

**Dry Creek Rancheria
Band of Pomo Indians**

Business Code

TITLE 8. FOOD CODE

TABLE OF CONTENTS

CHAPTER 1. PURPOSE AND DEFINITIONS

SECTION 1. Purpose

SECTION 2. Scope

SECTION 3. Definitions

CHAPTER 2. MANAGEMENT AND PERSONNEL

SECTION 1. Assignment

SECTION 2. Knowledge Demonstration

SECTION 3. Duties of Person in Charge

CHAPTER 3. EMPLOYEE HEALTH

SECTION 1. Disease or Medical Condition; Responsibility of the Person in Charge to Require Reporting by Food Employees and Applicants

SECTION 2. Exclusions and Restrictions

SECTION 3. Removal of Exclusions and Restrictions

SECTION 4. Responsibility of a Food Employee or an Applicant to Report to the Person in Charge

SECTION 5. Personal Cleanliness; Clean Condition; Cleaning Procedure

SECTION 6. Hygienic Practices

CHAPTER 4. FOOD

SECTION 1. Compliance with Food Law

SECTION 2. Food in a Hermetically Sealed Container

SECTION 3. Fluid Milk and Milk Products

SECTION 4. Fish

SECTION 5. Molluscan Shellfish

SECTION 6. Wild Mushrooms

SECTION 7. Game Animals

SECTION 8. Temperature

SECTION 9. Additives

SECTION 10. Shell Eggs

SECTION 11. Eggs and Milk Products, Pasteurized

SECTION 12. Package Integrity

SECTION 13. Ice

SECTION 14. Shucked Shellfish, Packaging and Identification

SECTION 15. Shellstock Identification

SECTION 16. Shellstock, Condition

SECTION 17. Juice Treated

SECTION 18. Molluscan Shellfish, Original Container

SECTION 19. Shellstock, Maintaining Identification

SECTION 20. Preventing Contamination from Hands

SECTION 21. Preventing Contamination when Tasting

SECTION 22. Packaged and Unpackaged Food - Separation, Packaging, and Segregation

SECTION 23. Food Storage Containers, Identified with Common Name of Food

SECTION 24. Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes

SECTION 25. Protection from Unapproved Additives

SECTION 26. Washing Fruits and Vegetables

SECTION 27. Ice Used as Exterior Coolant, Prohibited as Ingredient

SECTION 28. Storage or Display of Food in Contact with Water or Ice

SECTION 29. Food Contact with Equipment and Utensils

SECTION 30. In-Use Utensils, Between-Use Storage

SECTION 31. Linens and Napkins, Use Limitation

SECTION 32. Wiping Cloths, Use Limitation

SECTION 33. Gloves, Use Limitation

SECTION 34. Using Clean Tableware for Second Portions and Refills

SECTION 35. Refilling Returnables

SECTION 36. Food Storage

SECTION 37. Food Storage, Prohibited Areas

SECTION 38. Vended Potentially Hazardous Food, Original Container

SECTION 39. Food Preparation

SECTION 40. Food Display

SECTION 41. Condiments, Protection

SECTION 42. Consumer Self-Service Operations

SECTION 43. Returned Food and Reservice of Food

SECTION 44. Returned Food and Reservice of Food

SECTION 45. Raw Animal Foods

SECTION 46. Microwave Cooking

SECTION 47. Plant Food Cooking for Hot Holding

SECTION 48. Freezing; Parasite Destruction

SECTION 49. Records, Creation and Retention

SECTION 50. Reheating; Preparation for Immediate Service

SECTION 51. Reheating for Hot Holding

SECTION 52. Other Methods; Treating Juice

SECTION 53. Frozen Food

SECTION 54. Potentially Hazardous Food, Slacking

SECTION 55. Thawing

SECTION 56. Cooling

SECTION 57. Cooling Methods

SECTION 58. Potentially Hazardous Food, Hot and Cold Holding

SECTION 59. Ready-to-Eat, Potentially Hazardous Food, Date Marking

SECTION 60. Ready-to-Eat, Potentially Hazardous Food, Disposition

SECTION 61. Time as a Public Health Control

SECTION 62. Variance Requirement
SECTION 63. Clostridium Botulinum Controls, Reduced Oxygen Packaging, Criteria
SECTION 64. Accurate Representation
SECTION 65. Labeling
SECTION 66. Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens
SECTION 67. Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food
SECTION 68. Pasteurized Foods, Prohibited Reservice, and Prohibited Food

CHAPTER 5. EQUIPMENT, UTENSILS, AND LINENS
SECTION 1. Materials for Construction and Repair
SECTION 2. Design and Construction
SECTION 3. Numbers and Capacities
SECTION 4. Location and Installation
SECTION 5. Maintenance and Operation
SECTION 6. Cleaning of Equipment and Utensils
SECTION 7. Sanitation of Equipment and Utensils
SECTION 8. Laundering
SECTION 9. Protection of Clean Items

CHAPTER 6. WATER, PLUMBING, AND WASTE
SECTION 1. Water
SECTION 2. Plumbing System
SECTION 3. Mobile Water Tank and Mobile Food Establishment Water Tank
SECTION 4. Sewage, Other Liquid Waste, and Rainwater
SECTION 5. Refuse, Recyclables, and Returnables

CHAPTER 7. PHYSICAL FACILITIES
SECTION 1. Materials for Construction and Repair
SECTION 2. Design, Construction, and Installation
SECTION 3. Numbers and Capacities
SECTION 4. Location and Placement
SECTION 5. Maintenance and Operation

CHAPTER 8. POISONOUS OR TOXIC MATERIALS
SECTION 1. Labeling and Identification
SECTION 2. Operational Supplies and Applications

CHAPTER 9. COMPLIANCE AND ENFORCEMENT
SECTION 1. Code Applicability
SECTION 2. Plan Submission and Approval
SECTION 3. Permit to Operate
SECTION 4. Inspection and Correction of Violations
SECTION 5. Prevention of Foodborne Disease Transmission by Employees

APPENDIX A.

CHAPTER 1. PURPOSE AND DEFINITIONS

SECTION 1. Purpose

Food Safety, Illness Prevention, and Honest Presentation. The purpose of this Code is to safeguard public health and provide to consumers food that is safe, unadulterated, and honestly presented, to establish the formal standards for food establishments licensed by the Tribe, to ensure that Tribally-licensed food establishments and others are aware of the Tribe's food code standards, and to provide written information for use as training, informational, legal and enforcement, and other purposes relating to the activities of food establishments.

SECTION 2. Scope

(A) This supplement is enacted pursuant to authority set forth in Title 3, 1.5(B)(9) of the Dry Creek Rancheria Tribal Code and serves as a supplement to and interpretative application of Title 8 of the Tribal Code.

(B) This Code establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities; and provides for food establishment plan review, permit issuance, inspection, employee restriction, and permit suspension.

(C) While the provisions of this Code may not directly apply to food related activities by virtue of issuance of a license or permit, the provisions of this Code shall be utilized for monitoring and responding to inquiries of any non-licensed public and private food-related activities identified in 1.3(KK)(3) of this Code which are conducted within the Rancheria.

(D) The issuance of a license or permit by the Tribe and the acceptance of such license or permit by an individual for conducting activities in a private home, or portion thereof, that are authorized under this Code shall be deemed consent by the licensee or permittee and the home owner for the regulatory authority to conduct inspections, take enforcement actions, monitor and take other actions relating to such licensed or permitted activities.

SECTION 3. Definitions

(A) Accredited program.

(1) "Accredited program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency approved by the Tribe as conforming to national standards for organizations that certify individuals.

(2) "Accredited program" refers to the certification process approved by the Tribe based upon an independent evaluation of factors such as the sponsor's

mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(3) "Accredited program" does not refer to training functions or educational programs, except where such activities are associated with the issuance of certificates of completion in an accredited program.

