Managing Food Safety: A Regulator's Manual For Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems

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Chapter 1 - Introduction

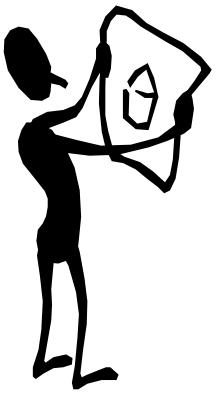
PURPOSE AND SCOPE

There is no doubt that you, the state, local, or tribal health inspector, play a significant role in reducing foodborne illness in your jurisdiction, yet your job can be overwhelming at times due to diminishing resources, increasing workload with limited staff, and growing liability. Many of you are continually forced to reassess your priorities due to increased media attention on food safety, threats from emerging pathogens, and food security, while being challenged to do more with less while maintaining your professional integrity.

Although the majority of these challenges are beyond your control, the allocation of your inspectional time is one element that you can change and continue to use to your advantage. You may undoubtedly become frustrated when you find the same violation at the same establishment, inspection after inspection. You may be able to change this pattern by focusing your inspection on the violations most likely to cause foodborne illness and by assisting retail and food service operators in the development or enhancement of food safety management systems to reduce the recurrence of these violations.

This Manual provides you with a manageable scheme for prioritizing your inspections using a risk-based approach. The traditional regulatory inspection places emphasis on assessing compliance with all applicable regulations. The same emphasis may be placed on structural violations of the code as those violations likely to lead to foodborne illness. Although this type of inspection has done a great deal to improve basic sanitation and to upgrade food facilities in the United States, it emphasizes reactive rather than preventive measures. The traditional regulatory inspection only seeks to obtain correction of food safety concerns that already exist, rather than to prevent future violations from occurring.

Each individual in the food chain from farmer to processor to retailer to consumer has some responsibility for food safety. The ultimate responsibility for food safety at the retail level lies not with the regulatory authority but with retail and food service operators and their ability to develop and maintain effective food safety management systems. Nevertheless, you can help industry with this responsibility by utilizing a risk-based inspection approach to identify



strengths and weaknesses in their systems and suggesting possible solutions for improvement during inspections.

This Manual was written to provide a "roadmap" for evaluating retail and food service establishments based on the application of HACCP principles. The acronym “HACCP” stands for “Hazard Analysis and Critical Control Point.” It is a preventive approach implemented by industry to control food safety hazards. Using HACCP principles during inspections will help to assist you in evaluating the effectiveness of food safety management systems implemented by industry.

The voluntary strategies presented in this Manual also foster food safety partnerships between you and your retail or food service operators, which will facilitate your active role in improving their existing food safety management systems. Please note that this Manual is not a comprehensive resource for learning about HACCP principles; therefore, you should have a basic understanding of the principles of HACCP before using this Manual. Annex 1 lists several resources that are available to you should you require a more comprehensive explanation of HACCP.

Many regulatory jurisdictions are already conducting risk-based inspections using HACCP principles and other innovative approaches. This Manual is based on experience gained from many of these approaches and is provided to you, the regulatory food safety professional, to help you enhance the effectiveness of your inspections by incorporating a risk-based approach.

BACKGROUND

What are Foodborne Illness Risk Factors?

In an ideal world, determining the effectiveness of a retail and food service regulatory program would be based on the occurrence of foodborne illness within that jurisdiction. The occurrence of foodborne illness is, however, underreported, making it an unreliable program measurement. As an alternative, the occurrence of foodborne illness risk factors can be used to gauge program effectiveness.

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.”

The foodborne illness risk factors are:

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

Until recently, there were no standardized, systematically-compiled statistics for the incidence of occurrence of foodborne illness risk factors in retail or food service facilities. As a result, implementation of food safety management systems designed to improve conditions leading to out-of-control risk factors was difficult.

In 2000, FDA completed a project designed to fill this information void and published its results in 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 risk factors. A copy of the report is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/retrsk.html.

The measurable trends identified in CDC's 1993 - 1997 Surveillance Report and in FDA's Baseline Report indicate that routine regulatory inspections should place an increased focus on assessing an establishment's active managerial control over the five CDC-identified risk factors.

What is Meant by Active Managerial Control?

The term "active managerial control" is used extensively throughout this Manual to describe industry's responsibility for developing and implementing food safety management systems to reduce the occurrence of foodborne illness risk factors. Although the term may be new to some, the basic management principles are probably already being used in the day-to-day operations of most of the establishments you regulate.

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. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

There are many tools that can be used by industry to provide active managerial control of risk factors. Elements of an effective food safety management system may include the following:

- 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

How are HACCP Principles Being Used in Retail and Food Service?

For several decades, food safety professionals have recognized the importance of HACCP principles for controlling risk factors that directly contribute to foodborne illness. Within the retail and food service industries, the implementation of these science-based food safety management principles varies.

Many multi-unit corporations and institutions, as well as independent operators, have developed effective food safety management systems that incorporate the seven principles of HACCP. The FDA document, *"Managing Food Safety: A Manual for the Voluntary Implementation of HACCP Principles for Operators of Food Service and Retail Establishments,"* is designed to aid industry in establishing effective, voluntary food safety management systems based on the principles of HACCP. The manual is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/hret2toc.html.

The products made in retail and food service operations are as varied as the methods and processes used to make them. The resources available to retail and food service operators to help them with identifying and controlling the risk factors particular to their operations also vary. Due to this diversity, implementation of "textbook HACCP" is impractical in most retail and food service operations.

Like many other quality assurance programs, the principles of HACCP provide a common-sense approach to identifying and controlling "problems." Consequently, many food safety management systems at the retail level incorporate some, if not all, of the principles of HACCP. Given the diversity of retail and food service operations, however, it is important for you to recognize that there is more than one "correct" application of HACCP principles. Regulatory inspection programs must be flexible

enough to operate in a complementary and effective manner in this dynamic retail environment.

The DRAFT FDA *Voluntary National Retail Food Regulatory Program Standards* establish a framework that regulatory agencies can use to –

- Design and manage a comprehensive, risk-based retail food safety program
- Provide direction and focus on the causative factors of foodborne illness based on HACCP principles
- Reinforce sanitation, operational, and environmental prerequisite programs

The complete set of *Program Standards* is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/ret-toc.html.

SUMMARY

The ultimate responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems. The goal of this Manual is to provide you with a practical, HACCP-based approach to evaluate industry's active managerial control of foodborne illness risk factors. It is essential that regulatory program managers design an inspection program based on HACCP principles that guides and supports their field staff in assisting operators with incorporating these principles into their routine activities. Since food safety management systems are designed by retail and food service operators to best meet their own needs, you will need to use a risk-based methodology during your inspections to uncover the systems being used and to evaluate their effectiveness.

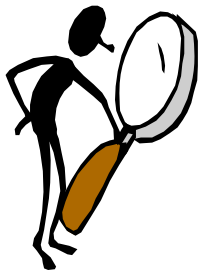
Chapter 2 – Conducting Risk-based Inspections

Regardless of the resource limitations you may have, you can still use the principles of HACCP to guide your inspections. Many of you already have the technical food safety knowledge needed to effectively use a HACCP approach.

For the purposes of this discussion, "hazards" are defined as the specific biological, chemical, or physical properties or agents that, if uncontrolled, may lead to illness or injury. Risk factors are the poor conditions, procedures, or practices that result in out-of-control food safety hazards. As stated in Chapter 1, risk factors include –

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

THE FOCUS OF RISK-BASED INSPECTIONS



Conducting a risk-based inspection requires you to focus on evaluating the degree of active managerial control that an operator has over risk factors. In order for you to properly assess active managerial control, you will need to spend the majority of your time observing the practices and procedures that are likely to lead to out-of-control risk factors and asking food workers questions to assess the operation.

Retail and food service operators implement "control measures" to ensure food safety. Control measures are actions or activities that are used to prevent, eliminate, or reduce food safety hazards. You will need to determine the control measures that should be implemented to prevent the occurrence of risk factors in each food preparation process. In order to determine the risk factors common to each operation, it is important for you to understand that the food preparation processes and all the associated control measures initiated by a retail or food service operator represent a food safety management system. It will be necessary for you to ask questions in order to gain information about the system already in place. Once you have done this, you will be able to determine the degree of active managerial control present in the facility and will be able to assist the operator in strengthening the system.

SETTING THE EXAMPLE

In focusing your inspection, it is important for you to realize that your nonverbal communication is just as important as your verbal communication in relaying important food safety messages to retail and food service operators. You set the example for them to follow during all phases of your inspection. The following are ways that you set the example:

- Washing your hands when entering the food preparation area at the beginning of the inspection and after engaging in any activities that might contaminate your hands
- Not working when you are suffering from symptoms such as diarrhea, fever, vomiting, or jaundice or if you are diagnosed with a disease transmittable by food
- Being careful not to touch ready-to-eat (RTE) food with your bare hands
- Washing and sanitizing your thermocouple probe at the start of the inspection and between taking temperatures of foods
- Using a proper hair restraint and practicing good personal hygiene
- Being careful not to contaminate clean and sanitized food contact surfaces with unclean hands or your inspection equipment

As an experienced food safety professional, you already demonstrate these personal practices in each of your inspections. You will need the additional support of your program management, however, in providing you with state-of-the-art equipment needed to perform a risk-based inspection. Utilizing the proper equipment demonstrates competency and preparedness to the operator and may convince the operator to also use the appropriate equipment. For instance, when you check the temperature of thin hamburgers using a needle probe thermocouple, you demonstrate to the operator the proper method for taking temperatures of thin products. At a minimum, you should have the following equipment to conduct a risk-based inspection:

- Thermocouple with the appropriate probes for the foods being tested
- Alcohol swabs or other suitable equipment for sanitizing probe thermometers
- Sanitization test kits
- Heat sensitive tape or maximum registering thermometer
- Flashlight

ESTABLISHING INSPECTION PRIORITIES

In planning for inspections you should consider the importance of timing. Several operational steps at retail such as receiving, preparation, and cooling can only be evaluated during limited time periods. Times may need to be varied from inspection to inspection to ensure that all critical processes are evaluated.

