

# **4 Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors**

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## **1. ACTIVE MANAGERIAL CONTROL**

- (A) What is the common goal of operators and regulators of retail food and food service establishments and what is presently being done to achieve this goal?**

The common goal of operators and regulators of retail and food service establishments is to produce safe, quality food for consumers. Since the onset of regulatory oversight of retail and food service operations, regulatory inspections have emphasized the recognition and correction of food safety violations that exist at the time of the inspection. Recurring violations have traditionally been handled through re-inspections or enforcement activities such as fines, suspension of permits, or closures. Operators of retail and food service establishments routinely respond to inspection findings by correcting violations, but often do not implement proactive systems of control to prevent violations from recurring. While this type of inspection and enforcement system has done a great deal to improve basic sanitation and to upgrade facilities in the United States, it emphasizes reactive rather than preventive measures to food safety. Additional measures must be taken on the part of operators and regulators to better prevent or reduce foodborne illness. Annex 5 of the Food Code provides additional information on conducting risk-based inspections. It should be reviewed in

conjunction with the material found in this Annex to better understand the role of the regulator in facilitating active managerial control by the operator.

**(B) Who has the ultimate responsibility for providing safe food to the consumer?**

The responsibility of providing safe food to the consumer is shared by many people in every stage in the production of food, including consumers, themselves. Since most consumers receive their food from retail and food service establishments, a significant share of the responsibility for providing safe food to the consumer rests with these facilities. Working together with their regulatory authorities, operators of retail and food service establishments can make the greatest impact on food safety.

**(C) How can foodborne illness be reduced?**

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

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

In 1998, FDA initiated a project designed to determine the incidence of foodborne illness risk factors in retail and food service establishments. Inspections focusing on the occurrence of foodborne illness risk factors were conducted in establishments throughout the United States. The results of this project are published in the 2000 *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, commonly referred to as the "FDA Baseline Report." The Baseline Report is available from FDA through the following website: <http://www.cfsan.fda.gov/~dms/retrsk.html>. The data collection project was repeated in 2003 and the results are published in the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)*. This second report is available from FDA through the following website: <http://www.cfsan.fda.gov/~dms/retrsk2.html>. An additional data collection project is planned for 2008.

The CDC Surveillance Report and the results from the FDA Baseline Report and second data collection project, support the concept that operators of retail and food service establishments must be proactive and implement food safety management systems that will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors. By reducing the occurrence of foodborne illness risk factors, foodborne illness can also be reduced.

## **(D) How can the occurrence of foodborne illness risk factors be reduced?**

To effectively reduce the occurrence of foodborne illness risk factors, operators of retail and food service establishments must focus their efforts on achieving active managerial control. The term “active managerial control” is used to describe industry’s responsibility for developing and implementing food safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors.

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 foodborne illness risk factors. Regulatory inspections and follow-up activities must also be proactive by using an inspection process designed to assess the degree of active managerial control that retail and food service operators have over the foodborne illness risk factors. In addition, regulators must assist operators in developing and implementing voluntary strategies to strengthen existing industry systems to prevent the occurrence of foodborne illness risk factors. Elements of an effective food safety management system may include the following:

- Certified food protection managers who have shown a proficiency in 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 foodborne illness risk factors.

A food safety management system based on Hazard Analysis and Critical Control Point (HACCP) principles contains many of these elements and provides a comprehensive framework by which an operator can effectively control the occurrence of foodborne illness risk factors.

## 2. INTRODUCTION TO HACCP

### (A) What is HACCP and how can it be used by operators and regulators of retail food and food service establishments?

Hazard Analysis and Critical Control Point (HACCP) is a systematic approach to identifying, evaluating, and controlling food safety hazards. Food safety hazards are biological, chemical, or physical agents that are reasonably likely to cause illness or injury in the absence of their control. Because a HACCP program is designed to ensure that hazards are prevented, eliminated, or reduced to an acceptable level before a food reaches the consumer, it embodies the preventive nature of “active managerial control.”

Active managerial control through the use of HACCP principles is achieved by identifying the food safety hazards attributed to products, determining the necessary steps that will control the identified hazards, and implementing on-going practices or procedures that will ensure safe food.

Like many other quality assurance programs, HACCP provides a common-sense approach to identifying and controlling problems that are likely to exist in an operation. Consequently, many food safety management systems at the retail level already incorporate some, if not all, of the principles of HACCP. Combined with good basic sanitation, a solid employee training program, and other prerequisite programs, a food safety management system based on HACCP principles will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors that lead to out-of-control hazards.

HACCP represents an important tool in food protection that small independent businesses as well as national companies can use to achieve active managerial control of risk factors. The *Food Code* requires a comprehensive HACCP plan when conducting certain specialized processes at retail such as when a variance is granted or when a reduced oxygen packaging method is used. However, in general, the implementation of HACCP at the retail level is voluntary. FDA endorses the voluntary implementation of food safety management systems based on HACCP principles as an effective means for controlling the occurrence of foodborne illness risk factors that result in out-of-control hazards.

While the operator is responsible for developing and implementing a system of controls to prevent foodborne illness risk factors, the role of the regulator is to assess whether the system the operator has in place is achieving control of foodborne illness risk factors. Using HACCP principles during inspections will enhance the effectiveness of routine inspections by incorporating a risk-based approach. This helps inspectors focus their inspection on evaluating the effectiveness of food safety management systems implemented by industry to control foodborne illness risk factors.

The principles of HACCP are also an integral part of the draft *FDA's Recommended Voluntary National Retail Food Regulatory Program Standards*. For regulatory program managers, the use of risk-based inspection methodology based on HACCP principles is a viable and practical option for evaluating the degree of active managerial control operators have over the foodborne illness risk factors. The complete set of *Program Standards* is

available from FDA through the following website: <http://www.cfsan.fda.gov/~dms/ret-toc.html>.

## **(B) What are the Seven HACCP Principles?**

In November 1992, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) defined seven widely accepted HACCP principles that explained the HACCP process in great detail. In 1997, NACMCF reconvened to review the 1992 document and compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene. Based on this review, NACMCF again endorsed HACCP and defined HACCP as a systematic approach to the identification, evaluation, and control of food safety. Based on a solid foundation of prerequisite programs to control basic operational and sanitation conditions, the following seven basic principles are used to accomplish this objective:

- Principle 1: Conduct a hazard analysis
- Principle 2: Determine the critical control points (CCPs)
- Principle 3: Establish critical limits
- Principle 4: Establish monitoring procedures
- Principle 5: Establish corrective actions
- Principle 6: Establish verification procedures
- Principle 7: Establish record-keeping and documentation procedures.