(B) Additive.

(1) "Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, ' 201(s) and 21 CFR 170.

(2) "Color additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, ' 201(t) and 21 CFR 70.

(C) "Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, ' 402.

(D) "Approved" means acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

(E) "aw" means water activity which is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol aw.

(F) "Beverage" means a liquid for drinking, including water.

(G) "Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(H) "Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.

(I) "Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

(J) CIP.

(1) "CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require

cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine.

(2) "CIP" does not include the cleaning of equipment such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

(K) "CFR" means Code of Federal Regulations. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers, such as 21 CFR 178.1010.

(L) "Code of Federal Regulations" means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which:

(1) Is published annually by the U.S. Government Printing Office; and

(2) Contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, and EPA rules in 40 CFR.

(M) "Commingle" means:

(1) To combine shellstock harvested on different days or from different growing areas as identified on the tag or label, or

(2) To combine shucked shellfish from containers with different container codes or different shucking dates.

(N) Comminuted.

(1) "Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing.

(2) "Comminuted" includes fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage; and a mixture of 2 or more types of meat that have been reduced in size and combined, such as sausages made from 2 or more meats.

(O) A Comprehensive Business Codes means the Comprehensive Business Codes of the Dry Creek Rancheria which are enacted as Titles 1 through 11 of the Tribal Code.

(P) "Confirmed disease outbreak" means a food borne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness.

(Q) "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

(R) "Corrosion-resistant material" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

(S) "Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

(T) Critical Item.

(1) "Critical item" means a provision of this Code, that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard.

(2) "Critical item" is an item that is denoted in this Code with an asterisk *.

(U) "Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

(V) Drinking Water.

(1) "Drinking water" means water that meets 40 CFR 141 National Primary Drinking Water Regulations.

(2) "Drinking water" is traditionally known as "potable water."

(3) "Drinking water" includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

(W) "Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous and dry goods such as single-service items.

(X) Easily Cleanable.

(1) "Easily cleanable" means a characteristic of a surface that:

(a) Allows effective removal of soil by normal cleaning methods;

(b) Is dependent on the material, design, construction, and installation of the surface; and

(c) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

(2) "Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified under Subparagraph (a) of this definition to different situations in which varying degrees of cleanability are required such as:

(a) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or

(b) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

(Y) "Easily movable" means:

(1) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and

(2) Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

(Z) "Egg" means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea.

(AA) "Employee" means the permit holder, person in charge, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food establishment.

(BB) "EPA" means the U.S. Environmental Protection Agency.

(CC) Equipment.

(1) "Equipment" means an article that is used in the operation of a food establishment such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine.

(2) "Equipment" does not include items used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

(DD) "Exclude" means to prevent a person from working as a food employee or entering a food establishment except for those areas open to the general public.

(EE) "FDA" means the U.S. Food and Drug Administration.

(FF) Fish.

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

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

(GG) "Food" means a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(HH) "Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

(II) "Food-contact surface" means:

(1) A surface of equipment or a utensil with which food normally comes into contact; or

(2) A surface of equipment or a utensil from which food may drain, drip, or splash:

(a) Into a food, or

(b) Onto a surface normally in contact with food.

(JJ) "Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

(KK) Food Establishment.

(1) "Food establishment" means a licensed or permitted operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption:

(a) Such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank; and

(b) That relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(c) A food processing plant; and

(d) That portion of a private home that is licensed as a food establishment.

(2) "Food establishment" includes:

(a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and

(b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the premises; and regardless of whether there is a charge for the food.

(3) "Food establishment" does not include:

(a) An establishment that offers only prepackaged foods that are not potentially hazardous;

(b) A produce stand that only offers whole, uncut fresh fruits and vegetables;

(c) A kitchen in a private home if only food that is not potentially hazardous is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law and if the consumer is informed by a clearly visible placard at the

sales or service location that the food is prepared in a kitchen that is not subject to regulation and inspection by the regulatory authority;

(d) An area where food that is prepared as specified in Subparagraph (3)(c) of this definition is sold or offered for human consumption;

(e) A kitchen or other areas in a private home that is not licensed as a food establishment;

(f) A private home that receives catered or home-delivered food, or

(g) An unlicensed portion of a private home.

(LL) "Food processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption whether or not it provides food directly to a consumer.

(MM) Game Animal.

(1) "Game animal" means an animal, the products of which are food, that is not classified as cattle, sheep, swine, goat, horse, mule, or other equine in 9 CFR Subchapter A -- Mandatory Meat Inspection, Part 301, as Poultry in 9 CFR Subchapter C -- Mandatory Poultry Products Inspection, Part 381, or as fish as defined under Section 3(Z).

(2) "Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

(3) "Game animal" does not include ratites such as ostrich, emu, and rhea.

(NN) "General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175.

(OO) "Grade A standards" means the requirements of the United States Public Health Service/FDA "Grade A Pasteurized Milk Ordinance" and "Grade A Condensed and Dry Milk Ordinance" with which certain fluid and dry milk and milk products comply.

(PP) "HACCP plan" means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods, and as further defined in Appendix No. 1 to this Code.

(QQ) "Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

(RR) "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

(SS) "Highly susceptible population" means persons who are more likely than other people in the general population to experience foodborne disease because they are:

(1) Immunocompromised; preschool age children, or older adults; and

(2) Obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

(TT) "Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(1) The number of potential injuries, and

(2) The nature, severity, and duration of the anticipated injury.

(UU) "Injected" means manipulating a meat so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the meat such as by processes which may be referred to as "injecting," "pinning," or "stitch pumping."

(VV) "Juice" means, when used in the context of food safety, the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée. Juice includes juice as a whole beverage, an ingredient of a beverage and a purée as an ingredient of a beverage.

(WW) "Kitchenware" means food preparation and storage utensils.

(XX) "Law" means applicable tribal, local, state, and federal statutes, regulations, and ordinances.

(YY) "License" means a business license issued pursuant to the Comprehensive Business Codes of the Dry Creek Rancheria.

(ZZ) "Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

(AAA) "Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals as specified under Subparagraphs 4.7(A)(3) and (4).

(BBB) "mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

(CCC) "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

(DDD) Packaged.

(1) "Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether packaged in a food establishment or a food processing plant.

(2) "Packaged" does not include a wrapper, carry-out box, or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer.

(EEE) "Permit" means permit or license issued by the Tribe that authorizes a person to operate a food establishment.

(FFF) "Permit holder" means the entity that:

(1) Is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person; and

(2) Possesses a valid permit or license to operate a food establishment.

(GGG) "Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

(HHH) "Person in charge" means the individual present at a food establishment who is responsible for the operation at the time of inspection.

(III) Personal Care Items.

(1) "Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance.

(2) "Personal care items" include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

(JJJ) "pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

(KKK) "Physical facilities" means the structure and interior surfaces of a food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

(LLL) "Plumbing fixture" means a receptacle or device that:

(1) Is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or

(2) Discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

(MMM) "Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

(NNN) "Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 4 categories:

(1) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(2) Pesticides, except sanitizers, which include substances such as insecticides and rodenticides;

(3) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and personal care items that may be deleterious to health; and

(4) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

(OOO) Potentially Hazardous Food.

(1) "Potentially hazardous food" means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

- (a) The rapid and progressive growth of infectious or toxigenic microorganisms;
- (b) The growth and toxin production of *Clostridium botulinum*; or
- (c) In raw shell eggs, the growth of *Salmonella Enteritidis*.

(2) "Potentially hazardous food" includes an animal food (a food of animal origin) that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (OOO) of this definition.

