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Chapter 1 – Introduction

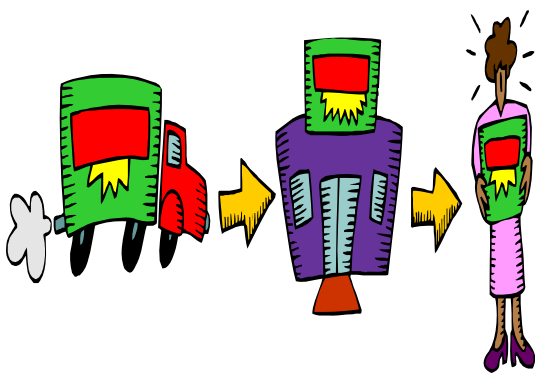
PURPOSE AND SCOPE

"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?

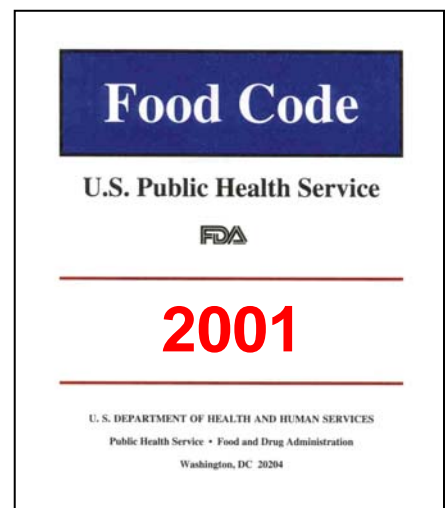
The procedures and information presented in this manual were prepared with feedback received from regional FDA food safety seminars and Food Safety Initiative grassroots meetings. In addition, the Conference for Food Protection (CFP) has reviewed and endorsed this manual and has provided FDA with comments 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 °F 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 partial listing of the types of businesses that are usually considered part of the retail and food service industries:

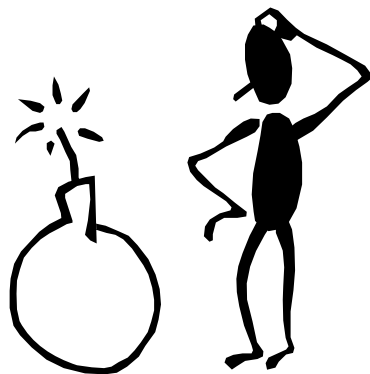
Back-country guided trips for groups	Health care facilities
Bakeries	Interstate conveyances
Bed and breakfast operations	Markets
Cafeterias	Meal services for home-bound persons
Camps - recreational, children's, etc.	Mobile food carts
Casinos, bares, and taverns	Penal institutions
Child and adult day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

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.

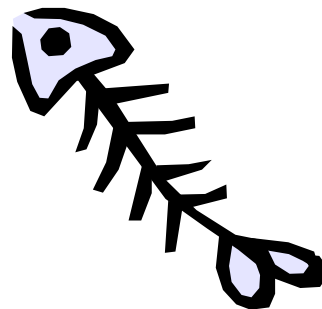
Food can become contaminated by toxic chemicals or toxins in your establishment or in the environment. Physical objects may also contaminate food and cause injury. Food may become naturally contaminated from the soil in which it is grown or from harvest, storage, or transportation practices. Some foods 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 –

