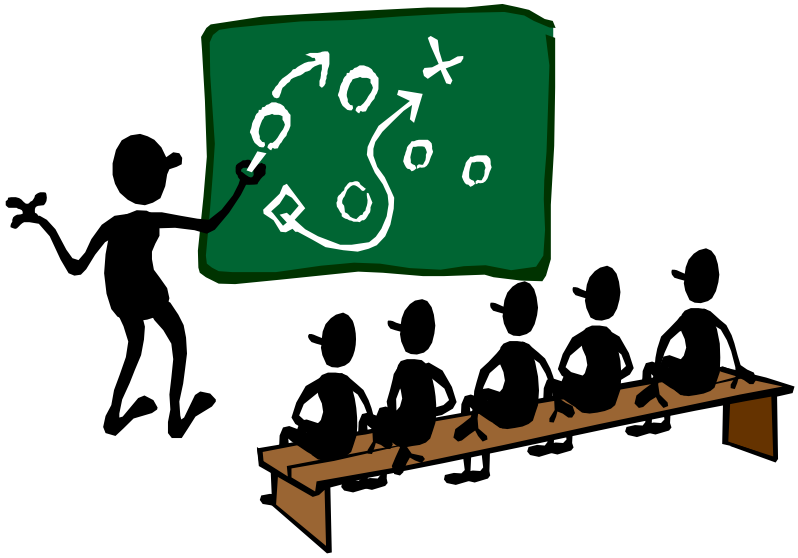
In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring that you have active managerial control over the following:

- **Cooking** to destroy bacteria and parasites
- **Cooling** to prevent the outgrowth of spore-forming or toxin-forming bacteria
- **Hot and cold holding or using time alone** to inhibit bacterial growth and toxin formation
- **Date marking** of ready-to-eat PHF held for more than 24 hours to control the growth of *Listeria monocytogenes*
- **Reheating** for hot holding, if applicable

Approved food source, proper receiving temperatures, and proper cold holding prior to cooking are also important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrotoxin. Consult Annex 2 of this Manual for special considerations related to seafood.

Chapter 3 – Developing Your Food Safety System

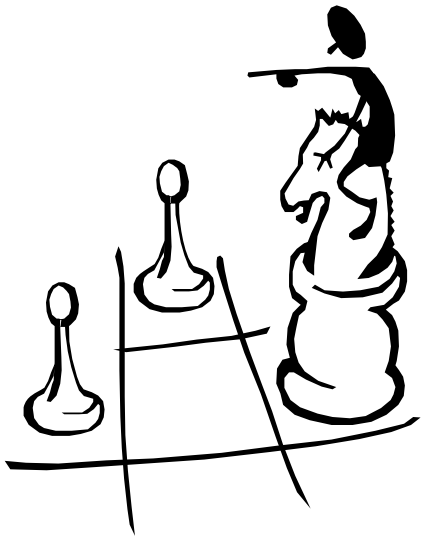
GETTING STARTED



What is food safety team?

Use of this Manual is most effective when a team approach is used. The team should at least have representation from all the areas of the operation that will be involved in the implementation process. This includes, but is not limited to, the owner, the managers, chefs, cooks, dishwashers, wait staff, and other individuals who might be actively involved in the preparation and service of the food. Although managers are responsible for designing the system, implementation involves the efforts and commitment of every employee. Training managers and employees in their respective roles is crucial to the success of your food safety management system. You may consider working with outside consultants, industry trade associations, university extension services, and your regulatory authority to ensure that your food safety management system is based on the best available science and that it will control the identified hazards.

HOW TO USE THIS MANUAL



Just like a well-played chess game, building a food safety management system takes time, patience, and determination. Careful consideration must be given to all aspects of your operation affecting food safety. To assist you in building your food safety management system, a series of procedural steps have been developed to guide you through the process.

Each procedural step includes a short discussion. For your convenience, you can use the tables provided in Annex 4 of this Manual to capture your food safety management system in writing. After you have read the discussion under each procedural step, it is recommended that you complete the tables in Annex 4 with the appropriate information for each food preparation process conducted in your establishment.

For example, when you are finished developing your prerequisite programs in Procedural Step 1, you may reference your prerequisite programs by title on the tables. Upon completion of Procedural Step 2 (grouping your menu items/products into one of the three processes), you may complete the menu item/product row on the tables for each food preparation process. When you are finished identifying the hazards in Procedural Step 3, you may fill in the appropriate columns. You may continue filling in the tables through Procedural Step 9. When you are done, you will have up to 3 tables containing all the information you need to implement your food safety management system.

Two sets of tables have been provided for you to use in building your system. You can use either set of these tables or you can modify them to best suit your operation's needs. The tables that are provided will enable you to –

- group menu items/products within your establishment into one of three food preparation processes
- conduct a hazard analysis on each process grouping and identify control measures
- decide how control measures will be managed (as CCPs in HACCP plans or through prerequisite programs
- identify the critical limits pertaining to the identified CCPs

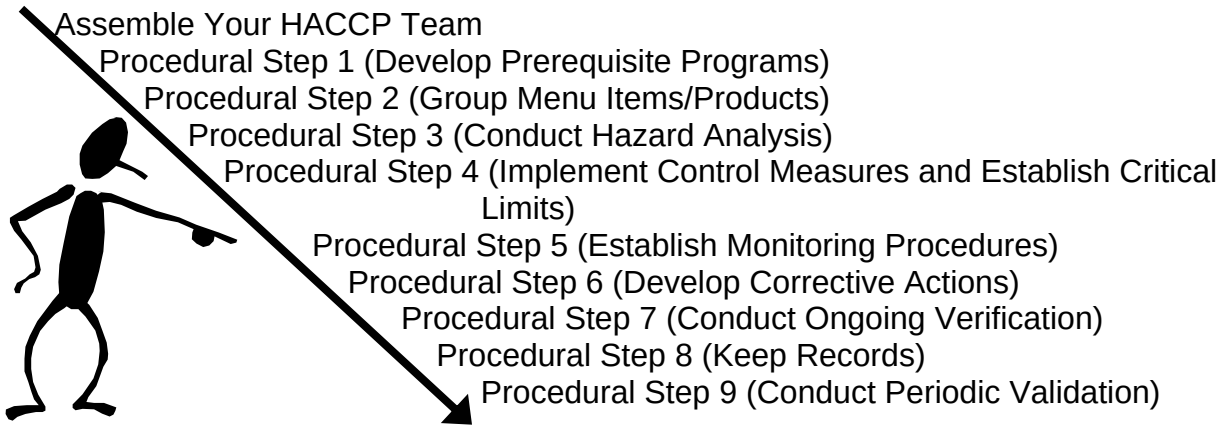
- develop monitoring procedures and corrective actions which are customized to fit your operation

- design the verification procedure needed

- determine the type of record keeping you need to document you are controlling significant food safety hazards

- validate that the system can effectively control the food safety hazards

The ideal progression of building a food safety management system according to this manual is as follows:



PROCEDURAL STEP 1

Develop Prerequisite Programs

If you want to build a sturdy home, you should start with a strong foundation. The same is true of a food safety management system. In order for your food safety management system to be effective, you should first develop and implement a strong foundation of procedures that address the basic operational and sanitation conditions within your operation. These procedures are collectively termed "prerequisite programs."

When prerequisite programs are in place, you can focus more attention on the hazards associated with the food and its preparation. Before beginning to write your food safety management system, it is recommended that you develop and implement prerequisite programs. Prerequisite programs may include such things as –

- Vendor certification programs
- Training programs
- Allergen management
- Buyer specifications
- Recipe/process instructions
- First-In-First-Out (FIFO) procedures
- Other Standard Operating Procedures (SOPs)

Basic prerequisite programs should be in place to –

- Protect products from contamination by biological, chemical, and physical food safety hazards
- Control bacterial growth that can result from temperature abuse
- Maintain equipment

Prerequisite Programs to Control Contamination of Food

These procedures ensure that –

- Soiled and unsanitized surfaces of equipment and utensils do not contact raw or cooked (ready-to-eat) food
- Workers with certain symptoms, such as vomiting or diarrhea, are restricted or excluded
- Raw animal foods do not contaminate cooked (ready-to-eat) food
- Effective handwashing is practiced
- Eating, smoking, and drinking in food preparation areas are prohibited
- Water in contact with food and food-contact surfaces and used in the manufacture of ice is potable
- Toxic compounds are properly labeled, stored, and safely used
- Contaminants such as condensate, lubricants, pesticides, cleaning compounds, sanitizing agents, and additional toxic materials do not contact food, food-packaging materials, and food-contact surfaces
- Food, food-packaging materials, and food-contact surfaces are not contaminated by physical hazards such as broken glass from light fixtures, jewelry, etc.
- An effective pest control system is in place
- Hair restraints are used
- Clean clothing is worn
- The wearing of jewelry (other than a wedding ring) is prohibited

Prerequisite Programs to Control Bacterial Growth

These procedures ensure that all potentially hazardous food is received and stored at a refrigerated temperature of 41 ºF or below. Note that the *Food Code* makes some allowances for specific foods that may be received at higher temperatures.

Prerequisite Programs to Maintain Equipment

These procedures ensure that –

- Food-contact surfaces, including utensils, are cleaned, sanitized, and maintained in good condition

- Temperature measuring devices (e.g., thermometer or temperature recording device) are calibrated regularly

- Cooking and hot holding equipment (grills, ovens, steam tables, conveyer cookers, etc.) are routinely checked, calibrated, and operated to ensure correct product temperature

- Cold holding and cooling equipment (refrigerators, rapid chill units, freezers, salad bars, etc.) are routinely checked, calibrated, and operated to ensure correct product temperature

- Warewashing equipment is operated according to manufacturer's specifications

- Toilet facilities are accessible to employees and maintained

The items addressed by this procedural step are the foundation by which your entire food safety management system is based. The success of any food safety management system is dependent on how well you control these basic sanitation issues in your establishment.

With this in mind, consider how you can actively monitor the activities associated with the prerequisite programs to ensure that they are being implemented properly. If you decide to control certain items in your food safety management system through prerequisite programs, monitoring of the programs is recommended. Just as monitoring allows you to prevent, eliminate, or reduce hazards in your HACCP plans, monitoring may also allow you an opportunity to detect weaknesses in your prerequisite programs. If you see areas needing improvement, you should take corrective actions immediately.