(3) "Potentially hazardous food" does not include:

- (a) An air-cooled hard-boiled egg with shell intact, or a shell egg that is not hard-boiled, but has been treated to destroy all viable *Salmonellae*;
- (b) A food with an aw value of 0.85 or less;
- (c) A food with a pH level of 4.6 or below when measured at 24°C (75°F);
- (d) A food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;
- (e) A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *S. Enteritidis* in eggs or *C. botulinum* can not occur, such as a food that has an aw and a pH that are above the levels specified under Subparagraphs (3)(b) and (c) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or
- (f) A food that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though

the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

(PPP) Poultry.

(1) "Poultry" means:

- (a) Any domesticated bird (chickens, turkeys, ducks, geese, or guineas), whether live or dead, as defined in 9 CFR 381 Poultry Products Inspection Regulations; and
- (b) Any migratory waterfowl, game bird, such as pheasant, partridge, quail, grouse, or guinea, or pigeon or squab, whether live or dead, as defined in 9 CFR 362 Voluntary Poultry Inspection Program.

(2) "Poultry" does not include ratites.

(QQQ) "Premises" means:

- (1) The physical facility, its contents, and the contiguous land or property under the control of the permit holder; or
- (2) The physical facility, its contents, and the land or property not described under Subparagraph (a) of this definition if its facilities and contents are under the control of the permit holder and may impact food establishment personnel, facilities, or operations, and a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.
- (3) That area of a private home that is licensed as a food establishment that is subject to the requirements of this Code and which is subject to the inspection by the Tribe as a food establishment.

(RRR) "Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.

(SSS) "Public water system" has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

(TTT) Ready-to-Eat Food.

(1) "Ready-to-eat food" means food that:

(a) Is in a form that is edible without additional preparation to achieve food safety, as specified under Chapter 3.45(A) (C) or Section 46 or Section 45; or

(b) Is a raw or partially cooked animal food and the consumer is advised as specified under 3.45(D)(1) and (2); or

(c) Is prepared in accordance with a variance that is granted as specified under Section 45(D)(1) and (3); and

(d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

(2) "Ready-to-eat food" includes:

(a) Raw animal food that is cooked as specified under 3.45 or 3.46, or frozen as specified under 3.45;

(b) Raw fruits and vegetables that are washed as specified under 3.26;

(c) Fruits and vegetables that are cooked for hot holding, as specified under 3.47;

(d) All potentially hazardous food that is cooked to the temperature and time required for the specific food under Subpart 3-401 and cooled as specified in 3.56;

(e) Plant food for which further washing, cooking, or other processing is not required for food safety, and from which rinds, peels, husks, or shells, if naturally present are removed;

(f) Substances derived from plants such as spices, seasonings, and sugar;

(g) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;

(h) The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham, country cured ham, and Parma ham; and dried meat and poultry products, such as jerky or beef sticks; and

(i) Foods manufactured according to 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

(UUU) Reduced Oxygen Packaging.

(1) "Reduced oxygen packaging" means:

(a) The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding, 21% oxygen atmosphere, and

(b) A process as specified in Subparagraph (1)(a) of this definition that involves a food for which *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form.

(2) "Reduced oxygen packaging" includes:

(a) Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package, such as sous vide;

(b) Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen; and

(c) Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(VVV) "Refuse" means solid waste not carried by water through the sewage system.

(WWW) "Regulatory authority" means the Tribe or federal enforcement body or authorized representative having jurisdiction over the food establishment.

(XXX) "Rancheria" means the Dry Creek Rancheria.

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

(ZZZ) "Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.

(AAAA) "Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

(BBBB) "Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

(CCCC) "Safe material" means:

- (1) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food;
- (2) An additive that is used as specified in ' 409 or 706 of the Federal Food, Drug, and Cosmetic Act; or
- (3) Other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

(DDDD) "Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99,999% reduction, of representative disease microorganisms of public health importance.

(EEEE) "Sealed" means free of cracks or other openings that allow the entry or passage of moisture.

(FFFF) "Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

(GGGG) "Servicing area" means an operating base location to which a mobile food establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

(HHHH) "Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

(IIII) "Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.

(JJJJ) "Shellstock" means raw, in-shell molluscan shellfish.

(KKKK) "Shiga toxin-producing Escherichia coli " means any E. coli capable of producing Shiga toxins (also called verocytotoxins or "Shiga-like" toxins). This includes, but is not limited to, E. coli reported as serotype O157:H7, O157:NM, and O157:H-."

(LLLL) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.

(MMMM) "Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

(NNNN) Single-Use Articles.

(1) "Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded.

(2) "Single-use articles" includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under 5.1(A), 5.2(A), and 5.2(B)(1) for multiuse utensils.

(OOOO) "Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach.

(PPPP) "Smooth" means:

(1) A food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;

(2) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(3) A floor, wall, or ceiling having an even or level surface with no roughness or projections that renders it difficult to clean.

(QQQQ) "Table-mounted equipment" means equipment that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

(RRRR) "Tableware" means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

(SSSS) "Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

(TTTT) "Temporary food establishment" means a food establishment that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

(UUUU) "Tribe" means the Dry Creek Rancheria or the Dry Creek Rancheria Department of Commerce and any of their authorized officials and representatives.

(VVVV) "USDA" means the U.S. Department of Agriculture.

(WWWW) "Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single-service, or single-use; gloves used in contact with food; temperature sensing probes of food temperature measuring devices; and probe-type price or identification tags used in contact with food.

(XXXX) "Variance" means a written document issued by the Tribe that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

(YYYY) "Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

(ZZZZ) "Vending machine location" means the room, enclosure, space, or area where one or more vending machines are installed and operated and includes the storage areas and areas on the premises that are used to service and maintain the vending machines.

(AAAA) "Warewashing" means the cleaning and sanitizing of utensils and food-contact surfaces of equipment.

(BBBBBB) "Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

CHAPTER 2. MANAGEMENT AND PERSONNEL

SECTION 1. Assignment

The permit holder shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the food establishment during all hours of operation.

SECTION 2. Knowledge Demonstration

Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the Tribe knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements of this Code. The person in charge shall demonstrate this knowledge by:

(A) Complying with this Code; and

(B) Responding correctly to the inspector's questions as they relate to the specific food operation. The areas of knowledge include:

(1) Describing the relationship between the prevention of food borne disease and the personal hygiene of a food employee;

(2) Explaining the responsibility of the person in charge for preventing the transmission of food borne disease by a food employee who has a disease or medical condition that may cause food borne disease;

(3) Describing the symptoms associated with the diseases that are transmissible through food;

(4) Explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food and the prevention of food borne illness;

(5) If relevant, explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish;

(6) Stating the required food temperatures and times for safe cooking of potentially hazardous food including meat, poultry, eggs, or fish;

(7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food;

(8) Describing the relationship between the prevention of food borne illness and the management and control of the following:

- (a) Cross contamination,
- (b) Hand contact with ready-to-eat foods,
- (c) Handwashing, and
- (d) Maintaining the food establishment in a clean condition and in good repair;

(9) Explaining the relationship between food safety and providing equipment that is:

- (a) Sufficient in number and capacity, and
- (b) Properly designed, constructed, located, installed, operated, maintained, and cleaned;

(10) Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;

(11) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;

(12) Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;

(13) Identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of food borne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code;

(14) Explaining the details of how the person in charge and food employees comply with the HACCP plan if a plan is required by the law, this Code, or an agreement between the Regulatory authority and the establishment; and

(15) Explaining the responsibilities, rights, and authorities assigned by this Code to the:

(a) Food employee,

(b) Person in charge, and

(c) Regulatory authority.