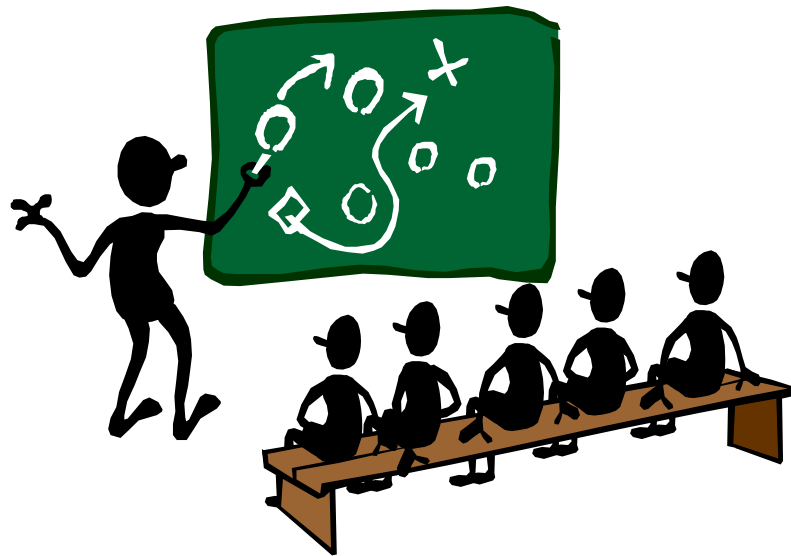
- Biological agents
 - Bacteria and their toxins
 - Parasites
 - Viruses

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



Chapter 3 – Developing Your Food Safety System

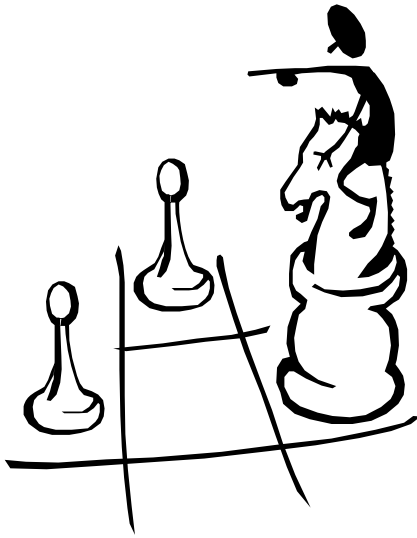
GETTING STARTED



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



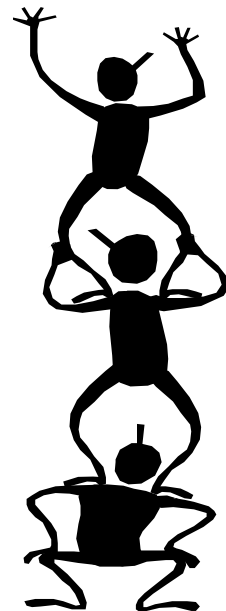
Just like a well-played chess game, building a food safety management system takes time, patience, and determination. Careful consideration must be given to all aspects of your operation affecting food safety. To assist you in building your food safety management system, a series of procedural steps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

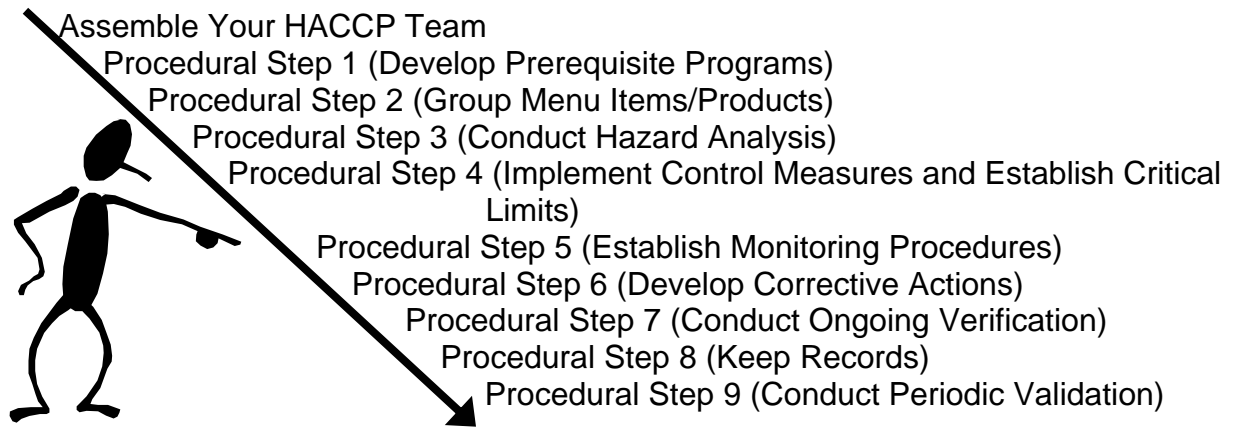
Two sets of tables have been provided for you to use in building your system. You can use either set of these tables or you can modify them to best suit your operation's needs. The tables that are provided will enable you to –