PROCEDURAL STEP 2

Group Your Menu Items/Products

To begin grouping your menu items/products, you should review how your menu items or products flow through your operation. You should note whether they undergo a cook step for same day service, receive additional cooling and reheating following a cook step, or have no cook step involved. You may refer to Chapter 2 for organizing your menu items or products by Process 1, 2, and 3.

Looking at your menu or food list, you should place each item into the appropriate food preparation process. You may discover that more than one food preparation process is conducted within your operation. You may also need to consult the annexes of this Manual to identify menu items or products that need special consideration.

TABLE 1: PROCESS-SPECIFIC LISTS

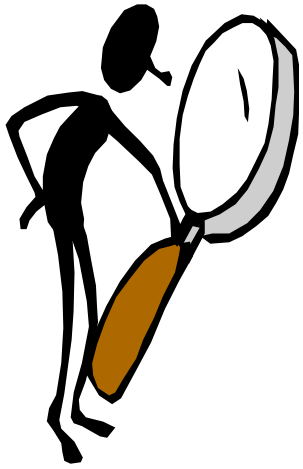
Example menu items or products that belong to each of the three food preparation processes can be found in the following table. Note that the same menu item can appear in more than one category depending on how it is prepared:

PROCESS #1 **Food Preparation with No Cook Step**	**PROCESS #2** **Food Preparation for Same Day Service**	**PROCESS #3** **Complex Food Preparation**
raw meat and seafood (to be cooked by consumer) salad greens fish for raw consumption fresh vegetables oysters or clams served raw tuna salad Caesar salad dressing Cole slaw sliced sandwich meats sliced cheese chicken salad (made from canned chicken)	fried chicken broiled fish fried oysters hamburgers soup du jour hot vegetables cooked eggs	soups gravies sauces large roasts chili taco filling egg rolls chicken salad (made from raw chicken)

PROCEDURAL STEP 3

Conduct a Hazard Analysis

In developing a food safety management system, you should identify the food safety hazards that exist in the flow of food in your operation from receiving to service or sale. By identifying the food safety hazards present in your system, you should then be able to determine the possible control measures that may be implemented to achieve active managerial control of the foodborne illness risk factors leading to out-of-control hazards. Control measures are any actions or activities that can be used to prevent, eliminate, or reduce an identified hazard.



While the hazard analysis in the process approach to HACCP is probably less complicated than in traditional HACCP, this section is not intended to provide all the information you will need to conduct a hazard analysis of your products. For a more in-depth discussion on the hazard analysis process, including questions to ask yourself and a listing of foods, associated hazards, and control measures in retail and food service, you may consult Annex 3 of this Manual. It is also recommended that you consult Annex 2 of this Manual if your establishment serves or sells seafood. In addition, FDA strongly recommends that you consult your health inspector or other food safety professional during this and all other phases of your food safety management system development.

As described in Chapter 2, the specific food safety hazards for each of the products within a particular food preparation process may be varied, but the recommended control measures for each of the products in each process will generally be the same. As you conduct the hazard analysis, you will most likely find that regardless of the specific food safety hazards present in the products in any particular food preparation process, the foods within each of the food preparation processes share common categories of hazards. This is why the control measures you apply to the products in each of the three food preparation processes will generally be the same. Because of this, you may use general categories to designate the types of food safety hazards present in your operation.

For example, in process 2 you may have baked chicken, fried fish, grilled hamburgers, and baked meatloaf that are all cooked and hot held before service. While each of these foods may have unique food safety hazards, they all share general categories of hazards and therefore the control measures that you may implement are basically the same. Vegetative bacteria are controlled through proper cooking, spore-forming or toxin-forming bacteria are controlled through proper hot holding, and fecal-oral route pathogens such as *Shigella*, *Salmonellae*, and viruses are controlled through good

hygienic practices such as proper handwashing, no bare hand contact with ready-to-eat food, and implementation of employee health policies. In addition, pathogens resulting from cross-contamination may be controlled by proper sanitization and storage practices. Other hazard categories and control measures may exist in this example.

The categories listed below are not all-inclusive and there may be overlap between them. You may use different terminology from what is outlined in this Manual. The category names that you use are unimportant as long as you know what hazards are present in your system. Examples of general hazard categories that you may use to fill in your tables are as follows:

- **BIOLOGICAL**

    1. Vegetative bacteria (such as *Salmonella*, *Campylobacter*, *E.coli*, and *Vibrio*)
    2. Spore-forming or toxin-forming bacteria (such as Bacillus cereus, Clostridium perfringens, Clostridium botulinum, and Staphylococcus aureus)
    3. Fecal-oral route pathogens (such as parasites, various bacteria, and viruses)
    4. Viruses (such as Hepatitis A and Noroviruses)
    5. Bacteria, parasites, or viruses from cross-contamination
       [applies to the transfer of disease-causing microorganisms to ready-to-eat food by hands, food-contact surfaces, sponges, cloth towels and utensils that are contaminated with disease-causing microorganisms. Also applies to the transfer of disease-causing microorganisms from raw animal foods with higher cook temperatures (i.e. chicken) to raw animal foods of less or cooking temperatures (i.e. pork)]

- **CHEMICAL**

    6. General chemical contamination (cleaning compounds, sanitizers, allergens, etc.)
    7. Scombroid toxin (histamine production in certain fish) (See Annex 2)
    8. Ciguatera toxin (natural toxin in certain fish) (See Annex 2)

- **PHYSICAL**

    9. General physical hazards such as bone or metal fragments, bandages, jewelry, etc.

Some questions to ask yourself as you evaluate the food safety hazards present in your products include:

- Are there any ingredients or menu items of special concern such as those listed in Annex 2?

- Is this a potentially hazardous food requiring specific temperature controls?

- How will it be served? Immediately? Held on a buffet?

- Does this food have a history of being associated with illnesses?

- Will this require a great deal of preparation, making preparation time, employee health, and bare hand contact with ready-to-eat food a special concern?

- How will employees exhibiting symptoms such as diarrhea or vomiting be handled?

- Are you serving food to a population that is known to be highly susceptible to foodborne illness (e.g., residents of health care facilities, persons in child or adult day care facilities, etc.)?

If you already have a working knowledge of the hazards associated with products in your establishment, you can fulfill the hazard analysis step by identifying the control measures in the *Food Code* that are associated with each operational step in your food preparation processes. You may consult Annex 3 of the FDA *Food Code* to help you in understanding the public health rationale behind the control measures and critical limits.

In the next procedural step, you should determine which of the control measures identified in your hazard analysis are essential to the food's safety, i.e. cooking. You may choose to implement control measures in your HACCP plans at CCPs or through your prerequisite programs.

PROCEDURAL STEP 4

Implement Control Measures in Prerequisite Programs or at CCPs in Your HACCP Plans and Establish Critical Limits

The objective of this procedural step is to implement control measures in your food safety management system to prevent, eliminate, or reduce hazards to acceptable levels. Once control measures have been identified in Procedural Step 3 – Hazard Analysis, you should determine how you will achieve active managerial control. Control may be achieved at Critical Control Points (CCPs) in your HACCP plans or through prerequisite programs.

By definition, a CCP is an operational step at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level. If an operational step is the last step at which control can be applied to prevent or eliminate a hazard or reduce it to an acceptable level, then you should consider controlling it as a CCP. If a step later in the process will control the hazards of concern, that step, rather than the one in question, will most likely be a CCP.

Depending on your operation, control measures may be effectively implemented in your prerequisite programs. For instance, you may decide that cold holding during storage is best controlled through prerequisite programs rather than through your HACCP plans. It is important to consider the flow of food as you make this determination.

The *Food Code* provides specific measurable criteria referred to as critical limits designed to prevent, eliminate, or reduce hazards in foods. The critical limits are based on the best available science and pertain to control measures applied within operational steps. Common examples might be time/temperature standards and no bare hand contact with ready-to-eat food.

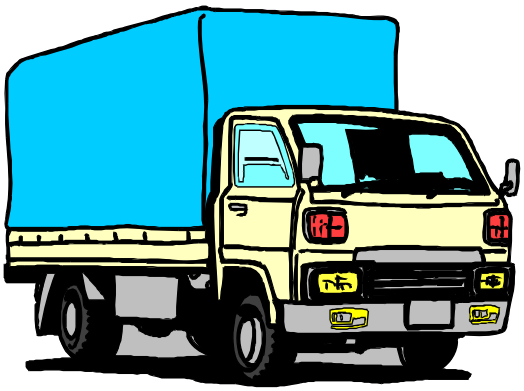
You should make sure that you have established the appropriate critical limits to control the identified hazards. It is recommended that you refer to the most recent version of the *Food Code* or your state, local, or tribal regulations for help with determining the appropriate critical limits for the identified control measures.

COMMON OPERATIONAL STEPS USED IN RETAIL AND FOOD SERVICE

The following information about the common operational steps conducted at retail is provided to assist in your decision-making as you move through the procedural steps presented in this document. Common operational steps conducted at retail include, but are not limited to, receiving, storing, preparing, cooking, cooling, reheating, hot and cold holding, assembly/set-up/packing, serving, and selling.

RECEIVING

Receiving is an important operational step to food safety. At receiving, your main concern is contamination from pathogens and the formation of harmful toxins.



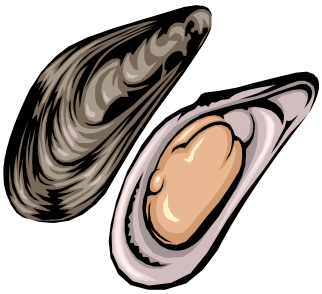
Two recommended control measures of importance during this operational step include –

- Receiving the food at proper temperatures and getting perishable food into cold storage quickly
- Obtaining food, ingredients, and packaging materials from approved sources (suppliers who are regulated and inspected by appropriate regulatory authorities)

Ready-to-eat, potentially hazardous food is a special concern at receiving. Because this food will not be cooked before service, pathogenic bacterial growth could be considered a significant hazard during this step for refrigerated, ready-to-eat foods. Having prerequisite programs in place to control product temperature is generally adequate to control the hazards present at receiving of most of these products. Besides checking the product temperature, you should check the appearance, odor, color, and condition of the packaging.

Seafood, whether ready-to-eat or not, requires special attention during receiving. Federal regulations require processors of seafood and seafood products for interstate distribution to have a HACCP plan. These processors are the only approved sources for seafood sold in interstate commerce; therefore, you may ask your interstate seafood supplier for documentation that the firm has a HACCP plan in place. Processors of seafood and seafood products that are sold or distributed only within a state may or may not be required to have a HACCP plan, depending on the state, local, or tribal regulations.