This Annex will provide a brief overview of each of the seven principles of HACCP. A more comprehensive discussion of these principles is available from FDA by accessing the NACMCF guidance document on the FDA Web Page at: <http://www.cfsan.fda.gov/~comm/nacmcfp.html>. Following the overview, a practical scheme for applying and implementing the HACCP principles in retail and food service establishments is presented.

## **(C) What are Prerequisite Programs?**

In order for a HACCP system to be effective, a strong foundation of procedures that address the basic operational and sanitation conditions within an operation must first be developed and implemented. These procedures are collectively termed “prerequisite programs.” When prerequisite programs are in place, more attention can be given to controlling hazards associated with the food and its preparation. Prerequisite programs may include such things as:

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

Basic prerequisite programs should be in place to:

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

Additional information about prerequisite programs and the types of activities usually included in them can be found in the FDA's Retail HACCP manuals discussed later in this Annex or by accessing the NACMCF guidance document on the FDA Web Page.

### **3. THE HACCP PRINCIPLES**

#### **(A) Principle #1: Conduct a Hazard Analysis**

##### **(1) What is a food safety hazard?**

A hazard is a biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

##### **(2) What are biological hazards?**

Biological hazards include bacterial, viral, and parasitic microorganisms. See Table 1 in this Annex for a listing of selected biological hazards. Bacterial pathogens comprise the majority of confirmed foodborne disease outbreaks and cases. Although cooking destroys the vegetative cells of foodborne bacteria to acceptable levels, spores of spore-forming bacteria such as *Bacillus cereus*, *Clostridium botulinum*, and *Clostridium perfringens* survive cooking and may germinate and grow if food is not properly cooled or held after cooking. The toxins produced by the vegetative cells of *Bacillus cereus*, *Clostridium botulinum*, and *Staphylococcus aureus* may not be destroyed to safe levels by reheating. Post-cook recontamination with vegetative cells of bacteria such as *Salmonellae* and *Campylobacter jejuni* is also a major concern for operators of retail and food service establishments.

Viruses such as norovirus, hepatitis A, and rotavirus are directly related to contamination from human feces. Recent outbreaks have also shown that these viruses may be transmitted via droplets in the air. In limited cases, foodborne viruses may occur in raw commodities contaminated by human feces (e.g., shellfish harvested from unapproved, polluted waters). In most cases, however, contamination of food by viruses is the result of cross-contamination by ill food employees or unclean equipment and utensils. Unlike bacteria, a virus cannot multiply outside of a living cell. Cooking as a control for viruses may be ineffective because many foodborne viruses seem to exhibit heat resistance exceeding cooking temperature requirements, under laboratory conditions. Obtaining food from approved sources, practicing no bare hand contact with ready-to-eat food as well as proper handwashing, and implementing an employee health policy to restrict or exclude ill employees are important control measures for viruses.

Parasites are most often animal host-specific, but can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross-contamination of ready-to-eat food with raw animal foods, untreated water, or contaminated equipment or utensils. Like viruses, parasites do not grow in food, so control is focused on destroying the parasites and/or preventing their introduction. Adequate cooking destroys parasites. In addition, parasites in fish to be consumed raw or undercooked can also be destroyed by effective freezing techniques. Parasitic contamination by ill employees can be prevented by proper handwashing, no bare hand contact with ready-to-eat food, and implementation of an employee health policy to restrict or exclude ill employees.

<b>Annex 4, Table 1. Selected Biological Hazards Found at Retail, Associated Foods, and Control Measures</b>		
<b>HAZARD</b>	<b>ASSOCIATED FOODS</b>	<b>CONTROL MEASURES</b>
<i>Bacteria</i>		
<i>Bacillus cereus</i> (intoxication caused by heat stable, preformed emetic toxin and infection by heat labile, diarrheal toxin)	Meat, poultry, starchy foods (rice, potatoes), puddings, soups, cooked vegetables	Cooking, cooling, cold holding, hot holding
<i>Campylobacter jejuni</i>	Poultry, raw milk	Cooking, handwashing, prevention of cross-contamination
<i>Clostridium botulinum</i>	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.
<i>Clostridium perfringens</i>	Cooked meat and poultry, Cooked meat and poultry products including casseroles, gravies	Cooling, cold holding, reheating, hot holding
<i>E. coli</i> O157:H7 (other shiga toxin-producing <i>E. coli</i> )	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
<i>Listeria monocytogenes</i>	Raw meat and poultry, fresh soft cheese, paté, smoked seafood, deli meats, deli salads	Cooking, date marking, cold holding, handwashing, prevention of cross-contamination
<i>Salmonella spp.</i>	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
<i>Shigella spp.</i>	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
<i>Staphylococcus aureus</i> (preformed heat stable toxin)	RTE PHF foods touched by bare hands after cooking and further time/temperature abused	Cooling, cold holding, hot holding, no bare hand contact with RTE food, handwashing
<i>Vibrio spp.</i>	Seafood, shellfish	Cooking, approved source, prevention of cross-contamination, cold holding
<i>Parasites</i>		
<i>Anisakis simplex</i>	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, freezing
<i>Taenia spp.</i>	Beef and pork	Cooking
<i>Trichinella spiralis</i>	Pork, bear, and seal meat	Cooking
<i>Viruses</i>		
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 (Rotavirus, Norovirus, Reovirus)	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
RTE = ready-to-eat PHF = potentially hazardous food (time/temperature control for safety food)		

### **(3) What are Chemical Hazards?**

Chemical hazards may be naturally occurring or may be added during the processing of food. High levels of toxic chemicals may cause acute cases of foodborne illness, while chronic illness may result from low levels.

The Code of Federal Regulations (<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>), Title 21 Food and Drugs, provides guidance on naturally occurring poisonous or deleterious substances, e.g., 21 CFR Parts 109 Unavoidable Contaminants in Food for Human Consumption and Food Packaging Material, and 184 Direct Food Substances Affirmed as Generally Recognized as Safe. The CFR also provide allowable limits for many of the chemicals added during processing, e.g., 21 CFR Part 172 Food Additives Permitted for Direct Addition to Food For Human Consumption.