- 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 °F 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

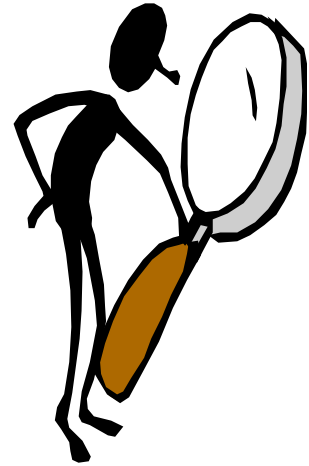
Example menu items or products that belong to each of the three food preparation processes can be found in the following table. Note that the same menu item can appear in more than one category depending on how it is prepared:

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.

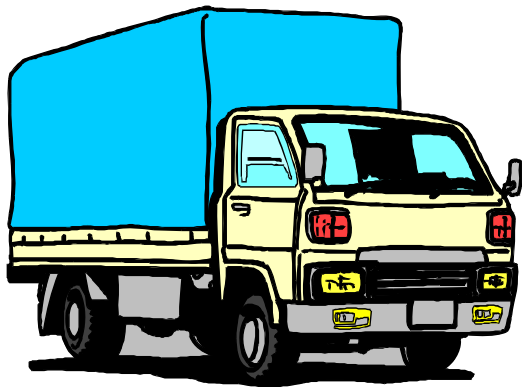
You should make sure that you have established the appropriate critical limits to control the identified hazards. It is recommended that you refer to the most recent version of the *Food Code* or your state, local, or tribal regulations for help with determining the appropriate critical limits for the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

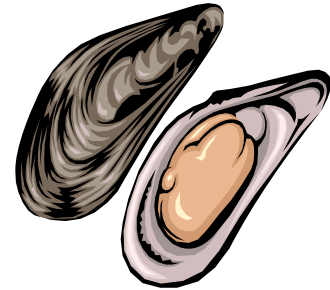
- Receiving the food at proper temperatures and getting perishable food into cold storage quickly
- Obtaining food, ingredients, and packaging materials from approved sources (suppliers who are regulated and inspected by appropriate regulatory authorities)

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.

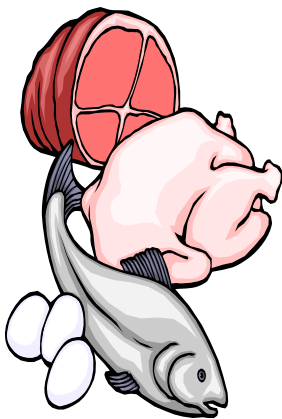


Finfish harvested from certain areas may naturally contain a toxin called ciguatera. Other finfish may develop a toxin after harvest if strict temperature control is not maintained. This toxin is called scombrototoxin (histamine). For finfish, temperature control and approved sources are important at 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 °F. This provides a safety cushion that allows you the opportunity to see a trend toward exceeding 41 °F 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 °F 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 °F 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

