

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.

Annex 4, Table 1. Selected Biological Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
<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)		

- 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

Chemical Hazards	Associated Foods	Control measures
Naturally Occurring:		
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"> • Purchase fish from approved sources. • Fish should not be harvested from an area that is subject to an adverse advisory.
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"> • from an approved source; and • properly tagged and labeled.
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

Chemical Hazards	Associated Foods	Control measures
Naturally Occurring:		
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.
Added Chemicals:		
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.