FDA's Compliance Policy Guidelines also provide information on naturally occurring chemicals ([http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm)). See Chapter 5 – Foods, Colors and Cosmetics. Examples include sections:

- 540.600 Fish, Shellfish, Crustaceans, and Other Aquatic Animals – Fresh, Frozen or Processed – Methyl Mercury,
- 555.400 Foods – Adulteration with Aflatoxin, and
- 570.200 Aflatoxin in Brazil Nuts, .375 Peanuts and Peanut Products, and .500 Pistachio Nuts.

Table 2 of this Annex provides additional examples of chemical hazards, both naturally occurring and added.

### **(4) Food Allergens As Food Safety Hazards**

Recent studies indicate that over 11 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally-occurring protein in a food or a food ingredient, which is referred to as an “allergen.” For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic response is commonly characterized by hives or other itchy rashes, nausea, abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.

Many foods, with or without identifiable allergens, have been reported to cause food allergies. However, FDA believes there is scientific consensus that the following foods can cause a serious allergic reaction in sensitive individuals; these foods account for 90% or more of all food allergies:

- Milk
- Egg
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans.

Consumers with food allergies rely heavily on information contained on food labels to avoid food allergens. Each year, FDA receives reports from consumers who have experienced an adverse reaction following exposure to a food allergen. Frequently, these reactions occur either because product labeling does not inform the consumer of the presence of the allergenic ingredient in the food or because of the cross-contact of a food with an allergenic substance not intended as an ingredient of the food during processing and preparation.

In August 2004, the Food Allergen Labeling and Consumer Protection Act (Public Law 108-282, Title II) was enacted, which defines the term “major food allergen.” The definition of “major food allergen” adopted for use in the Food Code (see paragraph 1-201.10(B)) is consistent with the definition in the new law. The following requirements are included in the new law:

- For foods labeled on or after January 1, 2006, food manufacturers must identify in plain language on the label of the food any major food allergen used as an ingredient in the food, including a coloring, flavoring, or incidental additive.
- FDA is to conduct inspections to ensure that food facilities comply with practices to reduce or eliminate cross-contact of a food with any major food allergens that are not intentional ingredients of the food.
- Within 18 months of the date of enactment of the new law (i.e., by February 2, 2006), FDA must submit a report to Congress that analyzes the results of its food inspection findings and addresses a number of specific issues related to the production, labeling, and recall of foods that contain an undeclared major food allergen.
- Within 2 years of the date of enactment of the new law (i.e., by August 2, 2006), FDA must issue a proposed rule, and within 4 years of the date of enactment of the new law (i.e., by August 2, 2008), FDA must issue a final rule to define and permit the use of the term “gluten-free” on food labeling.
- FDA is to work in cooperation with the Conference for Food Protection (CFP) to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments.

**Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures**

<b>Chemical Hazards</b>	<b>Associated Foods</b>	<b>Control measures</b>
<b>Naturally Occurring:</b>		
Scombrototoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies bonito, mackerel; Also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature abused prior to arrival in facility.
Ciguatoxin	Reef fin fish from extreme SE US, Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, and snappers	Ensure fin fish have not been caught: <ul style="list-style-type: none"> <li>• Purchase fish from approved sources.</li> <li>• Fish should not be harvested from an area that is subject to an adverse advisory.</li> </ul>
Tetrodotoxin	Puffer fish (Fugu; Blowfish)	Do not consume these fish.
Mycotoxins Aflatoxin	Corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination.	Check condition at receiving; do not use moldy or decomposed food.
Patulin	Apple juice products	Buyer Specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing.
Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved source.
Shellfish toxins Paralytic shellfish poisoning (PSP)	Molluscan shellfish from NE and NW coastal regions; mackerel, viscera of lobsters and Dungeness, tanner, and red rock crabs	Ensure molluscan shellfish are: <ul style="list-style-type: none"> <li>• from an approved source; and</li> <li>• properly tagged and labeled.</li> </ul>
Diarrhetic shellfish poisoning (DSP)	Molluscan shellfish in Japan, western Europe, Chile, NZ, eastern Canada	
Neurotoxin shellfish poisoning (NSP)	Molluscan shellfish from Gulf of Mexico	
Amnesic shellfish poisoning (ASP)	Molluscan shellfish from NE and NW coasts of NA; viscera of Dungeness, tanner, red rock crabs and anchovies.	

**Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures**

<b>Chemical Hazards</b>	<b>Associated Foods</b>	<b>Control measures</b>
<b>Naturally Occurring:</b>		
Pyrrrolizidine alkaloids	Plants food containing these alkaloids. Most commonly found in members of the Boraginaceae, Compositae, and Leguminosae families.	Do not consume of food or medicinals contaminated with these alkaloids.
Phytohaemmagglutinin	Raw red kidney beans (Undercooked beans may be more toxic than raw beans)	Soak in water for at least 5 hours. Pour away the water. Boil briskly in fresh water, with occasional stirring, for at least 10 minutes.
<b>Added Chemicals:</b>		
Environmental contaminants: Pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
PCBs	Fish	Comply with fish advisories.
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.
Toxic elements/compounds Mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel and swordfish. Grains treated with mercury based fungicides	Pregnant women/women of childbearing age/nursing mothers, and young children should not eat shark, swordfish, king mackerel or tilefish because they contain high levels of mercury.  Do not use mercury containing fungicides on grains or animals.
Copper	High acid foods and beverages	Do not store high acid foods in copper utensils; use backflow prevention device on beverage vending machines.
Lead	High acid food and beverages	Do not use vessels containing lead.
Preservatives and Food Additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Fresh fruits and Vegetables Shrimp Lobster Wine	Sulfiting agents added to a product in a processing plant must be declared on labeling.  Do not use on raw produce in food establishments.

**Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures**

<b>Chemical Hazards</b>	<b>Associated Foods</b>	<b>Control measures</b>
<b>Naturally Occurring:</b>		
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach  Meat and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrites.
Flavor enhancers Monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints)	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.
Allergens	Foods containing or contacted by: Milk Egg Fish Crustacean shellfish Tree nuts Wheat Peanuts Soybeans	Use a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients.

**(5) What are Physical Hazards?**

Illness and injury can result from foreign objects in food. These physical hazards can result from contamination or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment. As establishments develop their food safety management systems, Annex 4, Table 3 can be used to aid in the identification of sources of potential physical hazards to the food being prepared, served, or sold. Annex 4, Table 3 provides some examples of common physical hazards.