SECTION 3. Duties of Person in Charge

The person in charge shall ensure that:

(A) Food establishment operations are not conducted in an unlicensed area of a private home, or in a room used as living or sleeping quarters as specified under 7.2(B)(11);

(B) Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination;

(C) Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with this Code;

(D) Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing;

(E) Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt;

(F) Employees are properly cooking potentially hazardous food, being particularly careful in cooking those foods known to cause severe food borne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under 5.2(A)(2) and paragraph 5.5(B)(1);

(G) Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling;

(H) Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed as specified under 5.66 that the food is not cooked sufficiently to ensure its safety;

(I) Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing;

(J) Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets as specified under 3(34);

(K) Except when otherwise approved as specified in paragraph 4.20(B), employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; and

(L) Employees are properly trained in food safety as it relates to their assigned duties.

CHAPTER 3. EMPLOYEE HEALTH

SECTION 1. Disease or Medical Condition; Responsibility of the Person in Charge to Require Reporting by Food Employees and Applicants

Employer requires employee reporting. The permit holder shall require food employee applicants to whom a conditional offer of employment is made and food employees to report to the person in charge, information about their health and activities as they relate to diseases that are transmissible through food. A food employee or applicant shall report the information in a manner that allows the person in charge to prevent the likelihood of food borne disease transmission, including the date of onset of jaundice or of an illness specified under paragraph (C) of this section, if the food employee or applicant: health status employee is ill:

(A) Is diagnosed with an illness due to:

- (1) Salmonella Typha,
- (2) Shigella spp.,
- (3) Shiga toxin-producing Escherichia coli, or
- (4) Hepatitis A virus; employee has symptom of:

(B) Has a symptom caused by illness, infection, or other source that is: intestinal illness

- (1) Associated with an acute gastrointestinal illness such as:
 - (a) Diarrhea,

(b) Fever,

(c) Vomiting,

(d) Jaundice, or

(e) Sore throat with fever, or

(f) Boil or infected wound.

(2) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(a) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover,

(b) On exposed portions of the arms, unless the lesion is protected by an impermeable cover, or

(c) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;

(C) Employee previously ill/had a past illness from:

(1) S. Typha within the past three months,

(2) Shigella spp. within the past month,

(3) Shiga toxin-producing Escherichia coli, within the past month; or

(4) Hepatitis A virus; activities

(D) Meets one or more of the following high-risk conditions: employee at high risk of becoming ill: prepared or consumed food that caused disease

(1) Is suspected of causing, or being exposed to, a confirmed disease outbreak caused by S. Typha, Shigella spp., Shiga toxin-producing Escherichia coli, or hepatitis

A virus including an outbreak at an event such as a family meal, church supper, or festival because the food employee or applicant:

(a) Food implicated in the outbreak,

(b) Consumed food implicated in the outbreak, or

(c) Consumed food at the event prepared by a person who is infected or ill with the infectious agent that caused the outbreak or who is suspected of being a shedder of the infectious agent, lives with ill person.

(2) Lives in the same household as, and has knowledge about, a person who is diagnosed with a disease caused by *S. Typha*, *Shigella* spp., Shiga toxin-producing *Escherichia coli*, or hepatitis A virus, or lives with person involved in disease outbreak.

(3) Lives in the same household as, and has knowledge about, a person who attends or works in a setting where there is a confirmed disease outbreak caused by *S. Typha*, *Shigella* spp., Shiga toxin-producing *Escherichia coli*, or hepatitis A virus.

SECTION 2. Exclusions and Restrictions

The person in charge shall: excluding ill employees

(A) Exclude a food employee from a food establishment if the food employee is diagnosed with an infectious agent specified under paragraph Chapter 3.1(1)(A); restricting employees: (serving general population)

(B) Except as specified under paragraph (C) or (D) of this section, restrict a food employee from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles, in a food establishment if the employee is: with symptom of illness or of past illness (1) Suffering from a symptom specified under paragraph Chapter 3.1(B)(1)(a), (b), (c), and (e), or (2) Not experiencing a symptom of acute gastroenteritis specified under Chapter 3.1(B)(1) but has a stool that yields a specimen culture that is positive for *Salmonella Typha*, *Shigella* spp., or Shiga toxin-producing *Escherichia coli*; excluding employees:(serving high-risk population) with symptom of illness or of past illness

(C) If the population served is a highly susceptible population, Exclude a food employee who:

(1) Is experiencing a symptom of acute gastrointestinal illness specified under Chapter 3.1(B)(1)(a), (b), (c), or (e) and meets a high-risk condition specified under Chapter 3.1(D)(1)-(3),

(2) Is not experiencing a symptom of acute gastroenteritis specified under Chapter 3.1(B)(1) but has a stool that yields a specimen culture that is positive for *S. Typha*, *Shigella* spp., or Shiga toxin-producing *Escherichia coli*,

(3) Had a past illness from *S. Typha* within the last 3 months, or

(4) Had a past illness from *Shigella* spp. or Shiga toxin-producing *Escherichia coli* within the last month; and excluding and restricting jaundiced employees.

(D) For a food employee who is jaundiced:

(1) If the onset of jaundice occurred within the last seven (7) calendar days, Exclude the food employee from the food establishment, or

(2) If the onset of jaundice occurred more than seven (7) calendar days before:

(a) Exclude the food employee from a food establishment that serves a highly susceptible population, or

(b) Restrict the food employee from activities specified under paragraph 3.2(B), if the food establishment does not serve a highly susceptible population.

SECTION 3. Removal of Exclusions and Restrictions

Reinstating an excluded employee who is

(A) No longer ill; or

(B) Free of jaundice

(C) The person in charge may remove an exclusion specified under Section (A) or (B) if:

(1) The person in charge obtains approval from the regulatory authority; and

(2) The person excluded as specified under paragraph 3.2(A) provides to the person in charge written medical documentation from a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, that specifies that the excluded person may work as a food employee in a food establishment, including an establishment that serves a highly susceptible population, because the person is free of the infectious agent of concern as specified in 9.5(4) reinstating a restricted employee who is free of symptoms

(D) The person in charge may remove a restriction specified under:

(1) Subparagraph 3.2(B)(1) if the restricted person:

(a) Is free of the symptoms specified under paragraph 3.1(B)(1)(a), (b), (c), or (e) or (2) and no food borne illness occurs that may have been caused by the restricted person,

(b) Is suspected of causing food borne illness but:

(i) Is free of the symptoms specified under paragraph 3.1(B)(1)(a), (b), (c), or (e) or (2), and free of suspected infectious agent;

(ii) Provides written medical documentation from a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, stating that the restricted person is free of the infectious agent that is suspected of causing the person's symptoms or causing food borne illness, as specified in 9.5(4), or has symptoms that are not caused by an infectious agent.

(c) Provides written medical documentation from a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis; or no longer a shedder.

(2) Subparagraph 3.2(B)(2) if the restricted person provides written medical documentation from a physician, licensed to practice medicine, or, if allowed by law, a nurse practitioner or physician assistant, according to the criteria specified in 9.5(4) that indicates the stools are free of Salmonella Typha, Shigella spp., or Shiga toxin-producing Escherichia coli, whichever is the infectious agent of concern. reinstating an excluded employee serving: high-risk population

(E) The person in charge may remove an exclusion specified under paragraph 3.2(C) if the excluded person provides written medical documentation from a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant:

(1) That specifies that the person is free of the infectious agent of concern as specified in 9.5(4), or

(2) If the person is excluded under Subparagraph 3.2(C)(1), stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis. Reinstating an employee who is: not suspect source of illness

(F) The person in charge may remove an exclusion specified under Subparagraph 3.2(D)(1) and Subparagraph 3.2(D)(2)(a) and a restriction specified under Subparagraph 3.2(D)(2)(b) if:

(1) No food borne illness occurs that may have been caused by the excluded or restricted person and the person provides written medical documentation from a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, that specifies that the person is free of hepatitis A virus as specified in Subparagraph 9.5(4)(d)(i); or suspect source of illness

(2) The excluded or restricted person is suspected of causing food borne illness and complies with the requirements in Subparagraphs 9.5(4)(d)(ii) and (d)(ii).