With the limited time allotted for inspections, you must develop clear priorities to make the most efficient use of your time in each facility. Although basic sanitation issues generally do not change during the course of a routine inspection, critical practices and procedures leading to risk factors may only be observable during limited time intervals. For this reason, assessment of the active managerial control of risk factors should generally be performed before reviewing basic sanitation issues.

By setting priorities early in the inspection, observations attributed to out-of-control risk factors can be distinguished from those related to general sanitation and maintenance. You can set priorities by completing four activities early in your inspection:

- Establishing an open dialogue with the person in charge
- Reviewing previous inspection records
- Conducting a menu or food list review
- Conducting a quick walk-though

Establishing an Open Dialogue with the Person In Charge

Having an open dialogue with the person in charge during all phases of your inspection gives you an opportunity to learn important information about the existing food safety management system. It is important to know both the strengths and weaknesses of the existing food safety management system early in your inspection so that you can focus your inspection on weak areas. For instance, through your questioning, you learn that the facility cooks chicken that is used in several end products such as soups and salads. You also learn that the facility checks the temperature of the chicken to make sure that it is cooked, but you quickly realize that no further monitoring is conducted when the chicken is cooling. Knowing this, you begin your inspection by checking cooling.

Even if you are unable to have a discussion with the person in charge at the beginning of the inspection, questions about practices and procedures related to risk factors and *Food Code* interventions, like the facility's employee health policy and consumer advisory, can certainly be asked as you conduct your inspection. It is important to ask enough questions to fully understand the system being utilized in the establishment.

This is especially true when evaluating whether the employees are adhering to the established no bare hand contact and handwashing policies.

Asking the person in charge questions about important activities such as receiving, cooling, and preparation is also important in relating the seriousness of out-of-control risk factors. If the person in charge has the time, have him or her accompany you as you conduct your inspection. This will ultimately save you time because you can point out violations as they are observed. These violations should still be marked on your inspection form, but you can obtain immediate corrective action to abate the problem before someone gets sick. You can also use this time to share your knowledge about critical processes. By communicating the public health rationale behind your regulations, you will leave the person in charge with a clear understanding for why active managerial control of risk factors must be a top priority in the day-to-day operation of the business.

Reviewing Previous Inspection Reports

In order to detect trends of out-of-control risk factors, it is important for you to review past inspection reports prior to conducting your inspection. This can be done in your office or on-site at the facility. This activity is especially important in jurisdictions where health inspectors rotate from one inspection to the next. If the same risk factor is out-of-control during more than one inspection, it is strongly recommended that the operator develop an intervention strategy to prevent its recurrence (see Chapter 3). Knowledge of what has been corrected from the last inspection also gives you the opportunity to provide some positive feedback to the operator and allows you to track corrected violations in accordance with your jurisdiction's policy.

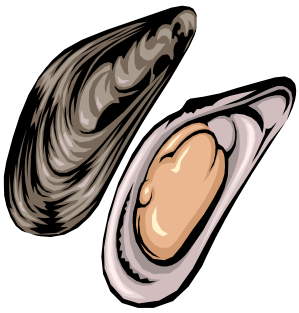
Conducting a Menu/Food List Review

The menu, whether written as in the case of restaurants, or a list of foods prepared and sold found in retail food stores, can be reviewed in a fairly simple manner. The review can either be done simultaneously with a quick walk-through of the operation (discussed later) or as a discussion with management at the beginning of the inspection. The menu/food list also does not need to be reviewed during every inspection. If a review was done during a recent inspection, you can simply ask the person in charge if there have been any changes since the last inspection. A review of the menu/food list allows you to begin to group food items into one of three broad process categories (discussed later) that will allow you to focus your inspection

on risk factors associated with each process. Conducting a review of the menu/food list also allows you to establish inspection priorities by identifying –

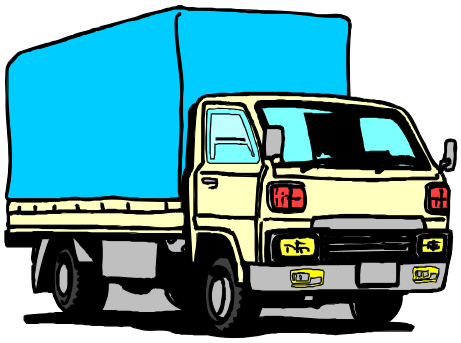
- High-risk foods or high-risk food preparation processes
- Operational steps requiring further inquiry such as receiving, preparation, cooking, and cooling

By identifying high-risk foods or high-risk food preparation processes, you can focus your inspection on those foods or processes that will most likely cause foodborne illness if uncontrolled. High-risk foods include products like raw chicken that naturally carry a high pathogenic load. If such products are used in a facility, practices related to cross-contamination and cooking should be a priority during the inspection. If there are foods that go through the temperature danger zone several times, cooling and holding practices should be reviewed. If the establishment is primarily a "Cook and Serve" operation, then time can best be spent on observing cooking practices.



The menu/food list review might be the only time you are made aware of specialized processes such as formulating a food so that it is not potentially hazardous or high-risk seasonal menu items such as raw oysters. Foods such as shellstock and certain fish for raw consumption require documentation that should be reviewed during the inspection. You may discover items on the menu such as Caesar salad or hollandaise sauce. Further inquiry is needed regarding the preparation of these items since they are sometimes prepared with raw eggs.

Several operational steps like receiving, preparation, cooking, and cooling may not be inspected as vigorously in retail and food service inspections due, in part, to the hours of the day in which these steps occur. If a facility is inspected in the afternoon hours, for example, receiving and food preparation might have already occurred. You should ask questions to obtain information about the operational steps that you cannot directly observe in order to evaluate the establishment's active managerial control.



Conducting a Quick Walk-through

As you discuss the menu or food list with the person in charge, it is suggested that you conduct a quick walk-through of the facility to observe what is going on at that time.

Conducting a quick walk-through is especially important to observe several activities that might otherwise go unnoticed until later in the inspection:

- Receiving
- Food preparation and handling
- Cooking
- Cooling
- Reheating

Noting that receiving or food preparation is occurring at the beginning of the inspection allows you to take advantage of “real-life” production processes and will help you to obtain a clear picture of the establishment's true practices. Receiving and food preparation only occur during limited times, so you may want to stop and observe these operational steps while they are happening.

For example, during the initial walk-through with the person in charge, you may see that salad is being prepared. In response, you might want to take some time to observe the preparation practices. This also offers you an excellent opportunity to interact with the food employees to observe if the food is being properly handled using utensils and to find out how the ingredients were received and stored prior to preparation. Speaking directly to the food service employees preparing the food is also an excellent way to assess the effectiveness of the establishment’s food safety training and Standard Operating Procedures (SOPs) for critical processes such as cooling.

Early in the inspection, it is also ideal to check the temperatures of potentially hazardous foods in the cooling process from the morning preparation if the inspection is in the afternoon or last night’s meal service if the inspection is occurring in the morning. Also, you might want to ask whether any food is currently being cooked or reheated. The observations you make, along with the feedback you get from questioning the person in charge or the food service employees, will help you evaluate whether foods appear to have been properly processed.

EVALUATING EXISTING FOOD SAFETY MANAGEMENT SYSTEMS

Although some establishments have formal HACCP plans in place, many do not. Even without a HACCP system, every establishment needs to have active managerial control of risk factors. This may be achieved through several means, such as training programs, manager oversight, or standard operating procedures. For example, some

establishments incorporate control measures into individual recipes, production schedules, or employee job descriptions to achieve active managerial control.

While a person in charge may require the maintenance of in-house written records by employees to ensure that monitoring is being performed using the correct method and at the proper frequency, risk factors may be managed without the use of formal record keeping. Monitoring, whether through direct observations or by taking appropriate measurements, is by far the most important step to ensuring food safety. If an operator is effectively monitoring all critical activities in the establishment and taking corrective actions when needed, safe food will result. With a few exceptions, maintaining formal records at retail is not required; therefore, records may not be in place for use during your inspection. As a result, it will be necessary to use direct observations and interviewing to determine whether an establishment is adequately monitoring risk factors in their existing food safety management system.

Every establishment has some type of set pattern of procedures even if it is simply described as “the way we do things.” A small, independent operation may not have written procedures, yet it may have adequate procedures that are routinely followed. Good communication is required to discover these types of informal management systems.

Many retail and food service establishments have implemented effective food safety management systems by establishing controls for the food preparation methods and processes common to their operation. Control of food preparation processes rather than individual food items is often called the “process approach” to HACCP. The process approach using the principles of HACCP can best be described as dividing the many food items in an operation into three food preparation processes then analyzing the risk factors associated with each process. By placing managerial controls on specific operational steps in the flow of food, foodborne illness can be prevented.

DETERMINING PROCESS FLOWS

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, and serving. Keep in mind that the terminology used for operational steps may differ between food service and retail food store operations. 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 while in the retail or food service facility)

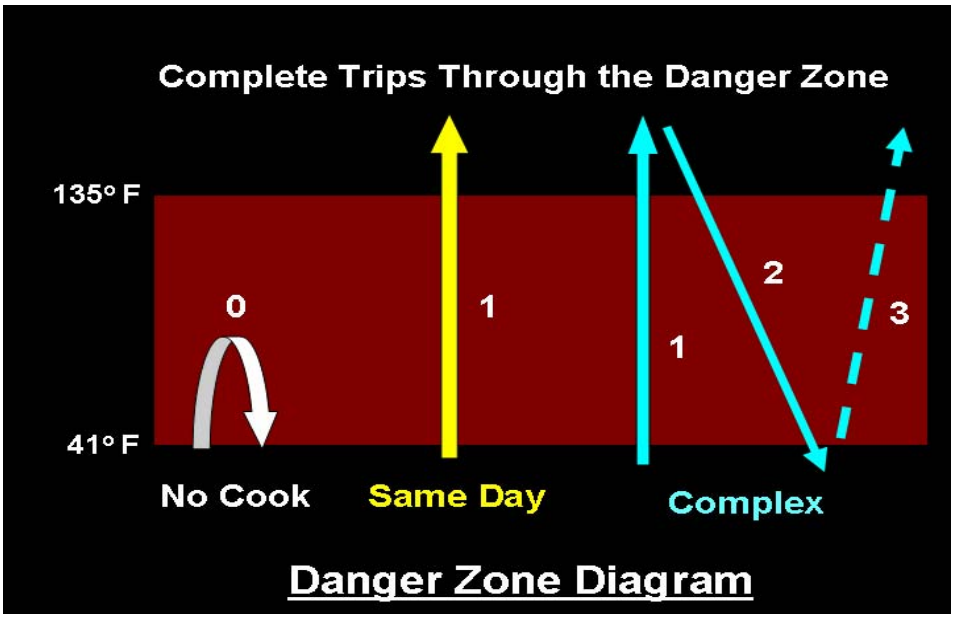
- **Process 2: Preparation for Same Day Service**

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 which go through the danger zone only once are classified as Same Day Service, while foods that go through more than once are Complex.