<b>Annex 4, Table 3. Main Materials of Concern as Physical Hazards and Common Sources<sup>a, b</sup></b>		
<b>Material</b>	<b>Injury Potential</b>	<b>Sources</b>
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees
<p><sup>a</sup> Adapted from Corlett (1991).</p> <p><sup>b</sup> Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman &amp; Hall, New York, NY.</p>		

## **(6) What is the purpose of the hazard analysis principle?**

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.

## **(7) How is the hazard analysis conducted?**

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 (time/temperature control for safety foods) are usually applied at critical control points (CCPs) in the HACCP plan (discussed later). 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).

## **(B) Principle #2: Determine Critical Control Points (CCPs)**

### **(1) What is the Critical Control Point (CCP)?**

A critical control point (CCP) means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk. Control can be applied at this point and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated, or reduced to acceptable levels. Common examples of CCPs include cooking, cooling, hot holding, and cold holding of ready-to-eat potentially hazardous foods (time/temperature control for safety foods). Due to vegetative and spore- and toxin-forming bacteria that are associated with raw animal foods, it is apparent that the proper execution of control measures at each of these operational steps is essential to prevent or eliminate food safety hazards or reduce them to acceptable levels.

### **(2) Are quality issues considered when determining CCPs?**

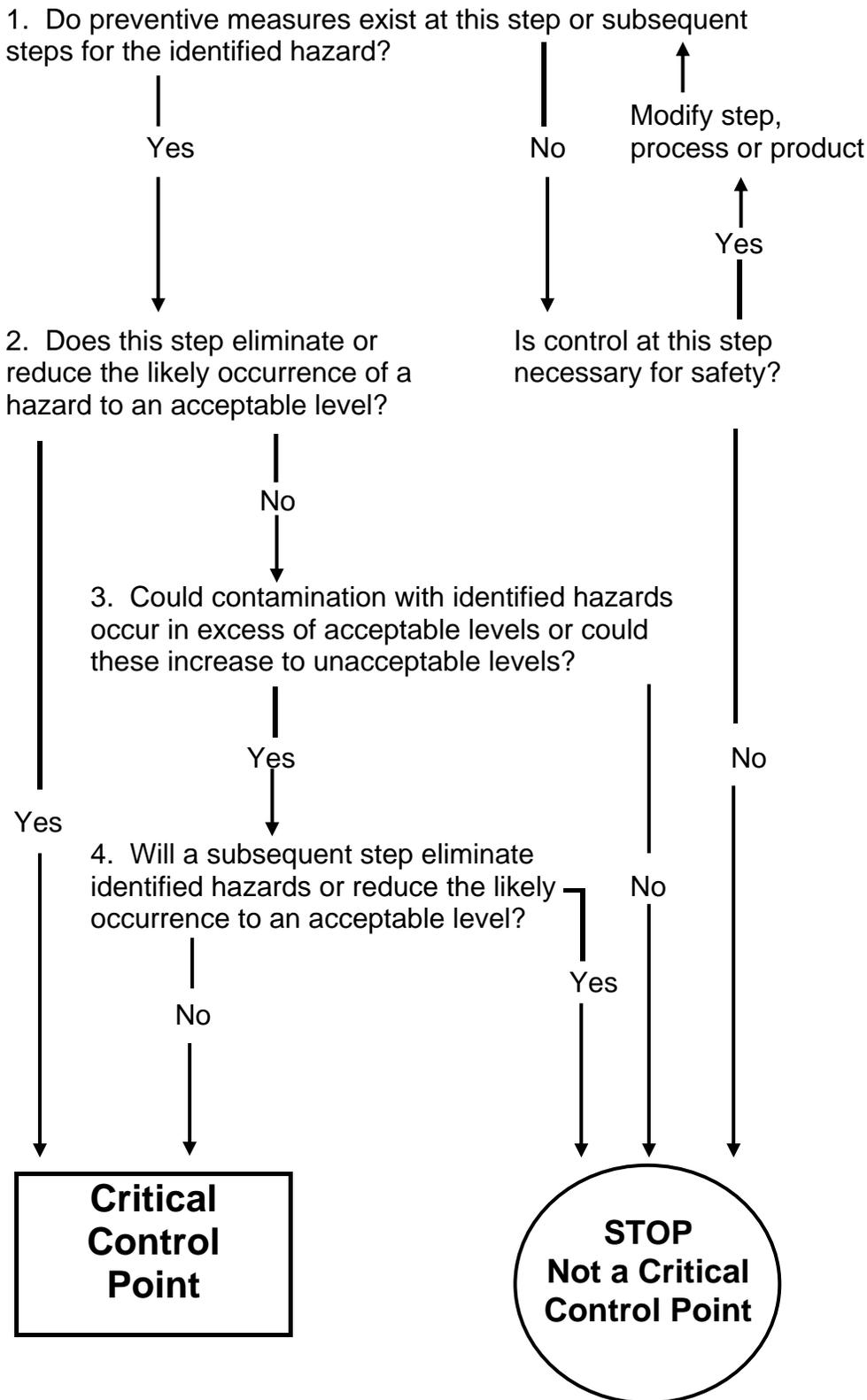
CCPs are only used to address issues with product safety. Actions taken on the part of the establishment such as first-in first-out (FIFO) or refrigerating nonpotentially hazardous foods (time/temperature control for safety foods) are to ensure food quality rather than food safety

and therefore should not be considered as CCPs unless they serve a dual-purpose of ensuring food safety.

### **(3) Are the CCPs the same for everyone?**

Different facilities preparing similar food items may identify different hazards and the CCPs. This can be due to differences in each facility's layout, equipment, selection of ingredients, and processes employed. In mandatory HACCP systems, there may be rigid regulatory requirements regarding what must be designated a CCP. In voluntary HACCP systems, hazard control may be accomplished at CCPs or through prerequisite programs. For instance, one facility may decide that it can best manage the hazards associated with cooling through a standardized procedure in its prerequisite programs rather than at a CCP in its HACCP plan. One tool that can be used to assist each facility in the identification of CCPs unique to its operation is a CCP decision tree.

### Annex 4 – CCP Decision Tree 1



Decision Tree adapted from NACMCF.