SECTION 4. Responsibility of a Food Employee or an Applicant to Report to the Person in Charge

A food employee or a person who applies for a job as a food employee shall:

(A) In a manner specified under Chapter 1, Section 3, report to the person in charge the information specified under paragraphs 3.1(A)-(D); and

(B) Comply with exclusions and restrictions that are specified under paragraphs 3.2(A)-(D). 3.4 Reporting by the Person in Charge.* The person in charge shall notify the regulatory authority that a food employee is diagnosed with an illness due to Salmonella Typha, Shigella spp., Shiga toxin-producing Escherichia coli, or hepatitis A virus.

SECTION 5. Personal Cleanliness; Clean Condition; Cleaning Procedure

Food Employees shall keep their hands and exposed portions of their arms clean.

(A) Except as specified in paragraph (B) of this section, food employees shall clean their hands and exposed portions of their arms (or surrogate prosthetic devices for hands or arms) for at least 20 seconds, using a cleaning compound in a lavatory that is equipped as specified under 6.2(B)(2).

(B) Food employees shall use the following cleaning procedure:

(1) Vigorous friction on the surfaces of the lathered fingers, finger tips, areas between the fingers, hands and arms (or by vigorously rubbing the surrogate prosthetic devices for hands or arms) for at least 10 to 15 seconds, followed by;

(2) Thorough rinsing under clean, running warm water; and

(3) Immediately follow the cleaning procedure with thorough drying of cleaned hands and arms (or surrogate prosthetic devices) using a method as specified under 7.3(A)(3).

(C) Food Employees shall pay particular attention to the areas underneath the fingernails during the cleaning procedure.

(D) If approved and capable of removing the types of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands.

(E) Special Handwash Procedures.

(1) When to Wash. Food Employees shall clean their hands and exposed portions of their arms as specified under 3.5(B) immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles and:

- (a) After touching bare human body parts other than clean hands and clean, exposed portions of arms;
- (b) After using the toilet room;
- (c) After caring for or handling service animals or aquatic animals as specified in paragraph 3.6(E)(2);
- (d) Except as specified in paragraph 3.6(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
- (e) After handling soiled equipment or utensils;
- (f) During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;
- (g) When switching between working with raw food and working with ready-to-eat food;
- (h) When working with or switching to different raw foods;
- (i) Before donning gloves for working with food; and
- (j) After engaging in other activities that contaminate the hands.

(2) Where to Wash. Food Employees shall clean their hands in a handwashing lavatory or approved automatic handwashing facility and may not clean their hands in a sink used for food preparation or warewashing, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.

(F) Hand Sanitizers. A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall comply with one of the following:

(1) Be an approved drug that is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness; or

(2) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, or

(3) Have components that are exempted from the requirement of being listed in federal food additive regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles; or

(4) Comply with and be listed in:

(a) 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a food additive with conditions of safe use, or

(b) 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food; and

(5) Be applied only to hands that are cleaned as specified under 3.5(B).

(6) If a hand sanitizer or a chemical hand sanitizing solution used as a hand dip does not meet the criteria specified under Subparagraph (F)(4) of this section, use shall be:

(a) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; or

(b) Limited to situations that involve no direct contact with food by the bare hands.

(7) A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine.

(G) Fingernails; Maintenance.

(1) Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.

(2) Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial fingernails when working with exposed food.

(H) Jewelry; Prohibition. While preparing food, food employees may not wear jewelry including medical information jewelry on their arms and hands. This section does not apply to a plain ring such as a wedding band.

(I) Outer Clothing. Food Employees shall wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

SECTION 6. Hygienic Practices

(A) Food Contamination Prevention; Eating, Drinking, or Using Tobacco. Except as specified in paragraph (B) of this section, an employee shall eat, drink, or use any form paragraph of tobacco only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection can not result.

(B) A food employee may drink from a closed beverage container if the container is handled to prevent contamination of:

(1) The employee's hands;

(2) The container; and

(3) Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(C) Discharges from the Eyes, Nose, and Mouth. Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

(D) Hair Restraints.

(1) Effectiveness.

(a) Except as provided in paragraph (b) of this section, food employees shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(b) This section does not apply to food employees such as counter staff who only serve beverages and wrapped or packaged foods, hostesses, and wait staff if they present a minimal risk of contaminating exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(E) Handling Prohibition.

(1) Except as specified in paragraph (2) of this section, food employees may not care for or handle animals that may be present such as patrol dogs, service animals, or pets that are allowed as specified in Subparagraphs 6-7.5(O)(2)(b)-(e).

(2) Food Employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified under 3.5(B) and paragraph 3.5(E)(1)(c).

CHAPTER 4. FOOD

SECTION 1. Compliance with Food Law

(A) Food shall be obtained from sources that comply with law.

(B) Food prepared in an unlicensed area of a private home may not be used or offered for human consumption in a food establishment.

(C) Packaged food shall be labeled as specified in law, including 21 CFR 101 Food Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under 4.14 and 4.15.

(D) Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified in 4.45(C)(1) may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified under 3.48; or frozen on the premises as specified under 4.48 and records are retained as specified under 4.46.

(E) Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in paragraph 4.45(C) shall be:

- (1) Obtained from a food processing plant that, upon request by the purchaser, packages the steaks and labels them, to indicate that the steaks meet the definition of whole-muscle, intact beef, or
- (2) Deemed acceptable by the regulatory authority based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef, and
- (3) If individually cut in a food establishment:
 - (a) Cut from whole-muscle intact beef that is labeled by a food processing plant as specified in Subparagraph (1) or identified as specified in Subparagraph (2) of this section,
 - (b) Prepared so they remain intact, and
 - (c) If packaged for undercooking in a food establishment, labeled as specified in Subparagraph (1) or identified as specified in (2) of this section.

(F) Meat and poultry that is not a ready-to-eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

(G) Shell eggs that have not been specifically treated to destroy all viable Salmonellae shall be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

SECTION 2. Food in a Hermetically Sealed Container

Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

SECTION 3. Fluid Milk and Milk Products

Fluid milk and milk products shall be obtained from sources that comply with grade A standards as specified in law.

SECTION 4. Fish

(A) Fish that are received for sale or service shall be:

- (1) Legally caught or harvested; or
- (2) Approved for sale or service.

(B) Molluscan shellfish that are recreationally caught may not be received for sale or service.

SECTION 5. Molluscan Shellfish

(A) Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(B) Molluscan shellfish received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

SECTION 6. Wild Mushrooms

(A) Except as specified in paragraph (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert.

(B) This section does not apply to:

- (1) Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or
- (2) Wild mushroom species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

SECTION 7. Game Animals

(A) If game animals are received for sale or service they shall be:

- (1) Commercially raised for food and:
 - (a) Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, or

(b) Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, and

(c) Raised, slaughtered, and processed according to:

(i) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;

(2) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR 352 Voluntary Exotic Animal Program or rabbits that are "inspected and certified" in accordance with 9 CFR 354 Rabbit Inspection Program;

(3) As allowed by law, for wild game animals that are live-caught:

(a) Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction, and

(b) Slaughtered and processed according to:

(i) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee; or

(4) As allowed by law, for field-dressed wild game animals under a routine inspection program that ensures the animals:

(a) Receive a postmortem examination by an approved veterinarian or veterinarian's designee, or

(b) Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(c) Are processed according to laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.

SECTION 8. Temperature

(A) Except as specified in paragraph (B) of this section, refrigerated, potentially hazardous food shall be at a temperature of 5°C (41°F) or below when received.

(B) If a temperature other than 5°C (41°F) for a potentially hazardous food is specified in law governing its distribution, such as laws governing milk and molluscan shellfish, the food may be received at the specified temperature.

(C) Raw shell eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less.

(D) Potentially hazardous food that is cooked to a temperature and for a time specified under 4.45 – 4.47 and received hot shall be at a temperature of 60°C (140°F) or above.