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 item like a chicken salad sandwich that is created using several components that may be 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), 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 is cooking to the proper temperature.

- Additionally, if the products are held after cooking, then proper hot holding or time control is also necessary 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 that are not depicted here:

Process 2: Preparation for Same Day Service		
Example Products	**Baked Meatloaf**	**Baked 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)	Refrigeration 41 ºF or below	Refrigeration 41 ºF or below
	Cooking at 155 ºF for 15 seconds	**Cooking at 165 ºF for 15 seconds**
	Hot Holding at 135 ºF or above OR Time Control for 4 hours or less	Hot Holding at 135 ºF 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

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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 inspection on these risk factors, there may be other risk factors unique to an operation or process that are not listed here. You should evaluate each operation and food preparation process independently.

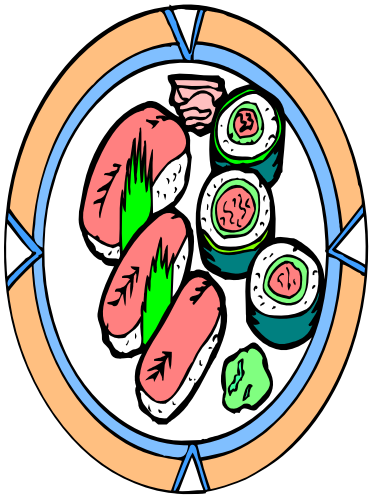
Facility-wide Considerations

In order to have active managerial control over personal hygiene and cross-contamination, an operator must implement control measures in all phases of the operation. The following control measures should be evaluated during your inspection regardless of the food preparation process used –

- **No bare hand contact with RTE 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 RTE 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, such as 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. During your inspection, you can ensure that the food received in the facility is as safe as possible by checking that the food is

received in good condition and from approved sources. Without a kill step to destroy pathogens, the primary responsibility of the operator will be to prevent further contamination by ensuring that employees follow good hygienic practices. In addition, 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.

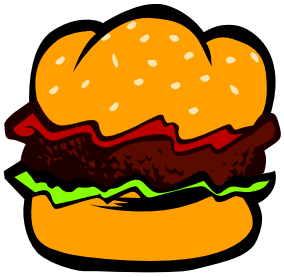
In addition to the facility-wide considerations, an inspection involving this food preparation process should focus on ensuring that the facility has active managerial control over the following:

- **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 3)
- **Receiving temperatures** (especially certain species of marine finfish due to concerns with scombrotoxin)
- **Date marking** of RTE 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 3)
- **Cooling from ambient temperature** 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 facility 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, an inspection involving this food preparation process should focus on ensuring that the facility has active managerial control over the following:



- **cooking** to destroy bacteria and parasites; and
- **hot holding or using time alone** to prevent the outgrowth of spore-forming bacteria.

Food source and receiving temperatures/cold holding prior to cooking are also important if dealing with certain marine finfish due to

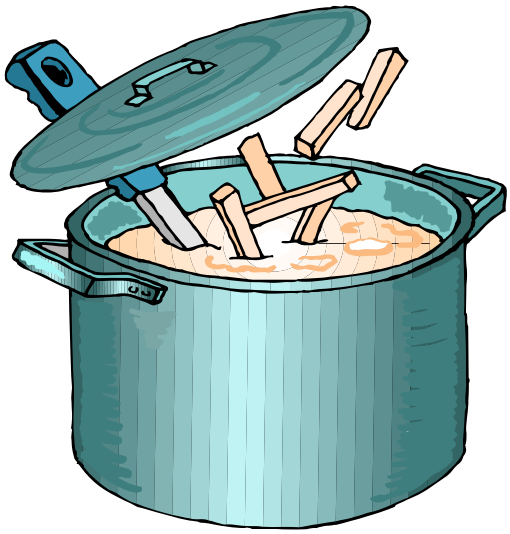
concerns with ciguatera toxin and scombrotoxin. Consult Annex 3 for other special considerations related to seafood.

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 will 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 *Listeria monocytogenes*, which could grow during refrigerated storage. The key to managing the operational steps within this food preparation process is to minimize the time foods are at unsafe temperatures.

In addition to the facility-wide considerations, an inspection involving this food preparation process should focus on ensuring that the facility has 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 RTE PHF held for more than 24 hours to control the growth of *Listeria monocytogenes*
- **reheating** for hot holding, if applicable.

Food source and receiving temperatures/cold holding prior to cooking are also important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrotoxin. Consult Annex 3 for other special considerations related to seafood.

ASSESSING ACTIVE MANAGERIAL CONTROL OF RISK FACTORS

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

At a minimum, an operator's food safety management system should be based on achieving the same level of safety established by the critical limits in the *Food Code*. When determining the degree of active managerial control an operator has over risk factors, you should observe whether the operator has established the appropriate control measures and critical limits and whether appropriate monitoring procedures are in place.

A sample list of questions to assist you in assessing an operator's active managerial control of risk factors at operational steps throughout the flow of food is in Annex 4 of this Manual. This list can be used in conjunction with any inspection form or simply as a tool to help you organize your inspection. In addition, Annex 4 of the 2001 FDA *Food Code* (or Annex 5 in the 2005 FDA *Food Code*) contains additional information on assessing the active managerial control of foodborne illness risk factors.

EVALUATING BASIC SANITATION AND FACILITIES

Systems to control basic operational and sanitation conditions within a facility, often referred to as Good Retail Practices (GRPs), Prerequisite Programs, or Standard Operating Procedures (SOPs), are the foundation of a successful food safety management system. With this in mind, consider how the establishment actively monitors these activities. Just as monitoring is required by the establishment to ensure that risk factors are controlled, monitoring of basic sanitation conditions in the facility allows the operator an excellent opportunity to detect weaknesses and initiate actions for improvement. Although the main focus of an inspection should be on evaluating the active managerial control of risk factors, overall sanitation should not be overlooked.

Basic operational and sanitation programs must 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 during storage
- Maintain equipment

Examples of concerns addressed by the programs above include the following:

- Receiving temperatures
- Pest control
- Toxic chemical storage and labeling
- Food protection (non-critical)
- Equipment cleaning and maintenance
- Water
- Plumbing
- Toilet facilities
- Sewage
- Garbage and refuse disposal
- Physical facilities

SUMMARY

Although retail and food service operators have the responsibility for establishing food safety management systems, you, the regulator, have a vital, multi-faceted role in consumer protection. Your primary responsibility is to ensure the operator has effective control of risk factors. Once you have conducted a menu review and established a dialogue with the person in charge and food service workers, you will have enough information to mentally place menu items into one of the three process flows. Your inspection can then focus on assessing the operator's active managerial control of risk factors associated with each process.

Once out-of-control risk factors are identified, your role shifts to assisting an operator with strengthening the existing food safety management system through intervention strategies designed to achieve immediate and long-term compliance. With your help, retail and food service operators can achieve long-term behavioral change resulting in a reduction in risk factor occurrence and an increase in public health protection.

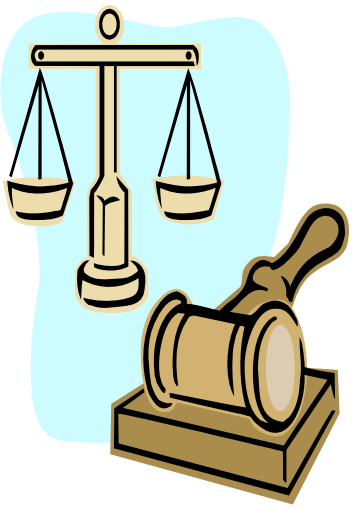
Chapter 3 - Intervention Strategies

This Chapter will introduce you to intervention strategies designed to immediately correct out-of-control risk factors and to prevent their recurrence. Your program manager can incorporate any of these strategies into your jurisdiction's compliance and enforcement protocol. You can use several of these strategies as suggestions to industry for achieving immediate and long-term active managerial control of risk factors.

THE ROLE OF INTERVENTION STRATEGIES IN COMPLIANCE AND ENFORCEMENT

Compliance and enforcement are essential elements of a regulatory program and involve all voluntary and involuntary corrections made by the operator. Voluntary corrections by the operator are referred to in this Manual as "intervention strategies." Intervention strategies can be divided into two groups:

- Those designed to achieve immediate on-site correction
- Those designed to achieve long-term compliance



Successful intervention strategies for out-of-control risk factors can be tailored to each operation's resources and needs. This will require you to work with the operator to identify weaknesses in their existing food safety management system and consulting with them to strengthen any weak areas noted. Intervention strategies can also be adopted as part of a progressive compliance and enforcement program. Many jurisdictions around the country have successfully used the intervention strategy concept as a "first step" in their compliance and enforcement protocol. If the operator is willing to work with you to gain ownership of food safety, a long-term behavior change will more likely result. This may help reduce the amount of enforcement proceedings that occur as a result of involuntary compliance.

Involuntary compliance results from the following enforcement activities:

- Warning letters
- Re-inspections
- Citations
- Administrative fines and hearings
- Permit suspensions

Although these enforcement activities are a necessary function in your regulatory work, obtaining voluntary corrections by the operator has proven to be more effective in achieving long-term compliance.