## **(C) Principle #3: Establish Critical Limits**

### **(1) What is a critical limit and what is its purpose?**

A critical limit is a prescribed parameter (e.g., minimum and/or maximum value) that must be met to ensure that food safety hazards are controlled at each CCP. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Each control measure at a CCP has one or more associated critical limits. Critical limits may be based upon factors like temperature, time, moisture level, water activity ( $a_w$ ), or pH. They must be scientifically-based and measurable.

### **(2) What are examples of critical limits?**

Examples of critical limits are the time/temperature parameters for cooking chicken (165 °F for 15 seconds). In this case, the critical limit designates the *minimum* criteria required to eliminate food safety hazards or reduce them to an acceptable level. The critical limit for the acidification of sushi rice, a pH of  $\leq 4.6$ , sets the *maximum* limit for pH necessary to control the growth of spore- and toxin-forming bacteria. Critical limits may be derived from regulatory standards such as the FDA *Food Code*, other applicable guidelines, performance standards, or experimental results.

## **(D) Principle #4: Establish Monitoring Procedures**

### **(1) What is the purpose of monitoring?**

Monitoring is the act of observing and making measurements to help determine if critical limits are being met and maintained. It is used to determine whether the critical limits that have been established for each CCP are being met.

### **(2) What are examples of monitoring activities?**

Examples of monitoring activities include visual observations and measurements of time, temperature, pH, and water activity. If cooking chicken is determined to be a CCP in an operation, then monitoring the internal temperature of a select number of chicken pieces immediately following the cook step would be an example of a monitoring activity. Alternatively, the temperature of an oven or fryer and the time required to reach an internal temperature of 165 °F could also be monitored.

### **(3) How is monitoring conducted?**

Typically, monitoring activities fall under two broad categories:

- measurements
- observations

Measurements usually involve time and temperature but also include other parameters such as pH. If an operation identifies the acidification of sushi rice as a CCP and the critical limit as the final pH of the product being  $\leq 4.6$ , then the pH of the product would be measured to ensure that the critical limit is met.

Observations involve visual inspections to monitor the presence or absence of a food safety activity. If date marking is identified as a CCP in a deli operation for controlling *Listeria monocytogenes* in ready-to-eat deli meats, then the monitoring activity could involve making visual inspections of the date marking system to monitor the sell, consume, or discard dates.

#### **(4) How often is monitoring conducted?**

Monitoring can be performed on a continuous or intermittent basis. Continuous monitoring is always preferred when feasible as it provides the most complete information regarding the history of a product at a CCP. For example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts.

If intermittent monitoring is used, the frequency of monitoring should be conducted often enough to make sure that the critical limits are being met.

#### **(5) Who conducts monitoring?**

Individuals directly associated with the operation (e.g., the person in charge of the establishment, chefs, and departmental supervisors) are often selected to monitor CCPs. They are usually in the best position to detect deviations and take corrective actions when necessary. These employees should be properly trained in the specific monitoring techniques and procedures used.

### **(E) Principle #5: Establish Corrective Actions**

#### **(1) What are corrective actions?**

Corrective actions are activities that are taken by a person whenever a critical limit is not met. Discarding food that may pose an unacceptable food safety risk to consumers is a corrective action. However, other corrective actions such as further cooking or reheating a product can be used provided food safety is not compromised. For example, a restaurant may be able to continue cooking hamburgers that have not reached an internal temperature of 155 °F for 15 seconds until the proper temperature is met. Clear instructions should be developed detailing who is responsible for performing the corrective actions, the procedures to be followed, and when.

## **(F) Principle #6: Establish Verification Procedures**

### **(1) What is verification?**

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

Validation is a component of verification which focuses on collecting and evaluating scientific and technical information to determine if the HACCP system, when properly implemented, will effectively control the hazards. Clear instructions should be developed detailing who is responsible for conducting verification, the frequency of verification, and the procedures used.

### **(2) What is the frequency of verification activities? What are some examples of verification activities?**

Verification activities are conducted frequently, such as daily, weekly, monthly, and include the following:

- observing the person doing the monitoring and determining whether monitoring is being done as planned
- reviewing the monitoring records to determine if they are completed accurately and consistently
- determining whether the records show that the frequency of monitoring stated in the plan is being followed
- ensuring that corrective action was taken when the person monitoring found and recorded that the critical limit was not met
- validating that the critical limits are achieving the desired results of controlling the identified hazard
- confirming that all equipment, including equipment used for monitoring, is operated, maintained, and calibrated properly.

## **(G) Principle #7: Establish Record Keeping Procedures**

### **(1) Why are records important?**

Maintaining documentation of the activities in a food safety management system can be vital to its success. Records provide documentation that appropriate corrective actions were taken when critical limits were not met. In the event that an establishment is implicated in a foodborne illness, documentation of activities related to monitoring and corrective actions can provide proof that reasonable care was exercised in the operation

of the establishment. Documenting activities provides a mechanism for verifying that the activities in the HACCP plan were properly completed. In many cases, records can serve a dual purpose of ensuring quality and food safety.

**(2) What types of records are maintained as part of a food safety management system?**

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

- records documenting the activities related to the prerequisite programs
- monitoring records
- corrective action records
- verification and validation records
- calibration records.

**4. THE PROCESS APPROACH – A PRACTICAL APPLICATION OF HACCP AT RETAIL TO ACHIEVE ACTIVE MANAGERIAL CONTROL**

**(A) Why Focus on HACCP Principles at Retail and Food Service?**

FDA recognizes that there are important differences between using HACCP principles in a food safety management system developed for food manufacturing plants and applying these same principles in food safety management system developed for use in retail and food service establishments.

Since the 1980's, operators and regulators have been exploring the use of the HACCP principles in restaurants, grocery stores, institutional care facilities, and other retail food establishments. During this time, much has been learned about how these principles can be used in these varied operations, collectively referred to as retail food establishments. Most of this exploration has centered around the focal question of how to stay true to the NACMCF definitions of HACCP and still make the principles useful to an industry that encompasses the broadest range of conditions.

Unlike industries such as canning, other food processing, and dairy plants, the retail industry is not easily defined by specific commodities or conditions. Consider the following characteristics that retail food establishments share that set them apart from most food processors:

1. Employee and management turnover is exceptionally high in food establishments, especially for entry level positions. This means the many employees or managers have little experience and food safety training must be continuously provided.