In order to destroy parasites in certain species of fish intended for raw consumption, either you or the seafood processor should freeze the fish at a given time and temperature. You should ask to see specifications on these species of fish to be sure that they have been frozen to destroy the parasites.



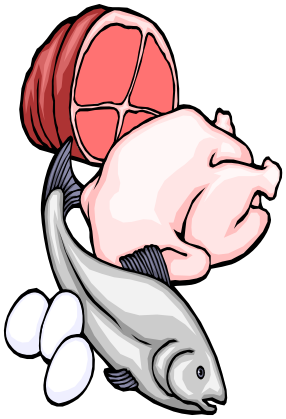
Molluscan shellfish (oysters, clams, mussels, and scallops) that are received raw in the shell or shucked should be purchased from suppliers who are listed on the FDA Interstate Certified Shellfish Shippers' List or on a list maintained by your state shellfish control authority. Shellfish received in the shell should bear a tag (or a label for shucked shellfish) that states the date and location of harvest, in addition to other specific information.

Finfish harvested from certain areas may naturally contain a toxin called ciguatera. Other finfish may develop a toxin after harvest if strict temperature control is not maintained. This toxin is called scombrotoxin (histamine). For finfish, temperature control and approved sources are important at receiving because cooking will not eliminate these toxins. For more information on toxins and parasites in fish, you may refer to Annex 2 of this Manual.

STORAGE

When food is in refrigerated storage, your food safety management system should focus on –

- Maintaining temperature control to limit the growth of pathogenic bacteria that may be present in a ready-to-eat product
- Storing food so that cross-contamination of ready-to-eat food with raw animal foods is prevented



When determining the storage temperature and monitoring frequency of products in cold storage, you may decide to set the temperature lower than what is required by your local regulations. By setting the temperature lower than what is required by your regulations, small upward deviations in temperature that you detect through frequent monitoring can be quickly corrected before bacteria begin to grow. For example, if you are storing potentially hazardous, ready-to-eat foods under refrigeration, you may decide to set a critical limit for the refrigeration units to operate at 38 ºF. This provides a safety cushion that allows you the opportunity to see a trend toward exceeding 41 ºF and to intervene with appropriate corrective actions before bacteria begin to grow to dangerous levels.

Monitoring procedures for ready-to-eat food ideally include internal product temperature checks. You should assess whether it is realistic and practical for you to do this depending on the volume of food you are storing.

You may choose to base your monitoring system on the air temperature of the refrigerated equipment as a prerequisite program. How often you should monitor the air temperature depends on –

- Whether the air temperature of the refrigerator accurately reflects the internal product temperature – (Remember, your food safety refrigeration temperature must be based on the internal product temperature of the food stored within a refrigeration unit, not the ambient air temperature)

- The capacity and use of your refrigeration equipment

- The volume and type of food products stored in your cold storage units

- The prerequisite programs that support monitoring this process

- Shift changes, volume of business, and other operational considerations

Special consideration should be given to the storage of scombroid toxin-forming fish due to the potential formation of histamine. To control histamine formation in scombroid toxin-forming fish, the critical limit temperature of 41 ºF should be managed either through your HACCP plan as a CCP or through your prerequisite programs. Also, your HACCP plan or prerequisite programs should ensure that reduced oxygen packaged smoked fish is maintained at 38 ºF to prevent the outgrowth of *Clostridium botulinum* Type E.

Separating raw foods from ready-to-eat products in your operation's refrigeration and storage facilities can control the potential for cross-contamination. When determining how you will arrange foods in your storage units to prevent cross-contamination, you should consider the flow of food. For example, if chicken and beef are stored side-by-side on a shelf, consider whether or not employee practices will allow the raw chicken to drip onto the beef. Also, you should consider storing ready-to-eat, potentially hazardous food away from the door, in the coolest part of the walk-in cooler. These products will not undergo any further kill step; thus, preventing the growth of spore-forming bacteria is especially important for these products.

PREPARATION

Of all the operational steps, preparation has the greatest variety of activities that should be controlled, monitored, and in some cases, documented. It is impossible to include in this Manual a summary that covers the diversity of menus, employee skills, and facility designs that impact the preparation of food. The preparation step may involve several processes, including thawing, mixing together ingredients, cutting, chopping, slicing, or breading.

At the preparation step, prerequisite programs can be developed to control some hazards and assist in the implementation of a food safety management system that minimizes –

- bacterial growth
- contamination from employees and equipment

Small batch preparation is an important tool for controlling bacterial growth because limiting the amount of food prepared minimizes the time the food is kept at a temperature that allows for growth. Pre-planning the volume of food and the time needed for preparation minimizes the time food is in the temperature danger zone at this operational step.

When thawing frozen foods, maintaining proper product temperature and managing time are the primary controls for minimizing bacterial growth. Procedures should be in place to minimize the potential for microbial, chemical, and physical contamination during thawing.

Use of pre-chilled ingredients to prepare a cold product such as tuna salad may assist you in maintaining temperature control for this process.

Front-line employees will most likely have the greatest need to work with the food. A well-designed and managed personal hygiene program that has been communicated to all employees will minimize the potential for bacterial, parasitic, and viral contamination. It is suggested that your program include instructions to your employees as to when and how to wash their hands. It is also very important to identify and restrict or exclude ill employees from working with food, especially if they have diarrhea, vomiting, fever, or jaundice.

Special consideration should be given to eliminating bare hand contact in the

preparation of ready-to-eat foods. How will you accomplish controlling the hazards presented by hand contact with ready-to-eat foods? Does the time of day, frequency, or duration of the preparation step allow for easy monitoring? You should review your operation to determine whether this operational step will be controlled as a CCP in your HACCP plans or as a prerequisite program.

Procedures should be in place to prevent cross-contamination from utensils and equipment. Designated areas or procedures that separate the preparation of raw foods from ready-to-eat foods minimize the potential for bacterial contamination. Proper cleaning and sanitizing of food-contact surfaces is recommended in this operational step.

COOKING

This operational step only applies to foods listed in Processes #2 and #3. Cooking foods of animal origin is the most effective operational step for reducing or eliminating biological contamination. Cooking to proper temperatures for a specified time will kill most harmful bacteria and parasites. Therefore, frequent monitoring of cooking temperatures is highly recommended.

You should determine the best system to use for ensuring that the proper cooking temperature and time are reached. Checking the internal product temperature is the desirable monitoring method. However, when large volumes of food are cooked, a temperature check of each individual item may not be practical. For instance, a quick service operation may cook several hundred hamburgers during lunch. Since checking the temperature of each hamburger will probably not be reasonable for you to do, you should routinely verify that the specific process and cooking equipment are capable of attaining a final internal product temperature at all locations in or on the cooking equipment.

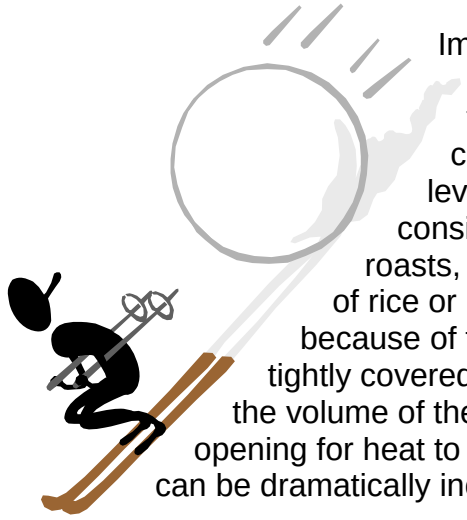
Once a specific process has been shown to work for you, the frequency of record keeping (to be discussed in Procedural Step 7) may be reduced. In these instances, a record keeping system should be established to provide scheduled product temperature checks to ensure that the process is working.

Special consideration should be given to time and temperature when cooking raw animal foods**.** In developing your HACCP plans or prerequisite programs, it is important to understand that the critical limits are product-specific during the cooking step. For example, the safe cooking temperature/time for poultry is 165 ºF for 15 seconds, while 155 ºF for 15 seconds is the safe cooking temperature for ground beef.
To ensure adequate destruction of pathogens by heat, the cooking operational step

should be managed either as a CCP in your HACCP plans or as a prerequisite program and be based upon the same level of safety established by the critical limits in the *Food Code*. Consult the latest edition of the *Food Code* available on the FDA/CFSAN website (http://www.cfsan.fda.gov/~dms/foodcode.html) or your local or state regulations for further guidance.

COOLING

One of the most labor-intensive operational steps is rapidly cooling foods to control bacterial growth. Improper cooling of potentially hazardous foods has been consistently identified as one of the factors contributing to foodborne illness. Foods that have been cooked and held at improper temperatures provide an excellent environment for the growth of spore-forming bacteria. Recontamination of a cooked food item by poor employee practices or cross-contamination from other food products, utensils, and equipment is also a concern at this operational step.



Improperly cooling food can begin a snowball effect that cannot be reversed. Even with proper reheating, toxins released by toxin-producing bacteria after cooking and improper cooling may not be destroyed to levels safe enough for human consumption. Special consideration should be given to large food items such as roasts, turkeys, thick soups, stews, chili, and large containers of rice or refried beans. These foods take a long time to cool because of their mass and volume. If the hot food container is tightly covered, the cooling rate will be further slowed. By reducing the volume of the food in an individual container and leaving an opening for heat to escape by keeping the cover loose, the rate of cooling can be dramatically increased.

Commercial refrigeration equipment is designed to hold cold food at the proper temperature, not cool large masses of food. Some alternatives for cooling foods include:

- Using rapid chill refrigeration equipment designed to cool the food to acceptable temperatures quickly by using increased compressor capacity and high rates of air circulation

- Avoiding the need to cool large masses by preparing smaller batches closer to periods of service

- Stirring hot food while the food container is in an ice water bath

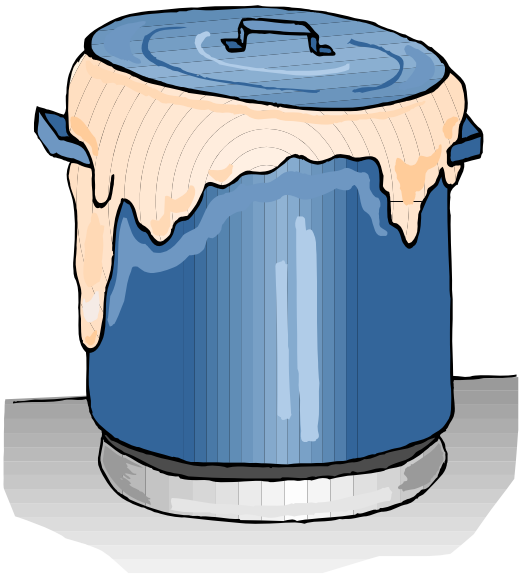
- In soups or stews, redesigning your recipe so that you cook a concentrated base and add enough cold water or ice to make up the volume that you need

- Prechilling ingredients used to make products such as chicken and tuna salad

Whichever cooling method you choose, you should verify that the process works. A record keeping system should be established to provide scheduled product temperature checks to ensure the process is working. If a specific process has been shown to work for you, the frequency of record keeping may be re-evaluated. To control biological hazards, it is recommended that the cooling operational step be managed either as a CCP in your HACCP plans or as a prerequisite program and be based upon the same level of safety established by the critical limits in the *Food Code*.