ON-SITE CORRECTION

On-site corrections are intended to achieve immediate corrective action of out-of-control risk factors posing an immediate, serious danger to the consumer during the inspection. Usually these violations are "operational" rather than structural and can be addressed by management at the time of the inspection. For example –

- Undercooking hamburger meat presents an immediate danger to the consumer that can be corrected on-site by additional cooking.

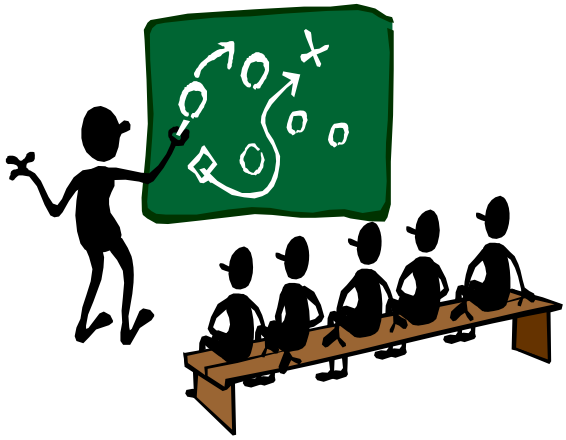
- Preparing lettuce on the same work surface previously used to cut raw chicken without having washed, rinsed, and sanitized the surface presents an immediate danger to the consumer that can be corrected on-site by discarding the contaminated lettuce.

Annex 6 provides a full list of suggested on-site corrections for out-of-control procedures found during your inspections.

It is essential to consumer protection and to regulatory credibility for on-site correction to be obtained for any out-of-control risk factors. Obtaining on-site correction conveys the seriousness of the violation to management. Failure to require on-site correction when an out-of-control risk factor has been identified implies that the risk factor has little importance to food safety. If the operation is briefly stopped to address the out-of-control risk factor, the operator may be more responsive to addressing the practices resulting in the out-of-control risk factor in the future. A more favorable impact on future behavior may result that might not have been achieved through discussion alone.

When recommending on-site correction, effective communication regarding out-of-control risk factors is essential and can often be accomplished by –

- Discussing food safety concerns in words that can be easily understood by the person in charge and the food service workers
- Conveying the seriousness of the out-of-control risk factors in terms of increased risk of illness or injury



Although the person in charge is ultimately responsible for the conditions in the facility and should therefore be informed of all out-of-control risk factors, timely training of the food service workers can in many cases have a great impact on future behavior. A translator and/or special training material may be necessary when language or education barriers exist. Remember that while it is important for both the person in charge and food service workers to know why they are having to make a correction, the long-term effectiveness of making the correction may be lost if you are too technical or scientific in your rationale.

During the discussion of inspection findings with the person in charge, you should keep the discussion focused on correction of violations that present an immediate danger to the consumer. **Discussion of lesser code violations should be deferred until out-of-control risk factors are discussed and on-site correction is obtained.** It is important to point out to the operator that while most basic sanitation problems do not pose a significant threat to the public, foodborne illness caused by out-of-control risk factors often results in significant losses to consumers and the operator. Negligence for not having a strong food safety management system in place to control risk factors can result in financial ruin for even the largest of retail operations.

DETERMINING THE APPROPRIATE ON-SITE CORRECTION

To assist you in determining the appropriate on-site correction, you should reference your existing regulatory policies and procedures. In the event that your jurisdiction does not have such policies and procedures, your experience and professional judgment will help you to offer the operator practical solutions for bringing the risk factors under control.

In most cases, selecting the most appropriate on-site correction when out-of-control risk factors are observed will be straightforward. For instance, if hamburgers are inadequately cooked, the on-site correction is to continue cooking until the appropriate cooking temperature is reached.

Determining the most appropriate on-site correction of out-of-control procedures such as inadequate hot and cold holding can be very complicated. Since determining on-site correction depends on a number of factors, you may need to conduct a hazard analysis of the food in order to determine the appropriate course of action to take. Annex 6 of this Manual lists the out-of-control procedures that may require a hazard analysis in order to determine the appropriate on-site correction. More information on conducting a hazard analysis is found in Annex 3.

Limitations of Reheating as an On-site Correction

One on-site correction used in the field is reheating. A common misconception is that reheating is a "magic step" for eliminating hazards resulting from improper holding or cooling. If a ready-to-eat, potentially hazardous food is improperly held or cooled, the potential for spore- or toxin-forming bacteria growth increases. Whether to recommend that the food be reheated or discarded depends on a number of factors including, but not limited to –

- the hazards of significance
- the nature of the food
- its intended use
- other important considerations discussed later in this section including the degree of time and temperature abuse

Although reheating can eliminate vegetative bacterial cells resulting from post-cook contamination (i.e. *Salmonella*) or from improper holding or cooling (i.e. *Clostridium perfringens)*, it has limitations that must be considered.

Some bacteria form spores that survive cooking. These spores can germinate and grow if food is improperly held after cooking. Bacterial spores are likely to be present in most foods. When a food is expected to contain spores of toxigenic bacteria such as *Clostridium botulinum* or *Bacillus cereus*, reheating may be ineffective. The emetic toxin of *B. cereus*, which has been largely associated with outbreaks in starchy foods, is very stable to heat. While the toxin of *C. botulinum* may be destroyed with extended reheating, the critical limit for reheating in the *Food Code* (165 ºF for 15 seconds) will not be effective in ensuring the food's safety.

Staphylococcus aureus does not produce spores, only a heat-stable toxin when present in large numbers. Time- or temperature-abused, RTE, PHFs that are touched by bare hands or otherwise contaminated with the organism are at risk.

Neither cooking nor reheating destroys chemical hazards such as ciguatera toxin or scombrotoxin in fish; therefore, fish that are subject to these hazards and are received from unapproved sources or at improper temperatures should be rejected.

Viruses are somewhat resistant to heat and given their low infectious dose may not be reduced to safe levels using the reheating parameters in the *Food Code*. Therefore, if ready-to-eat food is touched with bare hands, you will need to address several questions in order to make the appropriate on-site correction recommendation, including:

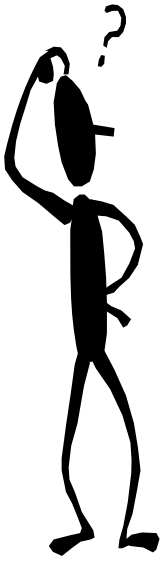
- Does the facility have an employee health policy to identify, restrict, and exclude ill employees?
- Did the employees working with the food in question effectively wash their hands and are handwashing facilities adequate?
- Is there an approved, alternate procedure to no bare hand contact in place and was it followed prior to the bare hand contact?
- Has there been an opportunity for the employee's hands to become contaminated?
- Was the bare hand contact with ready-to-eat food limited or extensive?

Use these questions as the framework for making a recommendation for on-site correction that is based on current science and your extensive knowledge of the operation. Once you have answered these questions, you should have enough information to determine the likelihood of occurrence of hazards transmitted by bare hands. Remember that viruses may not be destroyed to safe levels by reheating, so if you determine in your assessment that there is a high risk of viral contamination, then discarding the affected food may be the most appropriate recommendation for on-site correction.

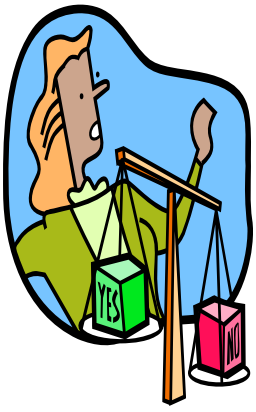
When bare hand contact with ready-to-eat food is not observed or when bare hand contact is observed but the risk of viral contamination is low, additional analysis is needed before recommending reheating as an on-site correction for food found out of temperature. In order to properly evaluate the degree of time and temperature abuse and the proper disposition of the affected ready-to-eat food, the following questions should be considered:

- Are there any written procedures in place for using time alone as a public health control and, if so, are they being followed properly?
- What are the ingredients of the food and how was it made?

- Is it likely that the food contains *C. perfringens*, C. *botulinum*, or *B. cereus* as hazards (see Annex 3)?
- Has there been an opportunity for post-cook contamination with raw animal foods or contaminated equipment?
- If there has been an opportunity for post-cook contamination, can the hazards of concern be eliminated by reheating?
- Are the food workers practicing good personal hygiene including frequent and effective handwashing?
- Was the food reheated or cooked to the proper temperature before being placed out of temperature control?
- What is the current temperature of the food when taken with a probe thermometer?
- How long has the food been out of temperature control (ask both the manager and food employees)?
- Are the answers of the food employees and the manager consistent with one another when asked how long the food has been out of temperature control?
- Is it likely that food has cooled to its current temperature after being out of temperature control for the alleged time?
- Will the food be saved as leftovers?
- How long before the food will be served?
- Given what you know about the food, the food's temperature, the handling of the food, and the alleged time out of temperature, is it reasonably likely that the food already contains hazards that cannot be destroyed by reheating?



The answers to these questions, in combination with observations you make during your inspection, should provide you with enough information to make the appropriate recommendation for on-site correction. If you are still unable to determine the most appropriate disposition of the food after you have conducted your assessment, you may want to consult your supervisor.



As you can see, there is no "catch-all" rule for determining the appropriate on-site correction. Due to the economic hardship that may be involved, it is important for you to base your recommendations on sound science. It is crucial that you have a significant, working knowledge of food microbiology. Your final decision should be based on the best scientific analysis and professional judgment after considering all the information that you have at hand. In some cases, you may even need to consult with other food safety professionals to determine if a food is safe to eat or whether a correction is needed.