2. Many establishments are start-up businesses operating without benefit of a large corporate support structure and having a relatively low profit margin and perhaps less capital to work with than other segments of the food industry.
3. There is an almost endless number of production techniques, products, menu items, and ingredients used which are not easily adapted to a simple, standardized approach. Changes occur frequently and little preparation time is available.

FDA fully recognizes the diversity of retail and food service establishments and their varying in-house resources to implement HACCP. That recognition is combined with an understanding that the success of such implementation is dependent upon establishing realistic and useful food safety strategies that are customized to the operation.

### **(B) What is the Process Approach?**

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

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

### **(C) What are the three food preparation processes most often used in retail and food service establishments and how are they determined?**

The flow of food in a retail or food service establishment is the path that food follows from receiving through service or sale to the consumer. Several activities or stages make up the flow of food and are called operational steps. Examples of operational steps include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling, packaging, serving, and selling. 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°F and 135°F:

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

**Example flow: Receive – Store – Prepare – Hold – Serve**

(other food flows are included in this process, but there is no cook step to destroy pathogens)

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

**Example flow: Receive – Store – Prepare – Cook – Hold – Serve**

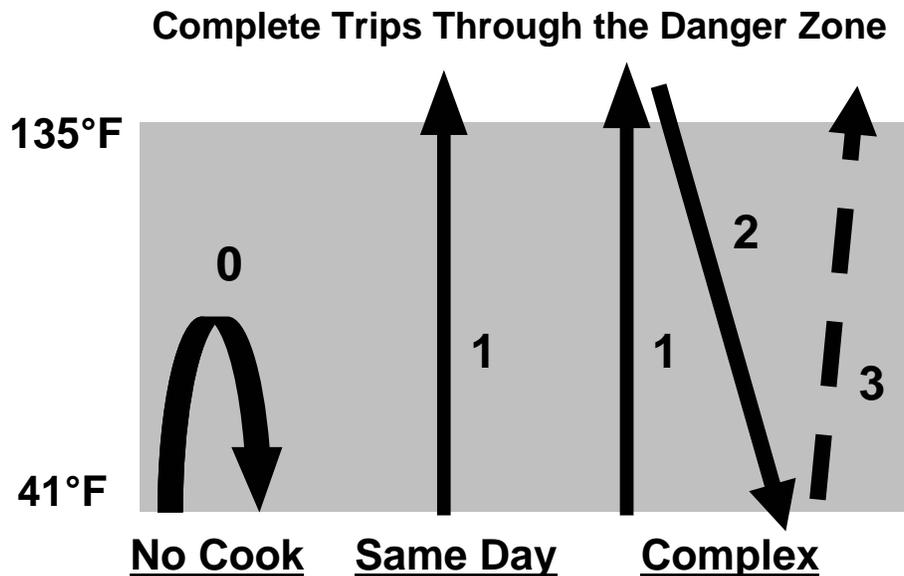
(other food flows are included in this process, but there is only one trip through the temperature danger zone)

- **Process 3: Complex Food Preparation**

**Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve**

(other food flows are included in this process, but there are always two or more complete trips through the temperature danger zone)

A summary of the three food preparation processes in terms of number of times through the temperature danger zone can be depicted in a Danger Zone diagram. Although foods produced using process 1 may *enter* the danger zone, they do not pass all the way through it. Foods that go through the danger zone only once are classified as Same Day Service, while foods that go through more than once are classified as Complex food preparation.



The three food preparation processes conducted in retail and food service establishments are not intended to be all-inclusive. For instance, quick service facilities may have “cook and serve” processes specific to their operation. These processes are likely to be different from the “Same Day Service” preparation processes in full service

restaurants since many of their foods are generally cooked and hot held before service. In addition, in retail food stores, operational steps such as packaging and assembly may be included in all of the food preparation processes before the product is sold to the consumer. It is also very common for a retail or food service operator to use multiple food preparation processes to create a single menu item.

#### **(D) How is a hazard analysis conducted in process HACCP?**

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 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 baked meatloaf) in the “Preparation for Same Day Service” category. Each of the food items may have unique hazards, but regardless of the 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* spp. 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* spp., *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 required 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°F for 15 seconds to control the pathogen load for *Salmonella* spp. Meatloaf, on the other hand, is a ground beef product and requires a final internal temperature of 155°F for 15 seconds to control the pathogen load for both *Salmonella* spp. and *E. coli* O157:H7. Some operational steps such as refrigerated storage or hot holding have critical limits that apply to all foods.

Annex 4, Table 4 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:

<b>Annex 4, Table 4: Examples of Hazards and Control Measures for Same Day Service Items</b>		
<b>Process 2: Preparation for Same Day Service</b>		
<b>Example Products</b>	<b>Baked Meatloaf</b>	<b>Baked Chicken</b>
<b>Example Biological Hazards</b>	<i>Salmonella</i> spp.	<i>Salmonella</i> spp.
	<i>E. coli</i> O157:H7	<i>Campylobacter</i>
	<i>Clostridium perfringens</i>	<i>Clostridium perfringens</i>
	<i>Bacillus cereus</i>	<i>Bacillus cereus</i>
	Various fecal-oral route pathogens	Various fecal-oral route pathogens
<b>Example Control Measures</b>	Refrigeration at 41°F or below	Refrigeration at 41°F or below
	Cooking at 155°F for 15 seconds	Cooking at 165°F for 15 seconds
	Hot Holding at 135°F or above OR Time Control	Hot Holding at 135°F or above OR Time Control
	Good personal hygiene (No bare hand contact with RTE food, proper handwashing, exclusion/restriction of ill employees)	Good personal hygiene (No bare hand contact with RTE food, proper handwashing, exclusion/restriction of ill employees)
RTE = ready-to-eat food		

**(E) How is the process approach helpful to industry in determining the measures that must be implemented to actively manage the foodborne illness risk factors that result in out-of-control hazards?**

Even though variations in foods and in the three food preparation process flows used to prepare them are common, the control measures will generally be the same based on the number of times the food goes through the temperature danger zone. Several of the most common control measures associated with each food preparation process are discussed in this Annex. Retail or food service establishments should use these simple control measures as the core of their food safety management systems; however, there may be other risk factors unique to an operation or process that are not listed here. Each operation should be evaluated independently.

In developing a voluntary food safety management system, active managerial control of risk factors common to each process can be achieved by implementing control measures at certain operational steps designated as critical control points (CCPs) or by implementing prerequisite programs. This is explained in more detail in the Operator's Manual discussed in Part 5 of this Annex.