REHEATING

This operational step applies only to those foods that you listed in Process #3. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides an important control for eliminating some of these organisms. Remember that although proper reheating will kill most organisms of concern, it will not eliminate toxins such as those produced by *Staphylococcus aureus* and *Bacillus cereus* or foodborne viruses.



Special consideration should be given to the time and temperature in the reheating of cooked foods. To control biological hazards, it is recommended that reheating be managed either as a CCP in your HACCP plans or as a prerequisite program and be based upon the same level of safety established by the critical limits in the *Food Code*.

HOLDING (HOT, COLD, OR TIME)

All three processes may involve the holding of foods, i.e. hot and cold holding or use of time alone as public health control. When there is a cooking step to eliminate bacteria, all but the spore-forming bacteria should be destroyed. If cooked food is not held at the proper temperature or, absent temperature control, for the appropriate time, the rapid growth of these spore-forming bacteria is a major concern.

When food is held, cooled, and reheated in a food establishment there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. Harmful bacteria that are introduced into a product that is not held at proper temperature have the opportunity to multiply to large numbers in a short period of time. Once again, management of personal hygiene and the prevention of cross-contamination impact the safety of the food at this operational step.

Keeping food products at 135 ºF or above during hot holding and keeping food products at or below 41 ºF is effective in preventing microbial growth**.** As an alternative to temperature control, the *Food Code* details actions when time alone is used as a control, including a comprehensive monitoring and food marking system to ensure food safety.

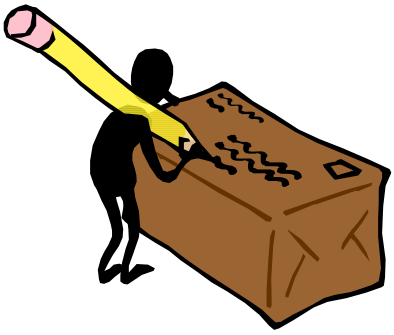
How often you monitor the temperature of foods during hot holding determines what type of corrective action you are able to take when 135 ºF is not met. If the critical limit is not met, your options for corrective action may include evaluating the time the food is out of temperature to determine the likelihood of hazards, and based on that evaluation, reheating or discarding the food. Your frequency of monitoring during this operational step may mean the difference between reheating the food to 165 ºF or discarding it.

When determining the monitoring frequency of cold product temperatures, it is recommended that the interval between temperature checks is established to ensure that hazards are being controlled and time is allowed for an appropriate corrective action. For example, if you are holding potentially hazardous ready-to-eat foods under refrigeration, such as potato salad at a salad bar, you may decide to set a critical limit at 41 ºF or below. You may also want to set a target, or operating limit, less than 41 ºF in order to provide a safety cushion that allows you the opportunity to see a trend toward exceeding 41 ºF and to intervene with appropriate corrective actions.

To control biological hazards, it is recommended that hot or cold holding or use of time alone as a public health control be managed either as a CCP in your HACCP plans or as a prerequisite program and be based upon the same level of safety established by the critical limits in the *Food Code*.

SET UP, ASSEMBLY, AND PACKING

Set up, assembly, and packing are operational steps used by some retail food establishments, including caterers [e.g., restaurant-caterers, interstate conveyance caterers, commissaries, grocery stores (for display cases), schools, nursing homes, hospitals, or food delivery services].



Set up, assembly, and packing may involve wrapping food items, assembling these items onto trays, and packing them into a transportation carrier or display case. An example would be an airline flight kitchen where food entrees are wrapped, assembled, and placed into portable food carts that are taken to a final holding cooler. Hospital kitchens would be another example where patient trays are assembled and placed into carriers for transportation to nursing stations. Food may be placed in bulk containers for transportation to another site where it is served.

Your food safety management system should address the potential for bacterial contamination and growth, bare hand contact with ready-to-eat foods, and proper handwashing.

SERVING/SELLING

This is the final operational step before the food reaches the customer. When employees work with food and food-contact surfaces, they can easily spread bacteria parasites, and viruses. Managing personal hygiene is important to controlling these hazards**.** It is recommended that a management program for employee personal hygiene be implemented that addresses the following:

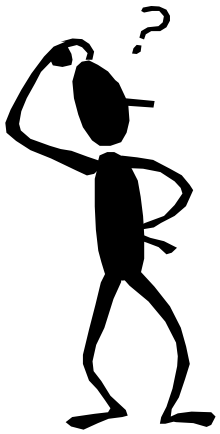
- Procedures for proper handwashing
- The appropriate use of gloves and dispensing utensils
- Control of bare hand contact with ready-to-eat foods
- Exclusion and restriction of ill employees

Specific procedures are recommended for customer self-service displays such as salad bars and buffet lines to protect food from contamination. Special consideration should be given to preventing cross-contamination from soiled utensils and equipment and minimizing contamination from the customer.

PROCEDURAL STEP 5

Establish Monitoring Procedures

Monitoring is observing or measuring specific operational steps in the food process to determine if your critical limits are being met. This activity is recommended to make sure your critical control points are under control. Monitoring will identify when there is a loss of control or a trend toward a loss of control so that corrective actions (discussed in Procedural Step 6) can be taken.



Consideration should be given to determining answers to the following questions:

- What will you monitor?
- How will you monitor?
- When and how often will you monitor?
- Who will be responsible for monitoring?

In your food safety management system, certain processes have been identified as requiring active managerial control. What you are going to monitor depends on the critical limits you have established. Final temperature and time measurements are very important, and you should determine how you will effectively monitor the critical limits for them.

Determining the appropriate means for monitoring is an important factor in developing your food safety management system. If equipment is selected to monitor a specific CCP, you should ensure that it is accurate and routinely calibrated to ensure critical limits are met. The equipment you choose should also be appropriate for the monitoring that is being done. For example, a thermocouple with a thin probe is the most appropriate tool for measuring the final product temperature of thin hamburger patties.

When deciding how often you will monitor, you should ensure that the monitoring interval will be reliable enough to ensure hazards are being controlled. Your procedure for monitoring should be simple and easy to follow.

Individuals chosen to be responsible for a monitoring activity may be a manager, line supervisor, or other reliable employee. FDA recommends that employees be given the training and equipment necessary to properly perform the monitoring activities.

PROCEDURAL STEP 6

Develop Corrective Actions

You should decide what type of corrective action to take if a critical limit is not met by asking yourself the following questions:

- What measures do you expect employees to take to correct the problem?
- Do your employees understand the corrective action?
- Can the corrective action be easily implemented?
- Are different options needed for the appropriate corrective actions depending on the process and monitoring frequency?
- How will these corrective actions be documented and communicated to management so the system can be modified to prevent the problem from occurring again?

Whenever a critical limit is not met, a corrective action must be carried out immediately. A corrective action may be simply continuing to heat food to the required temperature. Other corrective actions may be more complicated, such as rejecting a shipment of raw oysters that does not have the required tags or segregating and holding a product until an evaluation is done.

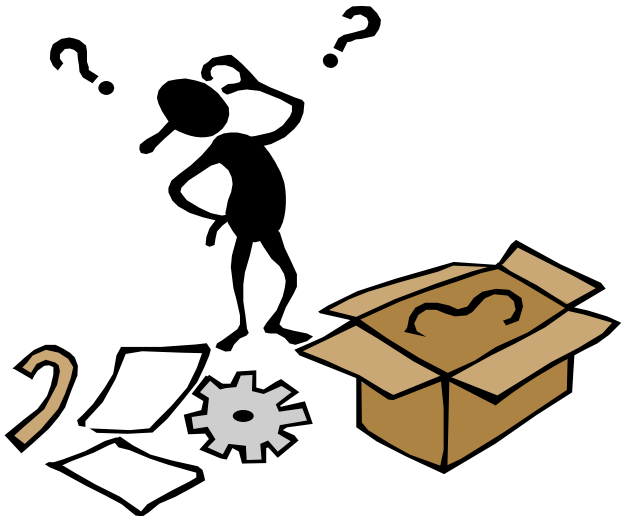
In the event that a corrective action is taken, you should review and modify your food safety management system, if necessary. Even with the best of systems, errors occur during food storage and preparation. A food safety management system based on the HACCP principles is designed to detect errors and correct them before a hazard occurs. A benefit to both you and your regulator is the ability to show that immediate corrective action was taken to ensure that no unsafe food was served or sold to the consumer. It is important to communicate to management all corrective actions in writing or electronically.

PROCEDURAL STEP 7

Conduct Ongoing Verification

Because HACCP is a system to maintain continuous control of food safety practices, implementation of the system should to be verified. Verification is simply making sure that you are performing the activities as described in your food safety management system.

Routine monitoring should not be confused with verification. Verification is making sure that all the activities carried out in the implementation of your food safety management system are being done properly and at the required frequency. Monitoring is one of the many activities that needs to be verified. This is a vital step in ensuring that you have established active managerial control of identified hazards.



Verification should be conducted by someone other than the person who is directly responsible for performing the activities specified in the food safety management system. That person might be a manager, supervisor, designated individual, food safety professional, or even your health inspector. If involved in the verification process, your inspector can offer suggestions for how you can strengthen your food safety management system.

Verification activities are conducted frequently, such as daily, weekly, monthly, etc., and may include –

- Observing that person(s) are carrying out the critical procedures correctly
- Observing the person doing the monitoring and determining whether monitoring is being done as planned
- Reviewing the monitoring records to determine if they are completed accurately and consistently
- Determining whether the records show that the frequency of monitoring stated in the plan is being followed

- Ensuring that corrective action was taken when the person monitoring found and recorded that the critical limit was not met

- Confirming that all equipment, including equipment used for monitoring, was operated, maintained and calibrated properly

Frequency of Verification

Verification should occur at a frequency that can ensure the food safety management system is being followed **continuously** to –

- Prevent unsafe food from reaching the consumer

- Take corrective action without loss of product

- Confirm that prescribed personnel practices are followed

- Ensure that personnel have the tools for proper personal hygiene and sanitary practices (e.g., handwashing facilities, sanitizing equipment, cleaning supplies, temperature measuring devices, etc.)