LONG-TERM COMPLIANCE

While on-site correction of out-of-control risk factors is essential to consumer protection, achieving long-term compliance is equally important. Overcoming several misconceptions about long term compliance will help you in achieving a desirable change of behavior. For example, in jurisdictions using a 44-item inspection report in which only observed violations are marked, it is often taken for granted that if there are no violations marked, the risk factors are being controlled. This is not necessarily true since the observation of code violations is subject to many variables such as the time of day or duration of the inspection. Another misconception is that training alone will result in risk factors being controlled. While training may help, there is no guarantee that knowledge acquired will equate to knowledge applied in the workplace. Another assumption is that enforcement actions such as citations or administrative hearings or on-site corrections will automatically result in future management control. Unfortunately, there is no assurance that any of these actions will result in the long-term control of risk factors.

Long-term compliance may best be achieved through voluntary actions by the operator. If an operator supports the concept that a food safety management system is needed, there is a better chance that long-term compliance will be achieved. The following system components may be used alone or in combination by the operator to provide voluntary active managerial control of risk factors:

Equipment and Layout – Critical limits are difficult to achieve when equipment does not work properly. Proper calibration of equipment is vital to achieving food safety. When calibration is unsuccessful or is not feasible, equipment should be replaced. In addition to equipment malfunctioning, poor equipment layout can present opportunities for cross contamination and must be considered. For example –

- Hamburgers with uniform thickness and weight are not all reaching a safe cooking temperature in a given time. Upon examination, it is determined that the grill is distributing heat unevenly. A new element is installed to correct the problem.

- Splash from a nearby handwashing sink is seen on a prep table. A splash guard is installed to prevent cross contamination from the handwashing sink to the prep table.

Buyer Specifications – Written specifications for the goods and services purchased by an establishment prevents many problems. For example –

- Fish posing a parasite hazard and intended for raw consumption has not been frozen for the specified time and temperature and no freezing equipment is on-site at the retail facility. Buyer specifications are established to place the responsibility for freezing the fish on the supplier.

- Lobster tails, hamburgers, or other products cooked with a set time parameter on a conveyor are not reaching the proper temperature in the specified time because they are larger than the size for which the conveyor is calibrated. Buyer specifications are established to restrict the size of products received from the supplier.

Recipe/Process Instructions – Simple control measures integrated into recipes and processes can improve management control over risk factors. For example –

- Process instructions that specify using color-coded cutting boards for separating raw animal foods from ready-to-eat products are developed to control the potential for cross contamination.

- Pasteurized eggs are substituted in recipes that call for raw or undercooked eggs to reduce the risk of foodborne illness.

- Commercially, precooked chicken is used in recipes calling for cooked chicken such as chicken salad to reduce the risk of contaminating food contact surfaces and ready-to-eat food with raw chicken.

First-In-First-Out (FIFO) – Product rotation is important for both quality and safety reasons. "First-In-First-Out" means that the first batch of product prepared and placed in storage should be the first one sold. Date marking foods as required by the *Food Code* facilitates the use of a FIFO procedure. The FIFO concept limits the potential for pathogen growth, encourages product rotation, and documents compliance with time/temperature requirements.

Standard Operating Procedures (SOPs) – Following standardized, written procedures for performing various tasks ensures that quality, efficiency, and safety criteria are met each time the task is performed. Although every operation is unique, the following list contains some common management areas that can be controlled with SOPs:

- Personnel (disease control, cleanliness, training)
- Facility maintenance
- Sanitary conditions (general cleaning schedule, chemical storage, pest control, sanitization of food contact surfaces)
- Sanitary facilities (approved water supply and testing, if applicable, plumbing, sewage disposal, handwashing and toilet facilities, trash removal)
- Equipment and utensil maintenance

SOPs can also be developed to detail procedures for controlling risk factors:

- Procedures are implemented for measuring temperatures at a given frequency and for taking appropriate corrective actions to prevent hazards associated inadequate cooking.

- Adequate handwashing is achieved by following written procedures that dictate frequency, proper technique, and monitoring.

Risk Control Plans (RCPs) – An RCP is a concisely written management plan developed by the retail or food service operator with input from the health inspector that describes a management system for controlling specific out-of-control risk factors. An RCP is intended to be a voluntary strategy that you and the person in charge jointly develop to promote long-term compliance for *specific* out-of-control risk factors. For example, if food is improperly cooled in the establishment, a system of monitoring and record keeping outlined in an RCP can ensure that new procedures are established to adequately cool the food in the future. By implementing basic control systems over a period of time (e.g., 60 – 90 days), it is likely that the new controls will become "habits" that continue.

An RCP should stress simple control measures that can be integrated into the daily routine. It should be brief, no more than one or two pages for a single risk factor, and address the following points in very specific terms:

- What is the risk factor to be controlled?
- How is the risk factor controlled?
- Who is responsible for the control?
- What monitoring and record keeping is required?
- Who is responsible for monitoring and completing records?
- What corrective actions should be taken when deviations are noted?
- How long is the plan to continue?
- How are the results of the RCP communicated to you?

By implementing an RCP, the retail or food service operator will have the opportunity to determine the appropriate corrective action for the identified problem and design an implementation strategy to best suit their facility and operation. Since the RCP is tailored to meet the needs of the establishment, the operator takes complete ownership of the plan and is ultimately responsible for its development and implementation. Your role as the health inspector is to consult with the operator by suggesting ways that the risk factor(s) might be controlled. By creating an RCP, the operator realizes that a problem exists in their food safety management system and commits to a specific correction plan rather than merely acknowledging a single violation. Follow up by telephone or in person indicates to the operator your interest in seeing their plan succeed. This also gives you an opportunity to answer any questions and offer feedback to make the RCP more useful. An example of an RCP, along with a blank template that you can use, is found in Annex 5 of this Manual.

Voluntary Food Safety Management Systems based on HACCP Principles: The *Food Code* only requires HACCP plans for a few specific specialized processes; however, the development of voluntary HACCP plans is always encouraged. The FDA document *"Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments"* is written for this purpose. A retail or food service operator, in consultation with an appropriate regulatory authority or other food safety professional, can use this document to establish an effective food safety management system based on the principles of HACCP. The document is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/hret2toc.html. Annex 2 contains tables that can be used by industry to develop HACCP plans. The use of HACCP as a food safety management system is discussed in more detail in Chapter 4 of this Manual.

SUMMARY

The regulatory inspection provides you with an opportunity to work with an operator to strengthen the existing food safety management system. Regulatory programs can integrate some, if not all, of these risk-based concepts into their compliance and enforcement protocol. At a minimum, you can suggest some of these intervention strategies to retail and food service operators as ways for them to take ownership of food safety by reducing the recurrence of out-of-control risk factors identified during your inspection. Integrating strategies designed to change long-term behavior will be the most effective way to reduce the risk of foodborne illness in a facility.

A list of suggested intervention strategies to achieve on-site correction and long-term compliance for out-of-control procedures is found in Annex 6 of this Manual. The list illustrates the application of intervention strategies in an inspection program.

Chapter 4 – Reviewing Voluntary Food Safety Management Systems

The FDA *Food Code* only requires a comprehensive HACCP plan when conducting certain specialized processes that present a significant health risk if not conducted under strict operational procedures. Examples include Reduced Oxygen Packaging (ROP) and formulating a food to render it non potentially hazardous by adding acids or preservatives. In most cases, however, the implementation of food safety management systems based on HACCP principles is a completely voluntary effort by retail and food service operators. As discussed in Chapter 3, a retail or food service establishment may wish to develop and implement a food safety management system based on HACCP principles as a way to control the occurrence of identified foodborne illness risk factors. This manual does not apply to mandatory HACCP as required by the FDA *Food Code*.

In order to provide feedback to an operator about their food safety management system and its implementation, an operator may invite you to review their system. In this capacity, you will act as an advisor or consultant to the operator by observing the establishment's actual practices and procedures. You may wish to make recommendations to the operator based on your observations of how they are implementing their system in comparison to what is written in their plan. This chapter provides you with information that may assist you in conducting a review of a voluntary food safety management system based on HACCP principles.

VOLUNTARY FOOD SAFETY MANAGEMENT SYSTEM BASED ON HACCP PRINCIPLES

In Chapter 3, several intervention strategies that can be implemented by an operator to achieve long-term compliance of risk factors were introduced. For example, an operator may develop a risk control plan as an intervention strategy for controlling a specific out-of-control process identified during an inspection.

The implementation of a comprehensive food safety management system to cover all processes conducted in a facility offers possible advantages to an operator by providing a mechanism for achieving active managerial control of multiple foodborne illness risk factors associated with an entire operation. In other words, rather than the operator "fixing" only the specific items that you identify as lacking active managerial control during the inspection, the operator might choose to implement a comprehensive food safety management system to ensure continuous control over all foodborne illness risk factors of concern.

Other advantages of using HACCP principles may include the following:

- Reduction in product loss
- Increased product quality
- Better control of product inventory
- Consistency in product preparation and processing
- Increased profit
- Increased employee awareness and participation in food safety
- ACTIVE, rather than PASSIVE, managerial control of risk factors

It is recommended that prior to reviewing a voluntary food safety management system based on HACCP principles you read the FDA document entitled, *Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishment*. Information on obtaining a copy is found in Annex 1.

VALIDATION

A voluntarily implemented food safety management system using HACCP principles needs to be "validated." Validation, for the purposes of this discussion, means to focus on scientific and technical information to determine if the system in place will effectively control the food safety hazards once implemented. You may use observations, measurements, and evaluations taken in the establishment, as well as scientific studies and other reference materials such as the *Food Code* or other applicable regulations when validating food safety management systems.

Since voluntarily implemented food safety management systems involve normal processes and not high-risk specialized processes that might otherwise *require* a HACCP plan, regulators or other food safety professionals should be able to validate a voluntary plan without assistance. This is especially true since the critical limits listed in the plan should either be the same or more stringent than those established by the *Food Code* or other applicable regulations.

Reviewing a voluntary food safety management system to determine whether the corrective actions and the monitoring, verification, and record keeping procedures are sufficient to support the system may be time consuming. Because of this, it may be helpful to seek expert advise from outside sources. Outside sources include, but are not limited to, members of academia, private food safety consultants, and other federal and state governmental officials.