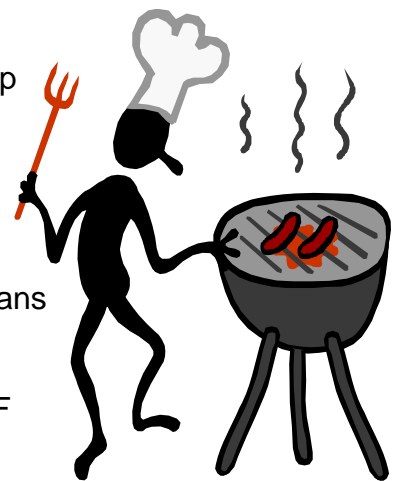
This operational step only applies to foods listed in Processes #2 and #3. Cooking foods of animal origin is the most effective operational step for reducing or eliminating biological contamination. Cooking to proper temperatures for a specified time will kill most harmful bacteria and parasites. Therefore, 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 °F for 15 seconds, while 155 °F for 15 seconds is the safe cooking temperature for ground beef.

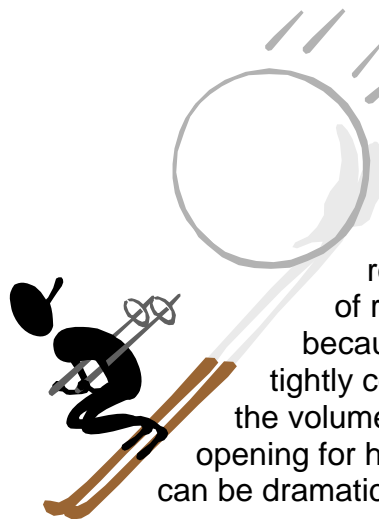
To ensure adequate destruction of pathogens by heat, the cooking operational step



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

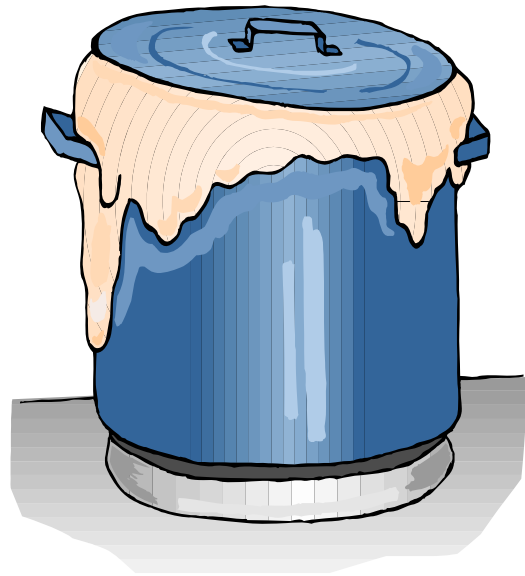
- In soups or stews, redesigning your recipe so that you cook a concentrated base and add enough cold water or ice to make up the volume that you need
- Prechilling ingredients used to make products such as chicken and tuna salad

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 °F or above during hot holding and keeping food products at or below 41 °F 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.

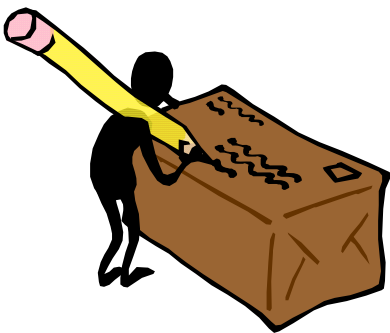
How often you monitor the temperature of foods during hot holding determines what type of corrective action you are able to take when 135 °F is not met. If the critical limit is not met, your options for corrective action may include evaluating the time the food is out of temperature to determine the 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 °F 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 °F or below. You may also want to set a target, or operating limit, less than 41 °F in order to provide a safety cushion that allows you the opportunity to see a trend toward exceeding 41 °F 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:

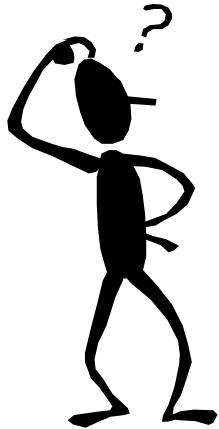
- Procedures for proper handwashing
- The appropriate use of gloves and dispensing utensils
- Control of bare hand contact with ready-to-eat foods
- Exclusion and restriction of ill employees

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.