- Comply with the established control procedures

Verification - Examples

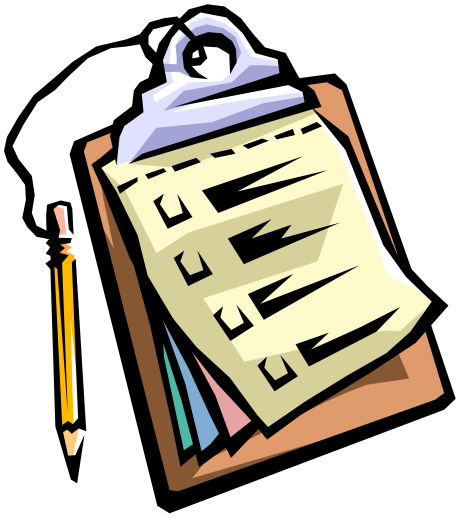
Listed below are four examples of verification procedures:

- Receiving logs: The manager reviews temperature logs of refrigerated products at various intervals, such as on a weekly basis, or even daily if –

  - Receiving a high volume
  - Products received include scombroid toxin-forming fish such as fresh tuna.

- Cooling logs: The kitchen manager checks that the "cooling log" is maintained for leftover foods on a weekly basis. The kitchen manager checks to see that the time the food is placed in the cooler, its initial temperature, and measurements of the time and temperature as the food is cooled are recorded and initialed on the log sheet.

- Handwashing and no bare hand contact logs: Nightly, the closing manager checks to see if the logs maintained at the handwashing sinks and preparation areas are complete.



- Cooking: The manager checks the time/temperature monitoring records for cooking nightly to see that the required number of temperature measurements were taken during each shift.

PROCEDURAL STEP 8

Keep Records

As the manager of your operation, you may have several duties to perform in addition to making sure that the activities in your food safety management system are being performed at the proper frequency and with the proper method. Documenting these activities provides one mechanism for verifying that the activities were properly completed.

While record keeping is voluntary in most retail and food service operations, maintaining documentation of the activities in your food safety management system may be vital to its success. Remember that by keeping records you are going above and beyond what your regulations normally require. Records provide documentation that appropriate corrective actions were taken when critical limits were not met. In the event your establishment is implicated in a foodborne illness, documentation of activities related to monitoring and corrective actions can provide proof that reasonable care was exercised in the operation of your establishment. Records may also show that on-going verification was conducted on the food safety management system. In many cases, your records can serve a dual purpose of ensuring quality and food safety.

In order to develop the most effective record keeping system for your operation, you should determine what documented information will assist you in managing the control of food safety hazards. A record keeping system can be simple and needs to be designed to meet the needs of your individual establishment. You do not necessarily need to develop new records to document the actions in the system.

Some recorded information like shellfish tags should already be part of your food safety management system, and an additional record may not be needed. Your record keeping system may use existing paperwork such as delivery invoices for documenting product temperature. Many retail and food service establishments have implemented comprehensive record keeping systems without having to generate a mountain of paperwork

Employees are an important source for developing simple and effective record keeping procedures. You should ask employees how they are currently monitoring CCPs or prerequisite programs and discuss with them the types of corrective actions they are currently taking when a critical limit is not met. Managers are responsible for designing the system, but effective day-to-day implementation involves every employee.

The simplest record keeping system that lends itself to integration into existing operations is always best. A simple, yet effective, system is easier to use and communicate to your employees.

Record keeping systems designed to document process rather than product information may be more useful in a retail and food service establishment, especially if you frequently change menu items or products. Accurately documenting processes like cooking, cooling, and reheating provides a mechanism for ensuring that you have active managerial control of risk factors.

There are at least 5 types of records that may be maintained to support your food safety management system:

- Records documenting the activities related to the prerequisite programs
- Monitoring records
- Corrective action records
- Verification and validation records (discussed under Procedural Step 9)
- Calibration records

Once a specific process has been shown to work for you, such as an ice bath method for cooling certain foods, the frequency of record keeping may be modified. This approach is extremely effective for labor-intensive processes related to –

- Cooking large volumes of food where a temperature check of each individual item is impractical

- Implementing a verified process that will allow employees to complete the procedure in a scheduled workday

- Cooling foods or leftovers at the end of the business day

- Maintaining cold holding temperatures of ready-to-eat, potentially hazardous foods in walk-in refrigeration units

Special Considerations Regarding Records

You are encouraged to periodically obtain feedback from your regulatory authority regarding how well your system is working. You can invite your regulatory authority to review or verify your voluntarily-implemented food safety management system. This allows them the opportunity to offer suggestions for problems that they find in the operation of your system, including discrepancies with the monitoring and record keeping procedures.

Remember that the maintenance of records is required in the *Food Code* only in a limited number of cases. When your food safety management system is voluntary, their review of your system is by invitation only and they can only document violations that they *observe* as they would during routine inspections. Records generated in support of a voluntary food safety management systems may not to be used to verify compliance with your regulations unless the records are specifically required by your regulations.

An example of when records may be used to verify compliance with your regulations would be the maintenance of shellstock tags. If there is a requirement in your regulations that shellstock tags be maintained in chronological order for at least 90 days, a health inspector may verify this requirement using your records.

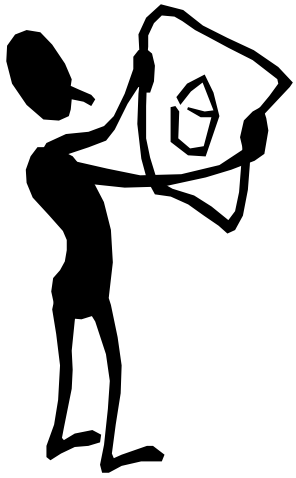
In contrast, if your health inspector finds documented cases of inadequately cooked or hot held foods being sold to consumers, he or she cannot take regulatory action against you based on the documentation. Documentation of hot holding and cooking, like most processes in your regulations, is probably not required. The fact that you are keeping records of these processes means that you are probably going above and beyond what is required by your regulations. Of course, your health inspector may point out discrepancies and offer recommendations to you in hopes of preventing the problems from happening again.

Of course, if during the review of your system evidence is found that a product still in circulation poses a serious health threat to the public, the health inspector may initiate an appropriate regulatory investigation as dictated by your regulatory agency. If it is known by your health inspector or you that a product still on the market poses a health threat to consumers, both of you should play your respective roles to remove the product immediately. This may involve voluntary recall of the suspected products.

PROCEDURAL STEP 9

Conduct Periodic Validation

Once your food safety management system is established, you should periodically review it to determine whether the food safety hazards are controlled when the system is implemented properly. In this Manual, this review is known as validation.



Changes in suppliers, products, or preparation procedures may prompt a revalidation of your food safety management system. A small change could result in a drastically different outcome from what you expect.

You may benefit from both internal (quality assurance) and external validations that may involve assistance from the regulatory authority or other consultants.

Validation is conducted less frequently (e.g., yearly) than on-going verification. It is a review or audit of the plan to determine if –

- Any new product/processes/menu items have been added to the menu
- Suppliers, customers, equipment, or facilities have changed
- Prerequisite programs are current and implemented
- Worksheets are still current
- CCPs are still valid, or if new CCPs are needed
- Critical limits are set realistically and are adequate to control the hazard (e.g., the time needed to cook a turkey to meet the *Food Code* internal temperature requirement)
- Monitoring equipment has been calibrated as planned

Validation helps you to –

- Improve the system and HACCP plan by identifying weaknesses
- Eliminate unnecessary or ineffective controls
- Determine if the HACCP plan needs to be modified or updated

You can use the Validation Worksheet that follows to assist with the validation process.

Validation Worksheet

Name of person responsible for validation: _____

Title: _____

Frequency at which the validation is done: _____

Reason, other than frequency, for doing the validation: _____

Date of last validation: _____

The length of time this record is kept on file (i.e. # months or years): _____

1.

(a) **Has a new product, process, or menu item been added since the last validation?**

No ___
Yes ___
Go to Question #1b

(b) **Has the supplier, customer, equipment, or facility changed since the last validation?**

Yes ___
No ___
Go to question #2

2. **Are the existing worksheets accurate and current?**

No ___ ➔ **Worksheet information updated:** **Date:** _____ **Name:** _____
Yes ___
Go to Question #3

3. **Are the identified hazards accurate and current?**

No ___ ➔ **Hazard analysis updated:** **Date:** _____ **Name:** _____
Yes ___
Go to Question #4

4. **Are the existing CCPs correctly identified?**

No ___ ➔ **CCPs updated:** **Date:** _____ **Name:** _____
Yes ___
Go to Question #5

5.	**Are the existing critical limits appropriate to control each hazard?**	**No ___ ➔ Yes ___ Go to Question #6**	**CLs updated:**	**Date: _____**	**Name: _____**
6.	**Do the existing monitoring procedures ensure that the critical limits are met?**	**No ___ ➔ Yes ___ Go to Question #7**	**Monitoring procedures updated:**	**Date: _____**	**Name: _____**
7.	**Do existing corrective actions ensure that no injurious food is served or purchased?**	**No ___ ➔ Yes ___ Go to Question #8**	**Corrective Actions updated:**	**Date: _____**	**Name: _____**
8.	**Do the existing on-going verification procedures ensure that the food safety system is adequate to control hazards and is consistently followed?**	**No ___ ➔ Yes ___ Go to Question #9**	**On-going verification procedures updated:**	**Date: _____**	**Name: _____**
9.	**Does the existing record keeping system provide adequate documentation that the critical limits are met and corrective actions are taken when needed?**	**No ___ ➔ Yes ___ Go to Question #10**	**Record keeping procedures updated:**	**Date: _____**	**Name: _____**
10.	**Are the existing prerequisite programs current?**	**No ___ ➔ Yes ___**	**Prerequisite Programs updated:**	**Date: _____**	**Name: _____**

The validation procedure is now complete. The next validation is due _____.

The changes made to the food safety management system were conveyed to the line supervisor or front-line employees on _____.

Completed by: **Name** _____

Title _____

Date _____

CONCLUSION

Whether you used this manual to build a new food safety management system for your operation or merely to enhance the one you already have in place, congratulations! You are taking proactive steps to improve the safety of foods prepared and sold in your establishment. Remember that if you have any questions or concerns, you should consult your regulatory authority or other food safety professional. They will be happy to work with you to accomplish our common goal of delivering safe, quality food to consumers.