The written plan for a voluntary food safety management system based on HACCP principles may be relatively simple and therefore probably will not include complex information that you might otherwise expect to see in a mandatory HACCP plan. You should be very flexible in the application of HACCP principles during your review. Generally, a written, voluntary food safety management system developed using the FDA document entitled, *Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishment*, will include:

- Types of food included in the plan by category or by food preparation process
- Materials and equipment layout
- Formulations or recipes
- A flow diagram showing the preparation of the food
- Training plans for managers and food employees
- Scientific data or other information supporting the plan

The proposed food safety management system should also detail:

- Significant food safety hazards
- Each Critical Control Point (CCP)
- Critical limits at each CCP
- Methods, frequency, and responsible personnel for monitoring
- Corrective actions to be taken if the critical limits at each CCP are not met
- Methods, frequency, and responsible personnel for verifying that monitoring is taking place and prerequisite programs are being followed
- Records to be maintained

As you review the identified hazards in the plan, it is recommended that you check to see that all control measures vital to food safety are somehow implemented in the operation. You may use Annex 3 of this Manual to assist you. Due to the flexible nature of voluntary food safety management systems, control measures, such as proper refrigeration or cooling, may be implemented as part of the establishment's Standard Operating Procedures and not as critical control points. Remember that the goal of voluntary food safety management systems is active managerial control of foodborne illness risk factors. How the establishment achieves this goal is clearly their choice.

As you review the critical limits associated with each CCP, be sure to verify that the critical limits are in compliance with the *Food Code* or other applicable regulation. If the critical limits are not the same or more stringent than those in the *Food Code* or other applicable regulation, it may be an oversight on the part of the operator or they could be conducting a specialized process without even knowing it. If the former is true, you may merely need to inform the operator of the applicable regulations for that food or process. If the latter is true, this Manual does not apply.

Your regulations will dictate how specialized processes and deviations from your code requirements are to be handled. In some jurisdictions, deviations from the requirements

stated in the regulations are not allowed. In other jurisdictions, including those that have adopted the FDA *Food Code*, a variance and HACCP plan would be required.

In reviewing monitoring procedures at each CCP, it is recommended that the monitoring procedures include answers to the following questions:

- How will each CCP be monitored?
- What will be monitored at each CCP?
- When and how often will the monitoring take place?
- Who will be responsible for the monitoring?

You should also look to see that the monitoring intervals are adequate enough to ensure hazards are being controlled. For instance, if hot holding is designated as a CCP and the plan states that the manager will check the product temperature only once per day, the lack of frequent temperature checks may allow time for spore-forming or toxin-forming bacteria to grow to dangerous levels without any ability to take corrective action. It is clear to see how important adequate monitoring is to achieving active managerial control.

In reviewing the corrective actions for each CCP, it is recommended that you use Chapter 3 and Annex 6 of this Manual. As you look at the corrective actions the establishment has listed for each CCP, ask yourself if the procedure listed will result in safe food. If it will, then ask yourself if the procedure listed includes a mechanism for making sure that the problem does not happen again. If the answer is no to either of these questions, changes probably need to be made to the plan. The plan should also list who is responsible for taking corrective actions.

In reviewing verification procedures, look to see that the plan contains who is responsible for the verification and at what frequency. It is also suggested that voluntarily implemented food safety management systems be reviewed periodically to make sure all food safety hazards are still adequately controlled. Changes in menu items, equipment, or buyer specifications often require a change in the system. In this Manual, this review and subsequent change in the system is referred to as "revalidation."

Lastly, when record keeping procedures are reviewed, look to see that the procedures are clearly outlined including what is to be recorded and who is responsible for documenting the activities. It is recommended that you focus your review on helping the establishment determine whether or not they are using the easiest record keeping system for them, not on whether or not records should be kept for certain activities. If you can think of a more efficient record keeping system than what is being implemented, you may want to make a suggestion to the manager for his or her consideration. You may propose something that the establishment did not consider when it was developing the plan. The idea is that simple records, especially those that are already part of the establishment's normal operation, will most likely be maintained.

However, the facility may be completely comfortable with the record keeping that is already specified in their plan.

If you see that records are not specified for certain CCPs but are for others, you may want to bring it to the manager's attention since records may be helpful in verifying that monitoring and corrective actions are conducted properly. Keep in mind that the facility has developed a voluntary food safety management system tailored to their needs and available resources. If the facility does not want to keep records, your opinion of what should be documented is irrelevant as long as active managerial control is achieved. Clearly your role as a *consultant* becomes particularly important with regard to your review of record keeping procedures.

FIELD VERIFICATION

The primary purpose of field verification is to determine whether the activities carried out in support of a validated food safety management system are conducted according to the written plan. In other words, "Is the firm accurately doing what it said it does and are they operating according to the food safety management system they have in place?" By conducting a verification inspection, you can help an operator identify strengths and weaknesses in the system and offer suggestions for improvement.

Keep in mind that that there are many different types of food safety management systems. Some may control foodborne illness risk factors using only some of the principles of HACCP. Therefore, flexibility is an important component when providing guidance for voluntarily implemented food safety management systems using HACCP principles.

THE VERIFICATION PROCESS

The verification of food safety management systems involves three major activities:

- Document Review
- Record Review
- On-site Verification

Step 1 - Document Review

The review of the documents related to the food safety management system should be completed before you make on-site observations and can either be done at the office or at the establishment prior to the inspection. In order for you to gain a better understanding of the food safety management practices and procedures in place, several documents may be reviewed, including the following:

- Past inspection or verification reports
- Prerequisite programs
- Training protocols
- The written system or plan in place

A preliminary review of the food safety management system and associated documents may provide you with the following information:

- Problems noted during past inspections
- Type, frequency, and appropriateness of training given in support of the plan
- Types of potentially hazardous food and the food preparation processes
- Materials and layout of equipment used in the preparation and processing of the food
- Calibration procedures and frequency of any equipment involved
- Formulations or recipes for the food

It is also recommended that before conducting the on-site verification you become familiar with the following:

- Significant food safety hazards
- Each CCP
- Critical limits for each CCP
- Method and frequency of monitoring
- Corrective actions to be taken when critical limits are not met
- In-house verification and record-keeping procedures

Step 2 - Record Review

The record review is a “spot check” to ensure that routine monitoring and in-house verification by management is occurring as specified in the plan. As you conduct the record review, ask yourself, “Do the records show that activities are being performed as specified in the plan?”

The record review should take place after the document review because it will provide –

- A better understanding of the strengths and weaknesses in the food safety management system allowing you to concentrate on those areas needing strengthening

- An opportunity to become more familiar with the types of forms used in the operation before actually reviewing them

There are at least 5 types of records or information generated to support the food safety management system that may be spot-checked:

- Prerequisite program records (i.e. training logs)
- Monitoring records (i.e. time-temperature logs)
- Corrective action records (i.e. shipment rejection logs)
- Calibration records (i.e. logs of thermometer or pH meter calibrations)
- Evidence of verification (i.e. management oversight of activities related to the food safety management system)

To review the records, two approaches are suggested:

1. Randomly select a variety of records, spot checking different time periods. Then review each record to verify that all the CCPs, associated critical limits, monitoring procedures and frequencies, corrective actions, verification and calibration activities have taken place on those days.

   For example: Pick one week from the previous month and identify the CCPs and critical limits for the processes used. Check to see if the monitoring was done properly and at the required frequency stated in the plan. If you note deviations from the critical limits, check to see that the appropriate corrective actions were documented. Additionally, check to make sure that the activities were verified and that the equipment used was properly calibrated.

2. Randomly select a few days of records, but focus only on the CCPs that appear difficult to monitor or that have shown record-keeping or compliance problems in the past. Use these records to review the associated critical limits, monitoring procedures and frequencies, corrective actions, verification and calibration activities for those days.

   For example: Looking over past inspection reports, you see that hot holding has historically been a problem in this establishment. You may select one week at random from the past month and check to see if hot holding was monitored properly and at the required frequency, as stated in the plan. If deviations from the hot holding critical limit were noted, check to see that the appropriate corrective actions were documented. Additionally, check to make sure that the activities were verified and that the equipment used was properly calibrated.

It is also a good idea to include the current day's records in your review. Seeing the real-time activities of the plan will give you insight into the accuracy and consistency of the monitoring prescribed in the plan.

Some questions to ask yourself as you review the records include:

- Do the recorded critical limits meet or exceed those specified in the plan?
- If deviations from critical limits are noted, do the records indicate that the appropriate corrective actions were taken?
- Do the records indicate the monitoring and verification frequencies and the individuals performing these duties?
- Do the records indicate that calibrations are being completed according to the prescribed frequency and method?

At the conclusion of the record review, determine if there are any patterns to the deviations. Multiple deviations at the same CCP can indicate that difficulties exist in controlling or monitoring that CCP. Such observations may trigger a revalidation of the system. Also, be sure to keep the group of records that you have reviewed with you so that you can continue to evaluate the critical limits, monitoring, corrective actions, etc. during the on-site verification portion of your inspection.

Special Considerations Regarding Records

Remember that the maintenance of records is required in the *Food Code* only in a limited number of cases. Records generated in support of a voluntary food safety management systems are 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 for the operator to maintain shellstock tags in chronological order for at least 90 days, you could verify this requirement just as you would during a normal routine inspection.

In contrast, if for instance you find documented cases of inadequately cooked or hot held foods being sold to consumers, you cannot take regulatory action based on the documentation. Documentation of hot holding and cooking, like most processes in your regulations, is not required. The fact that the establishment is keeping records of these processes means they are going above and beyond what is required by your regulations to establish a system that will ensure food safety. You do not want to discourage this effort by attempting to take regulatory action on voluntarily kept records. Of course, you should point these discrepancies out to management and offer

recommendations to the establishment to prevent the problems from happening again. Revalidation of the system may result from your recommendations.