## **(F) Facility-wide Considerations**

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

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

## **(G) Food Preparation Process 1 – Food Preparation with No Cook Step**

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

Several food flows are represented by this particular process. Many of these food flows are common to both retail food stores and food service facilities, while others only apply to retail operations. Raw, ready-to-eat food like sashimi, raw oysters, and salads are grouped in this category. Components of these foods are received raw and will not be cooked before 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 dairy products (such as yogurt). In addition, foods that are received and sold raw but are to be cooked by the consumer after purchase, e.g., hamburger meat, chicken, and steaks, are also included in this category.

All the foods in this category lack a cook step *while at the retail or food service facility*; thus, there are no complete trips through the danger zone. Purchase specifications can be required by the retail or food service establishment to ensure that foods are received as safe as possible. Without a kill step to destroy pathogens, preventing further

contamination by ensuring that employees follow good hygienic practices is an important control measure.

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

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

- **Cold holding or using time alone** to control bacterial growth and toxin production
- **Food source** (e.g., 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)
- **Receiving temperatures** (e.g., certain species of marine finfish due to concerns with scombrototoxin)
- **Date marking** of ready-to-eat PHF (TCS food) held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Freezing** certain species of fish intended for raw consumption due to parasite concerns
- **Cooling** from ambient temperature to prevent the outgrowth of spore-forming or toxin-forming bacteria.

#### **(H) 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, e.g., fried chicken, but can also be cooked and served immediately. In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

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

Approved food source, proper receiving temperatures, and proper cold holding before cooking would also be important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrototoxin.

## (I) Food Preparation Process 3 – Complex Food Preparation

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

Foods prepared in large volumes or in advance for next day service usually follow an extended process flow. These foods pass through the temperature danger zone more than one time; thus, the potential for the growth of spore-forming or toxigenic bacteria is greater in this process. Failure to adequately control food product temperatures is one of the most frequently encountered risk factors contributing to foodborne illness. Food handlers should minimize the time foods are at unsafe temperatures.

In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring 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 control bacterial growth and toxin formation
- **Date marking** of ready-to-eat PHF (TCS food) held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Reheating** for hot holding, if applicable.

Approved food source, proper receiving temperatures, and proper cold holding before cooking would also be important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrototoxin.

## 5. FDA RETAIL HACCP MANUALS

### (A) What guidance has been developed by FDA to assist operators of retail and food service establishments in achieving active managerial control of foodborne illness risk factors?

FDA, in partnership with Federal, State, and local regulators, industry, academia, and consumers, has written a guidance document entitled, *“Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments.”* Commonly referred to as the “Operator’s Manual,” this document is designed to assist operators with developing or enhancing food safety management systems based on the process approach to HACCP. The manual presents a step-by-step procedure for writing and voluntarily implementing a food safety management system based on the principles of HACCP. The desired outcome is an operator who employs a preventive rather than a reactive strategy to food safety.

The Operator's Manual embodies FDA's current thinking on the application of HACCP principles at retail. It advocates the voluntary use of HACCP principles using the process approach as a practical and effective means of reducing the occurrence of foodborne illness risk factors leading to out-of-control hazards. The Operator's Manual is strictly for the voluntary implementation of HACCP principles at retail and should not be used to develop HACCP plans that are required through Federal, State, or local regulations, ordinances, or laws. The document can be found on the FDA Web Page at <http://www.cfsan.fda.gov/~dms/hret2toc.html>.

**(B) What guidance has been developed by FDA to assist regulators of retail and food service establishments in assessing industry's active managerial control of foodborne illness risk factors?**

FDA has written a document for regulators of retail and food service establishments entitled, "*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.*" Commonly referred to as the "Regulator's Manual," this document was written to provide a risk-based inspectional "roadmap" for evaluating the degree of active managerial control an operator has over foodborne illness risk factors. In addition, the manual advocates the use of voluntary intervention strategies, including the development of food safety management systems or risk control plans to bring about a long-term behavior change that will result in a reduction in the occurrence of risk factors. In cases where an operator may want their inspector to provide them with feedback on their voluntarily-implemented food safety management system, the manual provides regulators with information on how to validate and verify an existing system.

The document can be found on the FDA Web Page at:  
<http://www.cfsan.fda.gov/~dms/hret3toc.html>.

Annex 5 of the Food Code outlines the basis for conducting successful risk-based inspections and is provided to assist industry in achieving active managerial control of foodborne illness risk factors as outlined in the draft *Recommended National Retail Food Regulatory Program Standards* and the *Regulator's Manual*.

## **6. ADVANTAGES OF USING THE PRINCIPLES OF HACCP**

**(A) What advantages does using HACCP principles offer operators of retail and food service establishments?**

Rather than relying solely on periodic feedback from inspections by regulatory agencies, an establishment operator who implements a food safety management system based on HACCP principles emphasizes continuous problem solving and prevention.

Additionally, HACCP enhances and encourages communication between industry and regulators.

A food safety management system based on HACCP principles offers many other advantages to industry. One advantage is that such a system may provide a method for achieving active managerial control of multiple risk factors associated with an entire operation. Other advantages include:

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

**(B) What advantages does using HACCP principles offer regulators of retail and food service establishments?**

Traditional inspections are relatively resource-intensive, inefficient, and reactive rather than preventive in nature. Using traditional inspection techniques allows for a satisfactory “snapshot” assessment of the requirements of the code at the time of the inspection. Unfortunately, unless an inspector asks questions and inquires about the activities and procedures being utilized by the establishment even at times when the inspector is not there, there is no way to know if an operator is achieving *active* managerial control.

With the limited time often available for conducting inspections, regulators must focus their attention on those areas that clearly have the greatest impact on food safety – foodborne illness risk factors. By knowing that there are only a few control measures that are essential to food safety and focusing on these during the inspection, an inspector can assess the operator’s active managerial control of the foodborne illness risk factors.

Regulators can provide invaluable feedback to an operator through their routine inspections. This is especially useful when utilizing a risk-based approach. By incorporating HACCP principles into routine inspections, an inspector can provide an operator with the constructive input needed to establish the control system necessary to bring the foodborne illness risk factors back under continuous control.

## **7. SUMMARY**

In order to make a positive impact on foodborne illness, retail and food service operators must achieve active managerial control of the risk factors contributing to foodborne illness. Combined with basic sanitation, employee training, and other

prerequisite programs, the principles of HACCP provide an effective system for achieving this objective.