Glossary

The definitions cited in Chapter 1 of the latest edition of the FDA *Food Code* should be used to supplement this Glossary. In some cases, this Glossary condenses those definitions for the purposes of this particular document.

ACCEPTABLE LEVEL means the presence of a food safety hazard at levels low enough not to cause an illness or injury.

APPROVED SOURCE means an acceptable supplier to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

ACTIVE MANAGERIAL CONTROL means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors.

BACTERIA means single-cell microorganisms without distinct nuclei or organized cell structures.

CCP means Critical Control Point.

CONTAMINATION means the unintended presence in food of potentially harmful substances, including microorganisms, chemicals, and physical objects.

CONTROL MEASURE means any action or activity that can be used to prevent, eliminate or reduce an identified hazard. Control measures determined to be essential for food safety are applied at critical control points in the flow of food.

CORRECTIVE ACTION means an activity that is taken by a person whenever a critical limit is not met.

CRITICAL CONTROL POINT (CCP) means an operational step in a food preparation process at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level.

CRITICAL LIMIT means one or more prescribed parameters that must be met to ensure that a CCP effectively controls a hazard.

CROSS-CONTAMINATION means the transfer of harmful substances or disease-causing microorganisms to food by hands, food-contact surfaces, sponges, cloth towels and utensils that touch raw food, are not cleaned, and then touch ready-to-eat foods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.

DEVIATION means the failure to meet a required critical limit for a critical control point.

DANGER ZONE means the temperature range between 5 ºC (41 ºF) and 57 ºC (135 ºF) that favors the growth of pathogenic microorganisms.

EXCLUDE means to prevent a person from working as a food employee or entering a food establishment except for those areas open to the general public.

FISH means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such life is intended for human consumption; and

includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.

FOOD means raw, cooked, or processed edible substance, ice, beverage, chewing gum, or ingredient used or intended for use or for sale in whole or in part for human consumption.

FOOD ESTABLISHMENT means an operation at the retail or food service level, i.e., that serves or offers food directly to the consumer and that, in some cases, includes a production, storage, or distributing operation that supplies the direct-to-consumer operation. Refer to Chapter 1, Defining Retail Food and Food Service Industries, for examples.

FOOD PREPARATION PROCESS means a series of operational steps conducted to produce a food ready to be consumed.

FOODBORNE ILLNESS means sickness resulting from the consumption of foods or beverages contaminated with disease-causing microorganisms, chemicals, or other harmful substances.

FOODBORNE OUTBREAK means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

HACCP means Hazard Analysis and Critical Control Point.

HACCP PLAN means, for the purposes of this document, a written document that is based on the principles of HACCP and describes the procedures to be followed to ensure the control of a specific process or procedure.

HACCP SYSTEM means the result of implementing the HACCP principles in an operation that has foundational comprehensive, prerequisite programs in place. A HACCP system includes the HACCP plan and all prerequisite programs.

HAZARD means a biological, physical, or chemical property that may cause a food to be unsafe for human consumption.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) means a prevention-based food safety system that identifies and monitors specific food safety hazards that can adversely affect the safety of food products.

INTERNAL TEMPERATURE means the temperature of the internal portion of a food product.

MEAT means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals.

MICROORGANISM means a form of life that can be seen only with a microscope; including bacteria, viruses, yeast, and single-celled animals.

MOLLUSCAN SHELLFISH means any edible species of raw fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

MONITORING means the act of observing and making measurements to help determine if critical limits are being met and maintained.

NATIONAL SHELLFISH SANITATION PROGRAM (NSSP) means the voluntary system by which regulatory authorities for shellfish harvesting waters and shellfish processing and transportation and the shellfish industry implement specified controls to ensure that raw and frozen shellfish are safe for human consumption.

NSSP means National Shellfish Sanitation Program.

OPERATIONAL STEP means an activity or stage in the flow of food through a food establishment, such as receiving, storage, preparation, cooking, etc**.**

PARASITE means an organism that lives on or in another, usually larger, host organism in a way that harms or is of no advantage to the host.

PATHOGEN means a microorganism (bacteria, parasites, viruses, or fungi) that causes disease in humans.

PERSONAL HYGIENE means individual cleanliness and habits.

pH means the measure of the acidity of a product.

POTENTIALLY HAZARDOUS FOOD:

means a food that is natural or synthetic and that requires temperature control because it is capable of supporting:

- the rapid and progressive growth of infectious or toxigenic microorganisms,
- the growth and toxin production of *Clostridium botulinum*, or
- in raw shell eggs, the growth of *Salmonella* Enteritidis; and

Includes foods of animal origin that are raw or heat-treated; foods of plant origin that are heat-treated or consists of raw seed sprouts, cut melons, and garlic in oil mixtures that are not acidified or otherwise modified at a processing plant in a way that results in mixtures that do not support growth of pathogenic microorganisms as described above.

PREREQUISITE PROGRAMS means procedures, including Standard Operating Procedures (SOPs), that address basic operational and sanitation conditions in an establishment.

PROCEDURAL STEP means an individual activity in applying this Manual to a food establishment's operations.

PROCESS APPROACH means a method of categorizing food operations into one of three categories:

- Process 1: Food preparation with no cook step wherein ready-to-eat food is received, stored, prepared, held and served;

- Process 2: Food preparation for same day service wherein food is received, stored, prepared, cooked, held and served; or

- Process 3: Complex food preparation wherein food is received, stored, prepared, cooked, cooled, reheated, hot held, and served.

READY-TO-EAT (RTE) FOOD means:

- raw animal foods that have been properly cooked;
- fish intended for raw consumption that has been frozen to destroy parasites;
- raw fruits and vegetables that are washed;
- fruits and vegetables that are cooked for hot holding;
- plant food for which further washing, cooking, or other processing is not required for food safety, and from which rinds, peels, husks, or shells, if naturally present, are removed;
- substances derived from plants such as spices, seasonings, and sugar; a bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;
- dry, fermented sausages, such as dry salami or pepperoni;
- salt-cured meat and poultry products, such as prosciutto ham, country-cured ham, and Parma ham; and
- dried meat and poultry products, such as jerky or beef sticks; and low acid foods that have been thermally processed and packaged in hermetically sealed containers.

RECORD means a documentation of monitoring observations and verification activities.

REGULATORY AUTHORITY means a federal, state, local, or tribal enforcement body or authorized representative having jurisdiction over the food establishment.

RESTRICT means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, and unwrapped single-service or single-use articles.

RISK FACTOR means one of the broad categories of contributing factors to foodborne illness outbreaks, as identified in the Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, that directly relates to foodborne safety concerns within retail and food service establishments. The factors are Food from Unsafe Sources, Inadequate Cooking Temperatures, Improper Holding Temperatures, Contaminated Equipment, and Poor Personal Hygiene.

SEVERITY means the seriousness of the effect(s) of a hazard.

SOP means Standard Operating Procedure.

SHELLFISH means bivalve molluscan shellfish.

SPORE means a very tough, dormant form of certain bacterial cells that is very resistant to desiccation, heat, and a variety of chemical and radiation treatments that are otherwise lethal to vegetative cells.

SPORE-FORMER means a bacterium capable of producing spores under adverse conditions.

STANDARD OPERATING PROCEDURE (SOP) means a written method of controlling a practice in accordance with predetermined specifications to obtain a desired outcome.

TEMPERATURE MEASURING DEVICE means a thermometer, thermocouple, thermistor, or other device for measuring the temperature of food, air, or water.

TOXIGENIC MICROORGANISMS means pathogenic bacteria that cause foodborne illness in humans due to the ingestion of poisonous toxins produced in food.

VALIDATION means 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.

VEGETATIVE CELL means a bacterial cell which is capable of actively growing.

VERIFICATION means, for the purpose of this document, ensuring that monitoring and other functions of a HACCP plan are being properly implemented.

VIRUS means a submicroscopic parasite consisting of nucleic acid (DNA or RNA) surrounded by a protein coat, and sometimes also encased in a lipid and glycoprotein envelope. Viruses are completely dependent on a living host cell to survive and multiply, and therefore can not multiply in or on food.

WATER ACTIVITY (A_w) means the quotient of the water vapor pressure of the substance, divided by the vapor pressure of pure water at the same temperature. Generally speaking, it is the amount of water available in the product to allow bacteria to live and grow.

Annex 1 - Resources and References

The following is a partial list of references and sources of information that may be helpful in developing a food safety management system in your establishment. Many other references that address specific foods are listed in the FDA *Food Code*, Annex 2. This list is not intended to be all-inclusive or exclusive and the listing of a material that is not published by the federal government does not imply or convey FDA endorsement of that material.

AGENCIES

United States Food and Drug Administration

- **Center for Food Safety and Applied Nutrition, Retail Food Protection Team**

U.S. Food and Drug Administration
FDA, HFS-627
5100 Paint Branch Parkway
College Park, MD 20740-3835

- **Center for Food Safety and Applied Nutrition, Office of Compliance**

Dr. John E. Kvenberg, Deputy Director, OC
U.S. Food and Drug Administration
HFS-600
5100 Paint Branch Parkway
College Park, MD 20740-3835

- **Regional Field Offices (Regional Retail Food Specialists)**

Northeast (Maine, New Hampshire, Massachusetts, Vermont, Rhode Island, Connecticut, and New York):

158-15 Liberty Avenue, HFR-NE4
Jamaica, NY 11433-1034
(718) 662-5621
FAX (718) 662-5434

One Montvale Avenue, HFR-NE250
Stoneham, MA 02180-3542
(781) 596-7700
FAX (781) 596-7896

Central - Mid Atlantic (New Jersey, Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, Kentucky, and Ohio):

101 West Broad Street
Suite 400
Falls Church, VA 22046
(703) 235-8440 ext. 502

Central – Mid West (Illinois, Indiana, Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin):

20 North Michigan Ave., Suite 50
HFR-MW15
Chicago, IL 60602-4811
(312) 353-9400
FAX (312) 886-1682

240 Hennepin Avenue
Minneapolis, MN 55401
(612) 334-4100 ext. 115
FAX (612) 334-4134

Southeast (Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Puerto Rico, Tennessee, and Virgin Islands):

60 – 8th Street, N.E.
HFR-SE13
Atlanta, GA 30309-3959
(404) 253-1200 ext. 1265, 1267, 1268, 1273
FAX (404) 253-1207