To avoid any confusion, it is not recommended that you conduct an on-site verification of a voluntary food safety management system at the same time as your regulatory inspection. If, due to time and resource constraints, you must conduct an on-site verification at the same time as your regulatory inspection, remember that items on your inspection form can only be marked for violations of procedures or practices that you observe during your inspection. Records may not be used to support a violation of the code unless their maintenance is specifically required in your regulations
Another important consideration is that a food safety management system may have critical limits that exceed those of your regulations. For example, many operators choose to set their critical limits for cooking all foods at 180 ºF for 15 seconds. If you discover during your record review or on-site verification that foods are only cooked to 165 ºF, then they are adhering to your regulations but not their written plan. This should be pointed out to management so they can take whatever action they deem necessary.

Of course, if during your record review you find evidence that a product still in circulation poses a serious health threat to the public, you should not only alert the operator but you should also initiate an appropriate regulatory investigation as dictated by your regulatory agency. If it is known by either party that a product still on the market poses a health threat to consumers, both parties must play their respective roles to remove the product immediately. This may involve voluntary recall of the suspected products.

Step 3 – On-site Verification

On-site verification is used in conjunction with the document review and record review to determine whether the activities carried out in support of the food safety management system are conducted according to the written plan. During the on-site verification, remember to look at whether activities you observe are consistent with what is noted in the records and supporting documents.

On-site verification involves observing activities of all the elements involved in the plan, i.e. the employees, the person in charge, the equipment, etc. It is important to spend sufficient time during the inspection to get a feeling for whether the activities in the plan are really part of the operation's daily routine. Be sure to ask the person in charge *and* the food employees many open-ended questions to obtain information that you need about the operation. For example, ask, "How often do you check the temperature?" rather than, "Do you check the temperature every 2 hours?" The information you gather from the person in charge and the food employees, along with your own observations, should provide answers to the following questions:

- Are required activities being performed according to established procedures as outlined in the food safety management system?

- Are activities checked or monitored according to the established methods, with proper equipment, procedures, etc.?
- Do the individuals performing the activity understand their duties?
- Have the individuals performing the activity noted any problems that may be of concern?
- Are on-site observations consistent with the records kept and reviewed in the record review portion of your verification inspection?

One key objective of on-site verification should be to confirm that the flow diagrams and the equipment layout are still accurate. This can be done by selecting a sample of menu items, with diverse preparation requirements, and "walking" through the food preparation process from receipt to service.

During the on-site observation, place special emphasis on determining whether corrective actions are taken when critical limits are not met. You should assume that corrective actions were anticipated in the operation of the system.

For example, if you note that critical limits are not being met at a CCP, observe and record the food worker's response based on the following:

- Was the deviation handled in a manner prescribed in the plan?
- If not, how was the deviation handled?
- How was the process brought back under control so that the deviation would not recur?

Verification Report

At the conclusion of the on-site verification, a report similar to the one in Annex 7 of the Manual may be completed. The report in Annex 7 contains a suggested checklist to use when evaluating a food safety management system. It can be modified to the particular needs of your jurisdiction or a particular establishment.

SUMMARY

FDA has provided guidance to operators of retail and food service establishments who wish to implement voluntary food safety management systems based on HACCP principles. Periodic review of these systems provides the operator with valuable information that can be used to make improvements. As a food safety professional, your knowledge and expertise make you qualified to conduct such reviews, but only at the request of the operator. It should be noted, however, that you can sufficiently determine if an operator has active managerial control of foodborne illness risk factors by simply conducting a risk-based inspection. Validation and verification of voluntarily implemented food safety management systems are services you can offer your industry partners to provide them with feedback on how well their system is working.

Glossary

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

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.

COMPETITIVE MICROFLORA means the microorganisms naturally present in potentially hazardous food that compete with pathogens for the available water, nutrients, and oxygen.

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

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 conducted by a person when 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 food safety hazard or reduce it to an acceptable level.

CRITICAL LIMIT means one or more prescribed parameters that must be met to ensure that food safety hazards are controlled at a CCP.

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.

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

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

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.

EXTRINSIC FACTORS OF FOOD means the factors that people can readily control involving food, such as temperature, acidity, and availability of oxygen.

FOOD PREPARATION PROCESS means the series of operational steps conducted to produce a food ready to be consumed, i.e. Preparation of Ready-to-eat Food with No Cook Step, Preparation for Same Day Service, and Complex Food Preparation.

FOODBORNE ILLNESS means illness 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.

HAZARD means a biological, chemical, or physical 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.

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

HACCP SYSTEM means the result of the implementation of the HACCP plan. A HACCP system includes the HACCP plan and all the prerequisite programs.

HIGHLY SUSCEPTIBLE POPULATION (HSP) means persons who are more likely than other populations to experience foodborne disease because they are either immunocompromised, preschool age children (infants or toddlers), or older adults.

INFECTIOUS MICROORGANISMS means pathogenic bacteria, viruses, or parasites, that when ingested, cause foodborne illness in humans.

INTRINSIC FACTORS OF FOOD means the factors that are inherent to the food and are not readily controlled by people in a retail facility, such as water activity, nutrient content, and competitive microflora.

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

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

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 manner that harms or is of no advantage to the host. Parasites, like *T. spiralis* or *T. gondii*, do not grow in food, only inside of the body once ingested.

PATHOGEN means a microorganism (bacterium, parasite, virus, or fungi) that causes disease in humans.

PATHOGENIC LOAD means the expected amount of pathogens on a raw product, i.e. amount of *Salmonella* on chicken.

PERSON IN CHARGE means the individual present at a food establishment who is responsible for the operation at the time of inspection.

pH means the measure of the acidity of a product.

POTENTIALLY HAZARDOUS FOOD (PHF) means a natural or synthetic food that requires temperature control because it is in a form capable of supporting:

- The rapid and progressive growth of infectious or toxigenic microorganisms;
- The growth and toxin formation of *Clostridium botulinum*; or
- In raw shell eggs, the growth of *Salmonella* Enteritidis.

PHF includes:

- animal food (a food of animal origin) that is raw or heat treated
- a food of plant-origin that is heat-treated or consists of raw seed sprouts
- cut melons
- garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support the growth of pathogenic microorganisms

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

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.

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

RISK CONTROL PLAN (RCP) means a concisely written management plan developed by the retail or food service operator with input from the health inspector that describes a management system for controlling specific out-of-control risk factors**.**

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.

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..

> Spore-formers in food include *Clostridium botulinum*, *Bacillus cereus,* and *Clostridium perfringens*.

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

TOXIGENIC MICROORGANISM means pathogenic bacteria that causes foodborne illness in humans due to the ingestion of toxins produced in food.

> Toxigenic microorganisms in food include *Staphylococcus aureus*, *Bacillus cereus,* and *Clostridium botulinum*.

VALIDATION means, for the purpose of this Manual, to focus on scientific and technical information to determine if the food safety management system in place will effectively control the food safety hazards once implemented.

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

VERIFICATION means those activities, other than monitoring, that determine the validity of the HACCP plan and show that the system is operating according to the plan.

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 – References

The following is a partial list of references and sources of information that may be helpful to you in evaluating food safety management systems that are developed by operators in your jurisdiction. This list is not intended to be all-inclusive. FDA does not endorse material that is not published by the federal government, though examples of such material may be listed for your reference.

AGENCIES

United States Food and Drug Administration

- **Center for Food Safety and Applied Nutrition (CFSAN), Retail Food Protection Branch**

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

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FDA PUBLICATIONS AND FEDERAL REGULATIONS

A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments, available on FDA/CFSAN website at: http://www.cfsan.fda.gov/~dms/hret2toc.html

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.

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Annex 2
Sample HACCP Tables

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

FOOD/MENU ITEMS:						
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

FOOD/MENU ITEMS:							
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

FOOD/MENU ITEMS:						
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

FOOD/MENU ITEMS:							
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

FOOD/MENU ITEMS:						
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

FOOD/MENU ITEMS:							
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 3 - Hazard Analysis

This Annex provides guidance for determining food safety hazards in foods and/or food preparation processes at retail.

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 Recommended 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 toxioinfection 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 cased 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.

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

Table 3. 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 4. 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 5. 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 4 - Food Safety Questions

In order to assure yourself that you are conducting comprehensive, risk-based inspections, you may want to ask yourself the following sample list of questions before leaving establishments. This list addresses the significant food safety concerns for each operational step in the flow of food through the establishments. This sample list can be used as a tool to help you focus your inspections on assessing the active managerial control of foodborne risk factors. Assessment of whether establishments are actively monitoring critical processes is especially important in your assessment of establishments' active managerial control of foodborne illness risk factors. Note that this list is not intended to be a questionnaire for operators, but rather a tool to help you remember the critical processes to evaluate during your inspections.

RECEIVING

1. Is their food from an approved source?
2. How do they verify that their food is from an approved source?
3. How do they know if the food is at the proper temperature upon receipt?
4. What kind of refusal policy do they have?
5. Do they keep receiving logs (not required)?
6. How do they verify the source of shellfish?
7. How do they maintain certification records for fish that must be frozen to destroy parasites as specified in the Food Code?

COLD STORAGE/COLD HOLDING

1. How do they monitor their refrigeration units to ensure that they are maintaining proper temperature?
2. Is their date marking procedure acceptable?
3. How do their employees know what food is to be used first?
4. Are their storage practices for RTE and raw food acceptable?
5. Where are their thermometers stored? Are they calibrated? How often?
6. What kind of monitoring procedures do they implement for ensuring food is at the proper cold holding temperature?
7. Do they keep temperature logs (not required in most cases)?.

PREPARATION

1. What steps do they use to prevent cross-contamination?
2. What training is given for handwashing?
3. What is their handwashing policy?

4. How do they clean and sanitize their equipment?
5. How do their employees eliminate bare hand contact with RTE food?
6. How do their employees minimize bare hand contact with food that is not RTE?
7. How do they process fruits and vegetables before service?
8. Do they serve a highly susceptible population?

COOKING

1. Does the staff know the correct cooking temperatures?
2. Do they have a consumer advisory?
3. Are cooking temperatures monitored?
4. What corrective actions are taken when food does not reach the proper temperature?
5. Are cooking temperature logs maintained (not required)?

COOLING

1. How is food cooled?
2. How are temperatures monitored?
3. How do they ensure that the prescribed time frames are met?
4. What corrective actions do they take if the time frames are not met?
5. Are cooling records maintained (not required)?