(E) A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen.

(F) Upon receipt, potentially hazardous food shall be free of evidence of previous temperature abuse.

SECTION 9. Additives

Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170-180 relating to food additives, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186, substances that exceed amounts specified in 9 CFR Subpart C Section 424.21(b) Food ingredients and sources of radiation, or pesticide residues that exceed provisions specified in 40 CFR 185 Tolerances for Pesticides in Food.

SECTION 10. Shell Eggs

Shell eggs shall be received clean and sound and may not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in 7 CFR Part 56 " Voluntary Grading of Shell Eggs and United States Standards, Grades, and Weight Classes for Shell Eggs, and 9 CFR Part 590 " Inspection of Eggs and Egg Products.

SECTION 11. Eggs and Milk Products, Pasteurized

(A) Liquid, frozen, and dry eggs and egg products shall be obtained pasteurized.

(B) Fluid and dry milk and milk products complying with grade A standards as specified in law shall be obtained pasteurized.

(C) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in CFR 135 - Frozen Desserts.

(D) Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133 - Cheeses and Related Cheese Products, for curing certain cheese varieties.

SECTION 12. Package Integrity

Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants.

SECTION 13. Ice

Ice for use as a food or a cooling medium shall be made from drinking water.

SECTION 14. Shucked Shellfish, Packaging and Identification

(A) Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the:

(1) Name, address, and certification number of the shucker-packer or repacker of the molluscan shellfish; and

(2) The "sell by" date for packages with a capacity of less than 1.87 L (one-half gallon) or the date shucked for packages with a capacity of 1.87 L (one-half gallon) or more.

(B) A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified under paragraph (A) of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

SECTION 15. Shellstock Identification

(A) Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list:

(1) Except as specified under paragraph (C) of this section, on the harvester's tag or label, the following information in the following order:

(a) The harvester's identification number that is assigned by the shellfish control authority,

(b) The date of harvesting,

(c) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested,

(d) The type and quantity of shellfish, and

(e) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days;" and

(2) Except as specified in paragraph (D) of this section, on each dealer's tag or label, the following information in the following order:

(a) The dealer's name and address, and the certification number assigned by the shellfish control authority,

(b) The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested,

(c) The same information as specified for a harvester's tag under Subparagraphs (A)(1)(b)-(d) of this section, and

(d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days."

(B) A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under paragraph (A) of this section shall be subject to a hold order, as allowed by law, or seizure and destruction

in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

(C) If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first.

(D) If the harvester's tag or label is designed to accommodate each dealer's identification as specified under Subparagraphs (A)(2)(a) and (b) of this section, individual dealer tags or labels need not be provided.

SECTION 16. Shellstock, Condition

When received by a food establishment, shellstock shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells shall be discarded.

SECTION 17. Juice Treated

Pre-packaged juice shall:

(A) Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120;

(B) Be obtained pasteurized or otherwise treated to attain a 5-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR Part 120.24; Or

(C) Bear a warning label as specified in 21 CFR Section 101.17(g).
Original Containers and Records

SECTION 18. Molluscan Shellfish, Original Container

(A) Except as specified in paragraphs (B) and (C) of this section, molluscan shellfish may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(B) For display purposes, shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

(1) The source of the shellstock on display is identified as specified under 4.15 and recorded as specified under 4.19; and

(2) The shellstock are protected from contamination.

(C) Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

(1) The labeling information for the shellfish on display as specified under 4.17 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

(2) The shellfish are protected from contamination.

SECTION 19. Shellstock, Maintaining Identification

(A) Except as specified under Subparagraph (B)(2) of this section, shellstock tags shall remain attached to the container in which the shellstock are received until the container is empty.

(B) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date the container is emptied by:

(1) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the shellstock are sold or served; and

(2) If shellstock are removed from their tagged or labeled container:

(a) Preserving source identification by using a record keeping system as specified under Subparagraph (B)(1) of this section, and

(b) Ensuring that shellstock from one tagged or labeled container are not commingled with shellstock from another container before being ordered by the consumer.

SECTION 20. Preventing Contamination from Hands

(A) Food employees shall wash their hands as specified under 3.5(B).

(B) Except when washing fruits and vegetables as specified under 4.26 or when otherwise approved, food employees may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.

(C) Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.

SECTION 21. Preventing Contamination when Tasting

A food employee may not use a utensil more than once to taste food that is to be sold or served.

SECTION 22. Packaged and Unpackaged Food - Separation, Packaging, and Segregation

(A) Food shall be protected from cross contamination by:

(1) Separating raw animal foods during storage, preparation, holding, and display from:

(a) Raw ready-to-eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as vegetables, and

(b) Cooked ready-to-eat food;

(2) Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:

(a) Using separate equipment for each type, or

(b) Arranging each type of food in equipment so that cross contamination of one type with another is prevented, and

(c) Preparing each type of food at different times or in separate areas;

(3) Cleaning equipment and utensils as specified under paragraph 5.6(B)(1)(A) and sanitizing as specified under 5.7(C);

(4) Except as specified in paragraph (B) of this section, storing the food in packages, covered containers, or wrappings;

(5) Cleaning hermetically sealed containers of food of visible soil before opening;

(6) Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

(7) Storing damaged, spoiled, or recalled food being held in the food establishment as specified under 7.4(D); and

(8) Separating fruits and vegetables, before they are washed as specified under 4.26 from ready-to-eat food.

(B) Subparagraph (A)(4) of this section does not apply to:

(1) Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;

(2) Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;

(3) Whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;

(4) Food being cooled as specified under Subparagraph 4.57(B)(2); or

(5) Shellstock.

SECTION 23. Food Storage Containers, Identified with Common Name of Food

Working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the food except that containers holding food that can be readily and unmistakably recognized such as dry pasta need not be identified.

SECTION 24. Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes

Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and egg-fortified beverages that are not:

(A) Cooked as specified under Subparagraphs 4.45(A)(1) or (2); or

(B) Included in paragraph 4.45(D).

SECTION 25. Protection from Unapproved Additives

(A) Food shall be protected from contamination that may result from the addition of, as specified in 4.23:

(1) Unsafe or unapproved food or color additives; and

(2) Unsafe or unapproved levels of approved food and color additives.

(B) A food employee may not:

- (1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1; or
- (2) Serve or sell food specified under Subparagraph (B)(1) of this section that is treated with sulfiting agents before receipt by the food establishment, except that grapes need not meet this subparagraph.

SECTION 26. Washing Fruits and Vegetables

(A) Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form except as specified in paragraph (B) of this section and except that whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.

(B) Fruits and vegetables may be washed by using chemicals as specified under 8.2(D)(2).

SECTION 27. Ice Used as Exterior Coolant, Prohibited as Ingredient

After use as a medium for cooling the exterior surfaces of food such as melons or fish, ice, packaged foods such as canned beverages, or cooling coils and tubes of equipment, may not be used as food.

SECTION 28. Storage or Display of Food in Contact with Water or Ice

(A) Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container, or its positioning in the ice or water.

(B) Except as specified in paragraphs (C) and (D) of this section, unpackaged food may not be stored in direct contact with undrained ice.

(C) Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.

(D) Raw chicken and raw fish that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.

SECTION 29. Food Contact with Equipment and Utensils

Food shall only contact surfaces of equipment and utensils that are cleaned as specified under 5.6 of this Code and sanitized as specified under 5.7 of this Code.

SECTION 30. In-Use Utensils, Between-Use Storage

During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

(A) Except as specified under paragraph (B) of this section, in the food with their handles above the top of the food and the container;

(B) In food that is not potentially hazardous with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;

(C) On a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the food-contact surface of the food preparation table or cooking equipment are cleaned and sanitized at a frequency specified under 5.6(B)(1) and 5.7(B);

(D) In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;

(E) In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not potentially hazardous; or

(F) In a container of water if the water is maintained at a temperature of at least 60°C (140°F) and the container is cleaned at a frequency specified under Subparagraph 5.6(D)(7).