Southwest (Arkansas, Oklahoma, Texas, Colorado, New Mexico, Wyoming, Utah, Missouri, Kansas, Iowa, and Nebraska):

4040 N. Central Expressway, Suite 900
HFR-SW16
Dallas, TX 75204
(214) 253-4948, 4947, 4945 FAX (214) 253-4960
11510 W. 8th Street, HFR-SW36

Lenexa, KS 66285-5905
(913) 752-2401 FAX (913) 752-2487

Building 20, Denver Federal Center
P.O. Box 25087
Denver, CO 80225-0087
(303) 236-3026
FAX (303) 236-3551

Pacific (Alaska, Arizona, American Samoa, California, Hawaii, Guam, Nevada, Idaho, Oregon, Washington, and Montana):

Office of Regional Director - Pacific Region
Oakland Federal Bldg., HFR-PA16
1301 Clay Street, Suite 1180N
Oakland, CA 94612-5217
(510) 637-3960 ext. 27
FAX (510) 637-3976

51 West Third Street
Tempe, AZ 85281
(480) 829-7396 ext. 35
FAX (480) 829-7677

9780 SW Nimbus Avenue
Beaverton, OR 97008-7163
(503) 671-9711 ext. 16
(503) 671-9445

- **Division of Human Resource Development, State Training Team.**

15000 Crabbs Branch Rd. HFC-60
Rockville, MD 20855
(301) 594-0959
FAX (301) 594-1966

United States Department of Agriculture

- **Food Safety and Inspection Service**

Office of the Director
USDA FSIS PPID/HACCP
Room 6912, Suite 6900E
1099 - 14th Street, N.W.
Washington, DC 20250-3700
(202) 501-7319 FAX (202) 501-7639

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FDA PUBLICATIONS AND FEDERAL REGULATIONS

FDA Food Code, current edition, may be purchased from the U.S. Department of Commerce, National Technical Information Service, via telephone: (703) 487-4650 or electronically via the FDA website: http://www.cfsan.fda.gov/~dms/foodcode.html

Fish and Fishery Products - Code of Federal Regulations, Title 21, Part 123 Fish and Fishery Products.

Fish and Fishery Products Hazards and Controls Guide, Third Edition, June 2001. Food and Drug Administration, Washington, D.C. May be purchased from:

National Technical Information Service
U.S. Department of Commerce
703-487-4650.

The **Fish and Fishery Products Hazards and Controls Guide** is also available electronically at http://www.cfsan.fda.gov/~comm/haccpsea.html

Single copies may be obtained as long as supplies last from FDA district offices and from:

U.S. Food and Drug Administration
Office of Seafood
5100 Paint Branch Parkway
College Park, MD 20740-3835

National Shellfish Sanitation Program Model Ordinance for Molluscan Shellfish, available on the FDA/CFSAN website at: http://www.cfsan.fda.gov/~ear/nsspotoc.html or may be purchased from:

National Technical Information Service
U.S. Department of Commerce
703-487-4650.

Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors, available on the FDA/

CFSAN website at:
http://www.cfsan.fda.gov/~dms/retrsk.html

FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004), available on the FDA/CFSAN website at:
http://www.cfsan.fda.gov/~dms/retrsk2.html

Annex 2 – Seafood References

This Annex is provided to assist those segments of the retail and food service industry that deal with seafood. It is suggested that the tables that follow be used during the hazard analysis procedural step.

Table 1. Natural Toxins[1] in Seafood

Natural Toxins	Type of fish (species)	Control
Paralytic Shellfish Poisoning (PSP)	Molluscan Shellfish N.E. and N.W. coastal regions of N. America	NSSP approved waters (tags)[2] (FDA ICSSL listing)
Neurotoxic Shellfish Poisoning (NSP)	Molluscan Shellfish harvested along coast of Gulf of Mexico	NSSP approved waters (tags)[2] (FDA ICSSL listing)
Diarrhetic Shellfish Poisoning (DSP)	Molluscan Shellfish	NSSP approved waters (tags)[2] (FDA ICSSL listing)
Amnesic Shellfish Poisoning (ASP)	Molluscan Shellfish N.E. & N.W. coasts of N. America	NSSP approved waters (tags)[2] (FDA ICSSL listing)
Ciguatera Fish Poisoning (CFP)	fin fish from extreme S.E. U.S., Hawaii, Subtropical and Tropical areas: barracuda amberjack horse-eye jack black jack other larger species of jack king mackerel large groupers large snappers	Purchase from approved sources: • get fish from areas that are not subject of an adverse advisory, or • get fish from a reef area known to be monitored for toxicity and not covered by an adverse advisory.
Gempylotoxin, a strong purgative oil (can cause severe diarrhea)	Escolar	FDA recommendation: Escolar should not be marketed in interstate commerce
Etrodotoxin	Puffer Fish or Fugu, usually from Indo-Pacific ocean, however some noted from Atlantic Ocean, Gulf of Mexico and Gulf of California	Illegal to import or receive (exemption: an agreement with one N.Y. importer)

[1] Fish and Fishery Products Hazards and Controls Guide, Third Edition, June 2001
[2]The tags must contain a unique state issued "certification number" specific for each certified dealer. If the firm is engaged in interstate commerce, this number appears in FDA's Interstate Certified Shellfish Shippers List.

Table 2. Fish Considered to be Scombrotoxin-Forming Species[1]

Toxin Formation	Species - Market Names	Control
Scombrotoxin formation as a result of time/temperature abuse	Most scombroid poisonings from tuna, mahi-mahi and bluefish. Other species are: Amberjack or yellowtail Anchovy Bluefish Bonito Escolar or Snake Mackerel Gemfish Herring (not River herring) Jack Jobfish Kahawai Mackerel (not Atka) Mahi-Mahi Marlin Pilchard or Sardine Sardine Saury Shad & roe Shad, Gizzard Snapper (Pristipomoides ssp) Sprat or Bristling Trevally Tuna Wahoo	Buy from approved federally inspected suppliers. They are required to receive, hold, and process using a HACCP system. Check for an adequate quantity of ice or other cooling media. If not, a federally inspected supplier or directly from a fishing boat, check for the following at receipt: - an adequate quantity of ice or other cooling media - the time the fish were caught (from the vessel or supplier) - See * information below

[1] Fish and Fishery Products Hazards and Controls Guide, Third Edition, June 2001

* FDA Recommended HACCP Controls for Histamine – Quick reference

Secondary Processor (Controls at receipt)

Transport records (< 40 ºF throughout transit)	OR	Adequate Ice/cooling media surrounding product at delivery

Processing/ Storage

Fresh (not previously frozen)		Previously frozen	
≤ 4 hrs @ > 40 ºF if any exposure is > 70 ºF	≤ 8 hrs @ > 40 ºF if NO exposure is > 70 ºF	≤ 12 hrs @ > 40 ºF if any exposure is > 70 ºF	≤ 24 hrs @ > 40 ºF if NO exposure is > 70 ºF

Table 3. Common Parasites in Seafood[1]

Parasites[2]	Type of fish/species likely to be used in menu items that will not be cooked		Control
Nematodes or roundworm Cestodes or tapeworms Trematodes or flukes	Sea bass Capelin & roe Cod Flounder - Dab - Fluke Grouper Halibut Herring Jack Jobfish Kahawai Mackerel Monkfish Mullet	Chilean Sea Bass Ocean Perch Plaice Pollock Rockfish Sablefish Salmon & roe (aquacultured and wild) Seatrout Sole Sprat/Bristling Trout/steelhead/ rainbow Tuna, small Turbot Wolfish	Purchase from a processor, require the raw fish to have been: • Frozen and stored at -4 ºF (-20 ºC) or below for 7 days; or • Frozen at -31 ºF (-35 ºC) or below and stored at -31 ºF (-35 ºC) for 15 hours; or • Frozen at -31 ºF (-35 ºC) or below until solid and stored at -4 ºF (-20 ºC) for 24 hrs. Freezing can be done in your operation if it is done in accordance with the Food Code, Chapter 3.

[1] Fish and Fishery Products Hazards and Controls Guide, Third Edition, June 2001

[2] Some food products that have been implicated in human parasitic infection are:

ceviche	salmon roe	green herring	undercooked grilled fish
lomi lomi	sashimi	drunken crabs	
poisson cru	sushi	cold smoke fish	

Annex 3 – Hazard Analysis

This Annex provides guidance for determining food safety hazards in foods and/or food preparation processes at retail. Although the hazard analysis has been kept general for the purposes of developing your food safety management systems, it is still recommended that you consult with your regulatory authority or other food safety professional when conducting this procedural step.

HOW DO YOU CONDUCT A HAZARD ANALYSIS?

The purpose of hazard analysis is to develop a list of food safety hazards that are reasonably likely to cause illness or injury if not effectively controlled. The process of conducting a hazard analysis involves two stages:

1. Hazard Identification
2. Hazard Evaluation

Hazard identification can be thought of as a brain storming session. This stage focuses on identifying the food safety hazards that might be present in the food given the food preparation process used, the handling of the food, the facility, and general characteristics of the food itself. During this stage, a review is made of the ingredients used in the product, the activities conducted at each step in the process, the equipment used, the final product and its method of storage and distribution, as well as the intended use and consumers of the product. Based on this review, a list of potential biological, chemical, or physical hazards is made at each stage in the food preparation process.

In stage two, the hazard evaluation, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. The purpose of this stage is to determine which of the potential hazards listed in stage one of the hazard analysis warrant control in the HACCP plan. Severity is the seriousness of the consequences of exposure to the hazard. Considerations made when determining the severity of a hazard include understanding the impact of the medical condition caused by the illness, as well as the magnitude and duration of the illness or injury. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. Hazards that are not reasonably likely to occur are not considered in a HACCP plan. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage, and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled.

Upon completion of the hazard analysis, a list of significant hazards that must be considered in the HACCP plan is made, along with any measure(s) that can be used to

control the hazards. These measures, called control measures, are actions or activities that can be used to prevent, eliminate, or reduce a hazard. Some control measures are not essential to food safety, while others are.

Control measures essential to food safety like proper cooking, cooling, and refrigeration of ready-to-eat, potentially hazardous foods are applied at critical control points (CCPs) in the HACCP plan. 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. Likewise, more than one hazard may be addressed by a specific control measure (e.g. proper cooking).