REHEATING

1. What happens to leftovers?
2. How are food products reheated? Stove/oven, microwave, steam table, other?
3. How are temperatures monitored?
4. Are reheating records maintained (not required)?
5. What corrective actions are taken?

HOT HOLDING

1. How are cooked foods held until service?
2. How is temperature controlled? Steam table, stove/oven, hot box, other?
3. How are the temperatures monitored?
4. How are temperature records maintained (not required)?
5. What corrective actions are taken when food is found out of temperature?
6. Is temperature maintained during distribution if food is transported off-site?

TIME ALONE AS A PUBLIC HEALTH CONTROL

1. How long is PHF being held out of temperature before or after cooking?
2. How is the time out of temperature controlled?

3. How is time monitored?
4. How are time records maintained? As specified in the Food Code?

Annex 5 - Risk Control Plans

Example Risk Control Plan for Turkey Vegetable Soup

Establishment Name: ABC Establishment			**Type of Facility:** Full Service
Physical Address: 123 Any Street			**Person in Charge:** John Doe
City: Any City	**State:** Any State	**Zip:** 00000	**County:** Any County
Inspection Time In: 9:00 a.m.	**Inspection Time Out:** 12:30 p.m.	**Date:** July 12, 2001	**Inspector's Name:** Jane Doe
Agency: Your jurisdiction			

Specific observation noted during inspection:

Temperature of turkey vegetable soup in walk-in cooler was 65 ºF after cooling in the walk-in all night (12 hours).

Applicable code violation(s):

Food Code Section 3-501.14 – Soup not cooled from 140 ºF – 41 ºF in 6 hours or less

Risk factor to be controlled:

Improper Holding Temperatures (Cooling)

What must be done to achieve compliance in the future:

Cool from 140 to 41 ºF within 6 hours provided that food is cooled from 140 to 70 ºF in ≤ 2 hours.

How will active managerial control be achieved:

(Who is responsible for the control, what monitoring and record keeping is required, who is responsible for monitoring and completing records, what corrective actions should be taken when deviations are noted, how long is the plan to continue)

Conduct a Trial Run to Determine if Cooling Procedure Works

The head chef will portion soup at a temperature of 140 ºF in cleaned and sanitized 3-inch metal pans, and place them uncovered in the coolest, protected area of the walk-in cooler. He will record the time on the "Time-Temperature Log." Two hours later, the temperature of the soup will be checked and recorded. If the temperature of the soup is not 70 ºF or less, the soup will be reheated to 165 ºF, and the trial run will be restarted in an ice bath. When the temperature is 70 ºF or less within 2 hours, the time and temperature will be recorded, and cooling will continue. Four hours later, the temperature of the soup will again be checked and recorded. If the soup is 41 ºF or less, the cooling procedure will be established. If the soup is not 41 ºF or less, it will be discarded and other cooling options will be used (see below).

Procedure

When there is less than one gallon of soup left over at the end of the day, the head chef will log the volume and disposition of the soup. When the volume is greater than one gallon, the established procedure will be followed. The head chef will complete the Temperature Log daily for 30 days. The general manager will review the log weekly for completeness and adherence to the procedure**.**

Other options that may be suggested to the operator include: purchasing a data logger to record cooling overnight; discarding any leftover soup at the end of the day; using chill sticks/ice paddles; using a ice bath to cool leftovers prior to storage; and purchasing a blast chiller).

How will the results of implementing the RCP be communicated back to the inspector:

The log will be available for review by the regulatory authority upon request.

As the person in charge of the _____ located at _____,
I have voluntarily developed this risk control plan, in consultation with
_____ and understand the provisions of this plan.

_____ _____
(establishment manager) (date)

_____ _____
(regulatory official) (date)

Risk Control Plan

Establishment Name:			**Type of Facility:**
Physical Address:			**Person in Charge:**
City:	**State:**	**Zip:**	**County:**
Inspection Time In:	**Inspection Time Out:**	**Date:**	**Inspector's Name:**
Agency:			

Specific observation noted during inspection:

_____

_____

_____

Applicable code violation(s):

_____

_____

_____

Risk factor to be controlled:

_____

What must be achieved to gain compliance in the future:

_____

_____

_____

How will active managerial control be achieved:

(Who is responsible for the control, what monitoring and record keeping is required, who is responsible for monitoring and completing records, what corrective actions should be taken when deviations are noted, how long is the plan to continue)

How will the results of implementing the RCP be communicated back to the inspector:

As the person in charge of the _____ located at _____,
I have voluntarily developed this risk control plan, in consultation with
_____ and understand the provisions of this plan.

_____ _____
(establishment manager) (date)

_____ _____
(regulatory official) (date)

Annex 6
Suggested Intervention Strategies For Out-of-Control Procedures

Out-of-Control Procedure	Associated Hazards	On-site correction (COS)	Long-term Compliance
Bare Hand Contact with RTE Food	Bacteria, Parasites, and Viruses via Fecal-oral Route	Conduct Hazard Analysis (See Chapter 3 and Annex 3).	RCP, Train Employees, SOP/HACCP Development
Cold Holding	Vegetative Bacteria, Toxin-forming and Spore-forming Bacteria, Scrombrotoxin (Finfish)	Conduct Hazard Analysis (See Chapter 3 and Annex 3).	Change Equipment, RCP, Train Employees, Develop SOP/HACCP/Recipe
Contaminated Equipment	Bacteria, Parasites, and Viruses	Clean and Sanitize Equipment; Discard or Reheat RTE Food.	Train Employees, Change Equipment or Layout, Develop SOP
Cooking	Vegetative Bacteria, Parasites, and Possibly Viruses	Continue Cooking to Proper Temperature.	Change Equipment, RCP, Train Employees, Develop SOP/HACCP/Recipe
Cooling	Toxin-forming and Spore-forming Bacteria	Conduct Hazard Analysis (See Chapter 3 and Annex 3).	Change Equipment, RCP, Train Employees, Develop SOP/HACCP/Recipe
Cross-Contamination of RTE Foods with Raw Animal Foods	Bacteria, Parasites, and Possibly Viruses	Discard or Reheat RTE Food.	Change Equipment Layout, RCP, Train Employees, Develop SOP/HACCP/Recipe
Food Source/ Sound Condition	Bacteria/Parasites/ Viruses/Scombrotoxin/ Ciguatera Toxin	Reject or Discard.	Change Buyer Specifications, Train Employees
Freezing to Control Parasites	Parasites	Freeze Immediately; Discard; or Cook.	Change Buyer Specifications, RCP, Develop SOP/HACCP/Recipe, Change Equipment, Train Employees
Handwashing	Bacteria, Viruses, and Parasites	Wash Hands Immediately; Conduct Hazard Analysis (See Chapter 3 and Annex 3).	Change Equipment Layout, Train Employees, RCP, Develop SOP/HACCP
Hot Holding	Toxin-forming and Spore-forming Bacteria	Conduct Hazard Analysis (See Chapter 3 and Annex 3).	Change Equipment, RCP, Train Employees, Develop SOP/HACCP/Recipe
Receiving Temperatures	Scombrotoxin, Bacteria	Reject or Discard.	Change Buyer Specifications, Train Employees, Develop SOP/HACCP/Recipe
Reheating	Vegetative Bacteria; Toxin-forming and Spore-forming Bacteria	Conduct Hazard Analysis (See Chapter 3 and Annex 3).	Change Equipment, RCP, Train Employees, Develop SOP/HACCP/Recipe

Annex 7
Verification Inspection Checklist

Date: _____Time: _____ Scheduled (S)/Unscheduled (U): _____
Establishment Name:_____
Est. Address:_____
Person in Charge: _____ Health Inspector:_____

Document Review

1. Documents provided for review:

Type of Document	Reviewed (Y or N)	Comments/Strengths/ Weaknesses Noted
Prerequisite Programs (list them below)		
Menu or Food List or Food Preparation Process		
Flow Diagrams (Food Preparation)		
Equipment Layout		
Training Protocols		
Hazard Analysis		
Written Plan for Food Safety Management System		
Other		

2. List Critical Control Points (CCPs) and Critical Limits identified by the establishment's HACCP plan.

Food Item or Process	Critical Control Point	Critical Limits	Comments/Problems Noted

3. What monitoring records are required by the plan?

Type of Record (Prerequisite Program Activities, Monitoring, Corrective Action, CCP Verification, etc.)	Monitoring Frequency and Procedure (How often?, Initialed and dated?, etc.)	Record Location (Where kept?)

4. Describe the strengths or weaknesses with the current monitoring or record keeping regimen.

Comments:_____
_____
_____

5. Who is responsible for verification that the required records are being completed and being properly maintained?

Comments:_____
_____
_____

6. Describe the training that has been provided to support the system?

Comments:_____

7. Describe examples of any documentation that the above training was accomplished?

Comments:_____

Record Review and On-site Inspection

(Choose at random one week from the previous four)

8. Are monitoring actions performed according to the plan?
   ○ Full Compliance ○ Partial Compliance ○ Non-Compliance

Comments:_____

9. When critical limits established by the plan are not met, are immediate corrective actions taken and recorded? ○Yes ○ No

Comments: _____

10. Do the corrective actions taken reflect the same actions described in the establishment's plan? ○ Yes ○ No

Comments:_____

11. Are routine calibrations required and performed according to the plan?

○ Yes ○ No

Comments:_____

(Examine the current day's records, if possible)

12. Are the records for the present day accurate for the observed situation in the facility?

○ Yes ○ No

Comments:_____

13. Do managers and employees demonstrate knowledge of the system?

Managers: ○ Yes ○ No Employees: ○ Yes ○ No

Comments:_____

Continued Considerations

14. Have there been any changes to the menu or recipes since the last verification visit?

○ Yes ○ No

15. Was the system modified because of these menu or recipe changes?

○ Yes ○ No

Comments:_____

Additional Comments or Recommendations:

Annex 8
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 16 hours per response, 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
Division of Cooperative Programs (HFS-625)
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 03/31/2009).