The goal in applying HACCP principles in retail and food service is to have the operator take purposeful actions to ensure safe food. The process approach simplifies HACCP principles for use in retail and food service. This practical and effective method of hazard control embodies the concept of active managerial control by providing an on-going system of simple control measures that will reduce the occurrence of risk factors that lead to out-of-control hazards.

The role of retail and food service regulatory professionals is to conduct risk-based inspections using HACCP principles to assess the degree of control industry has over the foodborne illness risk factors. Regulators can assist industry in achieving active managerial control of risk factors by using a risk-based inspection approach to identify strengths and weaknesses and suggesting possible solutions and improvements.

## **8. ACKNOWLEDGEMENTS**

Much of this Annex is adapted from the National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point Principles and Guidelines, adopted August 14, 1997.

The physical hazards table (Table 3) was provided courtesy of “Overview of Biological, Chemical, and Physical Hazards” in “HACCP Principles and Applications,” Merle Pierson and Donald A. Corlett, Jr. (Eds.), 1992. p. 8-28. Chapman and Hall, New York.

Based on a recommendation from the Retail HACCP Committee of the Conference for Food Protection, the two HACCP Manuals have been endorsed by the Conference.

## **9. RESOURCES AND REFERENCES**

### **(A) Articles**

Bryan, Frank “Hazard Analyses of Street Foods and Considerations for Food Safety.” Dairy, Food and Environmental Sanitation, February 1995, pp. 64-69.

Bryan, Frank “HACCP: Present Status and Future in Contribution to Food Safety.” Dairy, Food & Environmental Sanitation, November 1994, pp. 650-655.

Bryan, Frank “Procedures for Local Health Agencies to Institute a Hazard Analysis Critical Control Point

Program for Food Safety Assurance in Food Service Operations.” Journal of Environmental Health, March/April 1985, pp. 241-245.

Bryan, Frank “Hazard Analysis of Food Service Operation.” Food Technology, February 1981, pp. 78-87.

Bryan, Frank “Hazard Analysis Critical Control Point Approach: Epidemiologic Rationale and Application to Food Service Operations.” Journal of Environmental Health, August 1981, pp. 7-14.

Bryan, Frank “Factors that Contribute to Outbreaks of Foodborne Disease.” Journal of Food Protection, October 1978, pp. 816-827.

Briley and Klaus “Using Risk Assessment as a Method of Determining Inspection Frequency.” Dairy and Food Sanitation, December 1985, pp. 468-474.

Centers for Disease Control and Prevention. Surveillance for Foodborne Disease Outbreaks – United States, 1993-1997. Morbidity Mortality Weekly Report, #49 (SS01), USPHS, March 17, 2000, pp. 1-51.

Mead, P.S., Slutsker, L., Dietz, V., McCraig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., Tauxe, R.V. “Food-related Illness and Death in the United States.” Emerg. Infect. Dis. Vol. 5, No. 5, 1999. Found at: <http://www.cdc.gov/ncidod/EID/vol5no5/mead.htm>.

National Advisory Committee on Microbiological Criteria for Food (NACMCF). 1997 Hazard Analysis and Critical Control Point System, USDA - FSIS Information Office, 1997.

National Advisory Committee on Microbiological Criteria for Food (NACMCF). 1992 Hazard Analysis and Critical Control Point System, Int. J. Food Microbiology, 16:1-23.

National Food Processors Assoc. “HACCP Implementation: A Generic Model for Chilled Foods.” Journal of Food Protection, December, 1993, pp. 1077-1084.

President's Council on Food Safety. The Food Safety Strategic Plan, 2001. Ch. 2: Vision, Goals, Objectives, and Action items. Found at:  
<http://www.foodsafety.gov/~fsg/cstrpl-4.html#chap2>.

Silliker, John, Ph.D. "Microbiological Testing and HACCP Programs." Dairy, Food and Environmental Sanitation, October 1995, pp. 606-610.

Stier, R.F., and Blumenthal, M.M., Ph.D. "Will HACCP be Carrot or Stick." Dairy, Food and Environmental Sanitation, October 1995, pp. 616 - 620.

Tisler, J.M. "The Food and Drug Administration's Perspective on HACCP," Food Technology, June 1991, pp. 125-127.

Tompkin, R.B. "The Use of HACCP in the Production of Meat and Poultry Products." Journal of Food Protection, September 1990, pp. 795-803.

Weingold, S.E., et al. "Use of Foodborne Disease Data for HACCP Risk Assessment." Journal of Food Protection, September 1994, pp. 820-830.

## **(B) Books**

Corlett, D.A. and Pierson, M.D. HACCP, Principles & Applications, ed., Chapman and Hall, New York, 1992.

Diseases Transmitted by Foods, 2nd ed., Centers for Disease Control, USPHS, 1982.

Fellows, P.J. Food Processing Technology, Principles and Practice, Ellis Horwood, New York, 1990.

Fennema, O.R. Food Chemistry, 2nd ed., Marcel Dekker, Inc., New York, 1985.

Foodborne Diseases, ed. D.O. Cliver, Academic Press, San Diego, California, 1990.

HACCP Reference Book, National Restaurant Assoc.,  
The Educational Foundation, Chicago, 1994.

Heymann, David L. MD, (Ed.), 2004. Control of  
Communicable Diseases Manual, 18th Ed.,  
American Public Health Association, Washington D.C.

Jay, J.M. Modern Food Microbiology, 4th ed., Van  
Nostrand Reinhold, New York, 1992.

Potter, N.N., J.H. Hotchkiss, 1999. Food Science, 5th  
ed., Kluwer Academic Publishers, Secaucus, NJ.

Stevenson, K.E., D.T. Bernard, 1999. HACCP: A  
Systematic Approach to Food Safety, 3rd ed., Food  
Processors Institute, Washington, DC, 1999.

### **(C) FDA Publications**

**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

Food and Drug Administration/U.S. Public Health Service, 2003. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, found at <http://www.cfsan.fda.gov/~ear/nss2orpd.html>.

*Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors, 2000.* The Baseline Report is available from FDA through the following website <http://www.cfsan.fda.gov/~dms/retrsk.html>.

*FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).* This second report is available from FDA through the following website <http://www.cfsan.fda.gov/~dms/retrsk2.html> .