The physical characteristics and composition of the food during and after preparation should be considered when determining the risk of a hazard. This means understanding the intrinsic and extrinsic factors of the food that would allow conditions that support the survival or growth of bacteria. Intrinsic factors are those that are inherent to the food and are not readily controlled by people in a retail establishment, such as water activity, nutrient content, and competitive microorganisms. Extrinsic factors are those that people can readily control, such as temperature, acidity, and availability of air.

Once the significant biological hazards are identified for a food, there are several issues to consider when determining if conditions exist that would support their growth or survival, including:

- The nature of the food (ground or intact; plant or animal)
- Whether the food is improperly cooled after cooking or improperly hot held, (*Clostridium perfringens* or *Bacillus cereus* could grow because their spores survive cooking and germinate)
- Whether the food is improperly cold held (*Listeria monocytogenes* and *Yersinia* will be a concern because they grow at refrigeration temperatures)
- Whether foods have a high salt content (*Vibrio* and *Staphylococcus aureus* are likely to grow because they are salt-tolerant)
- Whether air is unavailable, such as in the interior of a cooked food or a sealed modified-atmosphere package (*Clostridium botulinum* and *C. perfringens* will thrive when air is not present)
- Whether water activity is high (*Staphylococcus aureus* needs to have nutrients readily available in order to thrive, but it can produce a potent toxin in a food with a water activity that is lower than that needed by other organisms)

Several questions that you may ask yourself when assessing the food safety hazards in food include the following:

- Does the food permit survival or multiplication of pathogens and/or toxin formation in the food before or during preparation?
- Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation?
- What has been the safety record for the product in the marketplace? Is there an epidemiological history associated with this food?
- Is the food served to a highly susceptible population?
- What is known about the time/temperature exposure of the food?
- What is the water activity and pH of the food?
- Have bare hands touched the food, or otherwise cross-contaminated it?
- Is the food from a safe source?
- Do food workers practice good personal hygiene, including frequent and effective handwashing?
- Has the food been exposed to unclean or unsanitized equipment?
- Does the preparation procedure or process include a step that destroys pathogens or their toxins? (Consider both vegetative cells and spores)
- Is the product subject to recontamination after cooking?

Hazard identification, in conjunction with risk and severity estimation, provides a rational basis for determining hazards of significance. There may be differences of opinion, even among experts, as to the risk of a hazard and one may need to consult reliable information published in peer-reviewed literature or recognized experts in the field. The hazards must at least include those that are commonly associated with a specific product.

A list of specific food safety hazards found in common products follows. As pointed out in Procedural Step 3, each of these food safety hazards belong to more general categories of hazards that may used as you develop your food safety management system:

- *Salmonella* and *Campylobacter jejuni* in raw poultry
- *Salmonella* Enteriditis in undercooked eggs
- *E. coli* O157:H7 in raw ground beef
- *Listeria monocytogenes* in ready-to-eat foods, such as hot dogs and deli meat
- Bacterial pathogens associated with unpasteurized juice or milk
- *Staphylococcus aureus* toxin formation in ready-to-eat products that are contaminated and later temperature-abused, such as cooked ham
- *Bacillus cereus* spore survival and toxin formation in cooked rice
- *Clostridium perfringens* and *B. cereus* spore survival and subsequent growth in cooked meat/meat products

Table 1. Selected Biological and Chemical Hazards Found at Retail, Associated Foods, and Control Measures.

HAZARD		ASSOCIATED FOODS	CONTROL MEASURES
Bacteria	*Bacillus cereus* (intoxication caused by heat-stable, preformed emetic toxin or toxicoinfection caused by heat-labile, diarrheal toxin)	Meat, poultry, starchy foods (rice, potatoes), puddings, soups, cooked vegetables	Cooking, Cooling, Cold Holding, Hot Holding
	Campylobacter jejuni	Poultry, raw milk	Cooking, Handwashing, Prevention of Cross-contamination
	Clostridium botulinum (intoxication caused by preformed heat-labile toxin)	Vacuum-packed foods, reduced oxygen packaged foods, under-processed canned foods, garlic-in-oil mixtures, time/temperature abused baked potatoes/sautéed onions	Thermal Processing (Time + Pressure), Cooling, Cold Holding, Hot Holding, Acidification and Drying, etc.
	Clostridium perfringens	Cooked meat and poultry, Cooked meat and poultry products including casseroles, gravies	Cooling, Cold Holding, Reheating, Hot Holding
	E. coli O157:H7 (other shiga toxin-producing *E. coli*)	Raw ground beef, raw seed sprouts, raw milk, unpasteurized juice, foods contaminated by infected food workers via fecal-oral route	Cooking, No Bare Hand Contact with RTE Foods, Employee Health Policy, Handwashing, Prevention of Cross-contamination, Pasteurization or Treatment of Juice
	Listeria monocytogenes	Raw meat and poultry, fresh soft cheese, Pate, smoked seafood, deli meats, deli salads	Cooking, Date Marking, Cold Holding, Handwashing, Prevention of Cross-contamination
	Salmonella spp.	Meat and poultry, seafood, eggs, raw seed sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, Use of Pasteurized Eggs, Employee Health Policy, No Bare Hand Contact with RTE foods, Handwashing, Pasteurization or Treatment of Juice
	Shigella spp.	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, No Bare Hand Contact with RTE Foods, Employee Health Policy, Handwashing
	Staphylococcus aureus (intoxication caused by preformed heat-stable toxin)	RTE PHFs touched by bare hands after cooking and further time/temperature abused	Cooling, Cold Holding, Hot Holding, No Bare Hand Contact with RTE Food, Handwashing
	Vibrio spp.	Seafood, shellfish	Cooking, Approved Source, Prevention of Cross-contamination
Parasites	*Anisakis simplex*	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, Freezing
	Taenia spp.	Beef and pork	Cooking
	Trichinella spiralis	Pork, bear and seal meat	Cooking
Viruses	Hepatitis A and E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved Source, No Bare Hand Contact with RTE Food, Minimizing Bare Hand Contact with Foods Not RTE, Employee Health Policy, Handwashing
	Other Viruses (Rotaviruses, Noroviruses, Reoviruses)	Any food contaminated by infected worker via fecal-oral route	No Bare Hand Contact with RTE Food, Minimizing Bare Hand Contact with Foods Not RTE, Employee Health Policy, Handwashing

Table 2. Foods that might be served raw or undercooked.

(Refer also to last page of Annex 2 for parasitic considerations for fish.)

Raw Animal Food	Menu Items	Hazards
Beef	Steak Tartare Carpaccio	*Salmonella spp.* *Escherichia coli* O157:H7
Poultry	Duck	*Salmonella spp.* *Campylobacter jejuni*
Eggs	Quiche, hollandaise sauce, Eggs Benedict, homemade mayonnaise, meringue pie, some puddings and custards, Monte Cristo sandwich, mousse, tiramisu, chicken croquettes, rice balls, stuffing, lasagna, french toast, crab cakes, egg nog, fish stuffing, Caesar salad, ice cream	*Salmonella* Enteritidis
Raw Fish/Finfish	Lightly cooked fish, sushi, raw-marinated, cold-smoked fish, ceviche, tuna carpaccio	*Anisakis simplex* *Diphyllobothrium* spp. *Pseudoterranova decipiens* *Vibrio parahaemolyticus*
	Reef fish: (barracuda, amberjack, horse-eye jack, black/jack, other large species of jack, king mackerel, large groupers, large snappers)	Ciguatera toxin
Shellfish	Oysters Clams	*Vibrio vulnificus* *Vibrio* spp. Hepatitis A Norovirus
Raw Dairy Products	Raw or unpasteurized milk, some soft cheeses like Camembert, Brie, etc.	*Listeria monocytogenes* *Salmonella spp.* *Campylobacter jejuni* *E. coli* O157:H7

Annex 4
Sample HACCP Tables

Table 1a. Process #1 – Food Preparation with No Cook Step

MENU ITEMS/PRODUCTS:						
HAZARD(S)	**CRITICAL CONTROL POINTS (List Only the Operational Steps that are CCPs)**	**CRITICAL LIMITS**	**MONITORING**	**CORRECTIVE ACTIONS**	**VERIFICATION**	**RECORDS**
PREREQUISITE PROGRAMS						

Table 1b. Process #1 – Food Preparation with No Cook Step

MENU ITEMS/PRODUCTS:							
PROCESS STEP	**HAZARD(S)**	**CCP (Y/N)**	**CRITICAL LIMITS**	**MONITORING**	**CORRECTIVE ACTIONS**	**VERIFICATION**	**RECORDS**
RECEIVE							
STORE							
PREPARE							
HOLD							
SERVE							
Prerequisite Programs							

Table 2a. Process #2 – Preparation for Same Day Service

MENU ITEMS/PRODUCTS:						
HAZARD(S)	**CRITICAL CONTROL POINTS (List Only the Operational Steps that are CCPs)**	**CRITICAL LIMITS**	**MONITORING**	**CORRECTIVE ACTIONS**	**VERIFICATION**	**RECORDS**
PREREQUISITE PROGRAMS						

Table 2b. Process #2 – Preparation for Same Day Service

MENU ITEMS/PRODUCTS:							
PROCESS STEP	**HAZARD(S)**	**CCP (Y/N)**	**CRITICAL LIMITS**	**MONITORING**	**CORRECTIVE ACTIONS**	**VERIFICATION**	**RECORDS**
RECEIVE							
STORE							
PREPARE							
COOK							
HOLD							
SERVE							
Prerequisite Programs							

Table 3a. Process #3 – Complex Food Preparation

MENU ITEMS/PRODUCTS:						
HAZARD(S)	**CRITICAL CONTROL POINTS (List Only the Operational Steps that are CCPs)**	**CRITICAL LIMITS**	**MONITORING**	**CORRECTIVE ACTIONS**	**VERIFICATION**	**RECORDS**
PREREQUISITE PROGRAMS						

Table 3b. Process #3 – Complex Food Preparation

MENU ITEMS/PRODUCTS:							
PROCESS STEP	**HAZARD(S)**	**CCP (Y/N)**	**CRITICAL LIMITS**	**MONITORING**	**CORRECTIVE ACTIONS**	**VERIFICATION**	**RECORDS**
RECEIVE							
STORE							
PREPARE							
COOK							
COOL							
REHEAT							
HOLD							
SERVE							
Prerequisite Programs							

Annex 5 – Paperwork Reduction Act of 1995

This manual contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 20 hours to conduct the hazard analysis and 60 hours to develop a food safety management system (HACCP plan), including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Office of Compliance
Retail Food and Cooperative Programs
Coordination Staff/Retail Food Protection Team (HFS-320)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0578 (expires 01/31/2013).