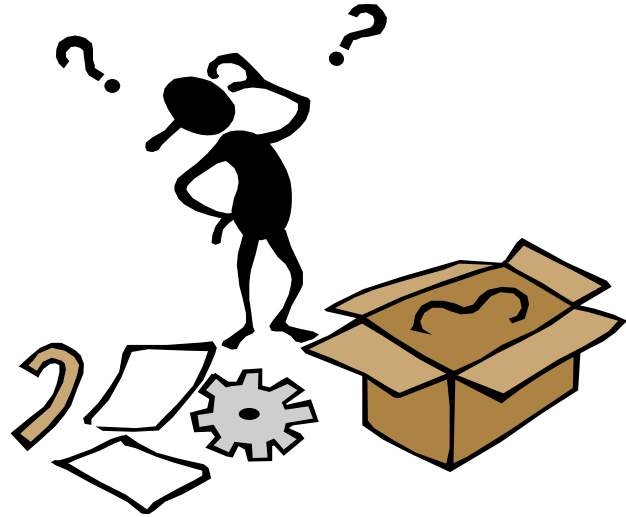
In the event that a corrective action is taken, you should review and modify your food safety management system, if necessary. Even with the best of systems, errors occur during food storage and preparation. A food safety management system based on the HACCP principles is designed to detect errors and 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

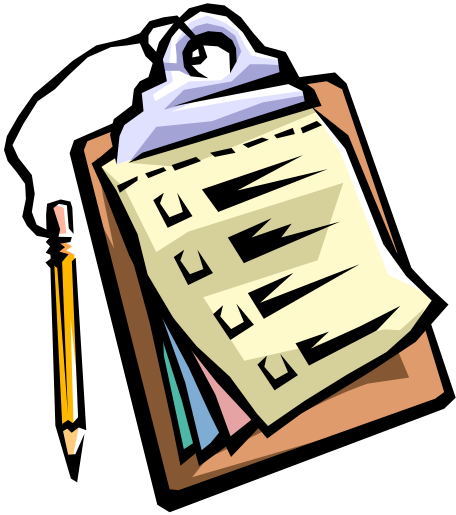
Verification should occur at a frequency that can ensure the food safety management system is being followed **continuously** to –

- 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.

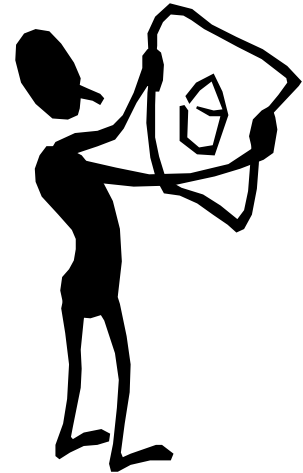
Validation is conducted less frequently (e.g., yearly) than on-going verification. It is a review or audit of the plan to determine if –

- 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 <input type="checkbox"/> →
Yes <input type="checkbox"/>
Go to Question #6 | CLs updated: | Date: _____ | Name: _____ |
| 6. | Do the existing monitoring procedures ensure that the critical limits are met? | No <input type="checkbox"/> →
Yes <input type="checkbox"/>
Go to Question #7 | Monitoring procedures updated: | Date: _____ | Name: _____ |
| 7. | Do existing corrective actions ensure that no injurious food is served or purchased? | No <input type="checkbox"/> →
Yes <input type="checkbox"/>
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 <input type="checkbox"/> →
Yes <input type="checkbox"/>
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 <input type="checkbox"/> →
Yes <input type="checkbox"/>
Go to Question #10 | Record keeping procedures updated: | Date: _____ | Name: _____ |
| 10. | Are the existing prerequisite programs current? | No <input type="checkbox"/> →
Yes <input type="checkbox"/> | 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 °C (41 °F) and 57 °C (135 °F) 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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Milk, Food and Environmental Sanitarians.

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>