SECTION 31. Linens and Napkins, Use Limitation

Linens and napkins may not be used in contact with food unless they are used to line a container for the service of foods and the linens and napkins are replaced each time the container is refilled for a new consumer.

SECTION 32. Wiping Cloths, Use Limitation

(A) Cloths that are in use for wiping food spills shall be used for no other purpose.

(B) Cloths used for wiping food spills shall be:

(1) Dry and used for wiping food spills from tableware and carry-out containers; or

(2) Wet and cleaned as specified under paragraph 5.8(B)(1), stored in a chemical sanitizer at a concentration specified in 5.5(A)(14), and used for wiping spills from food-contact and nonfood-contact surfaces of equipment.

(C) Dry or wet cloths that are used with raw animal foods shall be kept separate from cloths used for other purposes, and wet cloths used with raw animal foods shall be kept in a separate sanitizing solution.

(D) Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths shall be free of food debris and visible soil.

SECTION 33. Gloves, Use Limitation

(A) If used, single-use gloves shall be used for only one task such as working with ready-to-eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.

(B) Except as specified in paragraph (C) of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under 4.45-52 such as frozen food or a primal cut of meat.

(C) Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a single-use glove.

(D) Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required under 4.45-52 such as frozen food or a primal cut of meat.

SECTION 34. Using Clean Tableware for Second Portions and Refills

(A) Except for refilling a consumer's drinking cup or container without contact between the pouring utensil and the lip-contact area of the drinking cup or container, food employees may not use tableware, including single-service articles, soiled by the consumer, to provide second portions or refills.

(B) Except as specified in paragraph (C) of this section, self-service consumers may not be allowed to use soiled tableware, including single-service articles, to obtain additional food from the display and serving equipment.

(C) Drinking cups and containers may be reused by self-service consumers if refilling is a contamination-free process as specified under paragraphs 5.2(D)(3)(A), (B), and (D).

SECTION 35. Refilling Returnables

(A) A take-home food container returned to a food establishment may not be refilled at a food establishment with a potentially hazardous food.

(B) Except as specified in paragraph (C), a take-home food container refilled with food that is not potentially hazardous shall be cleaned as specified under paragraph 5.6(C)(7)(B).

(C) Personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under paragraphs 5.2(D)(3)(A), (B), and (D).

SECTION 36. Food Storage

(A) Except as specified in paragraphs (B) and (C) of this section, food shall be protected from contamination by storing the food:

- (1) In a clean, dry location;
- (2) Where it is not exposed to splash, dust, or other contamination; and
- (3) At least 15 cm (6 inches) above the floor.

(B) Food in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling equipment as specified under 5.2(D)(22).

(C) Pressurized beverage containers, cased food in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture.

SECTION 37. Food Storage, Prohibited Areas

Food may not be stored:

- (A) In locker rooms;
- (B) In toilet rooms;
- (C) In dressing rooms;
- (D) In garbage rooms;
- (E) In mechanical rooms;
- (F) Under sewer lines that are not shielded to intercept potential drips;
- (G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;

(H) Under unprotected stairwells; or

(I) Under other sources of contamination.

SECTION 38. Vended Potentially Hazardous Food, Original Container

Potentially hazardous food dispensed through a vending machine shall be in the package in which it was placed at the food establishment or food processing plant at which it was prepared.

SECTION 39. Food Preparation

During preparation, unpackaged food shall be protected from environmental sources of contamination.

SECTION 40. Food Display

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards; display cases; or other effective means.

SECTION 41. Condiments, Protection

(A) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.

(B) Condiments at a vending machine location shall be in individual packages or provided in dispensers that are filled at an approved location, such as the food establishment that provides food to the vending machine location, a food processing plant that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the vending machine location.

SECTION 42. Consumer Self-Service Operations

(A) Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish may not be offered for consumer self-service, except when otherwise specifically authorized and regulated by law. This paragraph does not apply to consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish; ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue; or raw, frozen, shell-on shrimp or lobster.

(B) Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination.

(C) Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures.

SECTION 43. Returned Food and Reservice of Food

(A) Except as specified in paragraph (B) of this section, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption.

(B) Except as specified under paragraph 4.68(C), a container of food that is not potentially hazardous may be transferred from one consumer to another if:

(1) The food is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

(2) The food, such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition.

SECTION 44. Returned Food and Reservice of Food

Food shall be protected from contamination that may result from a factor or source not specified hereunder.

SECTION 45. Raw Animal Foods

(A) Except as specified under paragraph (B) and in paragraphs (C) and (D) of this section, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for:

(a) Raw shell eggs that are broken and prepared in response to a consumer's order and for immediate service, and

(b) Except as specified under Subparagraphs (A)(2) and (3) and paragraph (B) of this section, fish, meat, and pork including game animals commercially raised for food as specified under Subparagraph 4.7(A)(1) and game animals under a voluntary inspection program as specified under Subparagraph 4.7(A)(2);

(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under Subparagraph 4.7(A)(1), and game animals under a voluntary inspection program as specified under Subparagraph 4.7(A)(2); and raw eggs that are not prepared as specified under Subparagraph (A)(1)(a) of this section:

Minimum Temperature °C (°F)	Time
63 (145)	3 minutes
66 (150)	1 minute
70 (158)	< 1 second (instantaneous)

;or

(3) 74°C (165°F) or above for 15 seconds for poultry, wild game animals as specified under Subparagraphs 4.7(A)(3) and (4), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry, or ratites.

(B) Whole beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham, shall be cooked:

(1) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:

Oven Type	Oven Temperature	Based on Roast Weight
Less than 4.5 kg (10 lbs)	4.5 kg (10 lbs)	Still Dry 177°C (350°F) or more 121°C (250°F) or more
or		Convection 163°C (325°F) or more 121°C (250°F) or more
More		High Humidity 1 121°C (250°F) or less 121°C (250°F) or less

(a) Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity; and

(2) As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature:

Temperature °C (°F)	Time in Minutes Temperature °C (°F)	Time in Seconds
54.4 (130)	112 63.9 (147)	134
55.0 (131)	89 65.0 (149)	85
56.1 (133)	56 66.1 (151)	54
57.2 (135)	36 67.2 (153)	34
57.8 (136)	28 68.3 (155)	22
58.9 (138)	18 69.4 (157)	14
60.0 (140)	12 70.0 (158)	0
	61.1 (142)	8
	62.2 (144)	5
	62.8 (145)	4

(a) Holding time may include postoven heat rise.

(C) A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:

(1) The food establishment serves a population that is not a highly susceptible population,

(2) The steak is labeled to indicate that it meets the definition of "whole-muscle, intact beef" as specified under paragraph 4.1(E), and

(3) The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.

(D) A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in paragraph (C) of this section, may be served or offered for sale in a ready-to-eat form if:

(1) The food establishment serves a population that is not a highly susceptible population, and

(2) The consumer is informed as specified under 4.66 that to ensure its safety, the food should be cooked as specified under paragraph (A) or (B) of this Section; or

(3) The regulatory authority grants a variance from paragraph (A) or (B) of this section as specified in 9.1(C)(1) based on a HACCP plan that:

(a) Is submitted by the permit holder and approved as specified under 9.1(C)(2),

(b) Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food, and

(c) Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions of the variance.

SECTION 46. Microwave Cooking

Raw animal foods cooked in a microwave oven shall be:

(A) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(B) Covered to retain surface moisture;

(C) Heated to a temperature of at least 74°C (165°F) in all parts of the food; and

(D) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

SECTION 47. Plant Food Cooking for Hot Holding

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 60°C (140°F).

SECTION 48. Freezing; Parasite Destruction

(A) Except as specified in paragraph (B) of this section, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish other than molluscan shellfish shall be:

(1) Frozen and stored at a temperature of -20°C (-4°F) or below for 168 hours (7 days) in a freezer; or

(2) Frozen at -35°C (-31°F) or below until solid and stored at -35°C (-31°F) for 15 hours.

(B) If the fish are tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern), the fish may be served or sold in a raw, raw-marinated, or partially cooked ready-to-eat form without freezing as specified under paragraph (A) of this section.

SECTION 49. Records, Creation and Retention

(A) Except as specified in paragraph 4.45(B) and paragraph (B) of this section, if raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish.

(B) If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 4.48 may substitute for the records specified under paragraph (A) of this section.

SECTION 50. Reheating; Preparation for Immediate Service

Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

SECTION 51. Reheating for Hot Holding

(A) Except as specified under paragraphs (B) and (C) and in paragraph (E) of this section, potentially hazardous food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74°C (165°F) for 15 seconds.

(B) Except as specified under paragraph (C) of this section, potentially hazardous food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74°C (165°F) and the food is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.

(C) Ready-to-eat food taken from a commercially processed, hermetically sealed container, or from an intact package from a food processing plant that is inspected by the food regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least 60°C (140°F) for hot holding.

(D) Reheating for hot holding shall be done rapidly and the time the food is between the temperature specified under paragraphs 4.58(A)(2) and 74°C (165°F) may not exceed 2 hours.

(E) Remaining unsliced portions of roasts of beef that are cooked as specified under paragraph 4.45(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under paragraph 4.45(B).

SECTION 52. Other Methods; Treating Juice

Juice packaged in a food establishment shall be:

(A) Treated under a HACCP plan as specified in paragraphs 9.2(A)(2)(b),(e) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance:

(1) As specified under 4.65, and

(2) As specified in 21 CFR 101.17(g) with the phrase, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

SECTION 53. Frozen Food

Stored frozen foods shall be maintained frozen.

SECTION 54. Potentially Hazardous Food, Slacking

Frozen potentially hazardous food that is slacked to moderate the temperature shall be held:

(A) Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under paragraph 4.58(A)(2)(b); or

(B) At any temperature if the food remains frozen.

SECTION 55. Thawing

Except as specified in paragraph (D) of this section, potentially hazardous food shall be thawed:

(A) Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under paragraph 4.58(A)(2)(b); or

(B) Completely submerged under running water:

(1) At a water temperature of 21°C (70°F) or below,

(2) With sufficient water velocity to agitate and float off loose particles in an overflow, and

(3) For a period of time that does not allow thawed portions of ready-to-eat food to rise above 5°C (41°F), or 7°C (45°F) as specified under paragraph 4.58(A)(2)(b), or

(4) For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under paragraph 4.45(A) or (B) to be above 5°C (41°F), or 7°C (45°F) as specified under paragraph 4.58(A)(2)(b), for more than 4 hours including:

(a) The time the food is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the food temperature to 5°C (41°F), or 7°C (45°F) as specified under paragraph 4.58(A)(2)(b);

(C) As part of a cooking process if the food that is frozen is:

(1) Cooked as specified under paragraph 4.45(A) or (B) or 4.46, or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or

(D) Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

SECTION 56. Cooling

(A) Cooked potentially hazardous food shall be cooled:

(1) Within 2 hours from 60°C (140°F) to 21°C (70°F); and

(2) Within 6 hours from 60°C (140°F) to 5°C (41°F) or less, or to 7°C (45°F) or less as specified under paragraph 4.58(A)(2)(b).

(B) Potentially hazardous food shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) as specified under paragraph 4.58(A)(2)(b) if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.

(C) Except as specified in paragraph (D) of this section, a potentially hazardous food received in compliance with laws allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in paragraph 4.8(B), shall be cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified under paragraph 4.58(A)(2)(b).

(D) Raw shell eggs shall be received as specified under paragraph 4.8(C) and immediately placed in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less.

SECTION 57. Cooling Methods

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under 4.56 by using one or more of the following methods based on the type of food being cooled:

- (1) Placing the food in shallow pans;
- (2) Separating the food into smaller or thinner portions;
- (3) Using rapid cooling equipment;
- (4) Stirring the food in a container placed in an ice water bath;
- (5) Using containers that facilitate heat transfer;
- (6) Adding ice as an ingredient; or
- (7) Other effective methods.

(B) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

- (1) Arranged in the equipment to provide maximum heat transfer through the container walls; and
- (2) Loosely covered, or uncovered if protected from overhead contamination as specified under Subparagraph 4.36(A)(2), during the cooling period to facilitate heat transfer from the surface of the food.

SECTION 58. Potentially Hazardous Food, Hot and Cold Holding

(A) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 4.61, and except as specified in paragraph (B) of this section, potentially hazardous food shall be maintained:

- (1) At 60°C (140°F) or above, except that roasts cooked to a temperature and for a time specified under paragraph 4.45(B) or reheated as specified in paragraph 4.51(E) may be held at a temperature of 54°C (130°F); or
- (2) At a temperature and time specified in the following:

(a) 5°C (41°F) or less for a maximum of 7 days; or

(b) At 7°C (45°F) or between 5°C (41°F) and 7°C (45°C) for a maximum of 4 days in existing refrigeration equipment that is not capable of maintaining the food at 5°C (41°F) or less if:

- (i) The equipment is in place and in use in the food establishment, and
- (ii) Within 2 years of the regulatory authority's issuance of a variance, the equipment is upgraded or replaced to maintain food at a temperature of 5°C (41°F) or less.

(B) Shell eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less.

SECTION 59. Ready-to-Eat, Potentially Hazardous Food, Date Marking

On-premises preparation-prepare and held cold:

(A) Except as specified in paragraph (D) of this section, refrigerated, ready-to-eat, potentially hazardous food prepared and held in a food establishment for more than 24 hours shall be clearly marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in paragraph 4.58(A)(2)(b). The day of preparation shall be counted as Day 1.

Commercially processed food open and held cold:

(B) Except as specified in paragraphs (D) and (E) of this section, refrigerated, ready-to-eat, potentially hazardous food prepared and packaged by a food processing plant shall be clearly marked, at the time the original container is opened in a food establishment and if the food is held for more than 24 hours, to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in paragraph 4.58(A)(2)(b); and

- (1) The day the original container is opened in the food establishment shall be counted as Day 1; and
- (2) The day or date marked by the food establishment may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on food safety.

(C) A refrigerated, ready-to-eat potentially hazardous food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical,

such as soft serve mix or milk in a dispensing machine, may be marked as specified in paragraph (A) or (B) of this section, or by an alternative method acceptable to the regulatory authority.

(D) Paragraphs (A) and (B) of this section do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.

(E) Paragraph (B) of this section does not apply to the following when the face has been cut, but the remaining portion is whole and intact:

- (1) Fermented sausages produced in a federally inspected food processing plant that are not labeled "Keep Refrigerated" and which retain the original casing on the product;
- (2) Shelf stable, dry, fermented sausages; and
- (3) Shelf stable salt-cured products such as prosciutto and Parma (ham) produced in a federally inspected food processing plant that are not labeled "Keep Refrigerated".

(F) A refrigerated, ready-to-eat, potentially hazardous food ingredient or a portion of a refrigerated, ready-to-eat, potentially hazardous food that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest-prepared or first-prepared ingredient.

SECTION 60. Ready-to-Eat, Potentially Hazardous Food, Disposition

(A) A food specified in paragraph 4.59(A) or (B) shall be discarded if it:

- (1) Exceeds either of the temperature and time combinations specified in paragraph 4.58(A)(2)(b), except time that the product is frozen;
- (2) Is in a container or package that does not bear a date or day; or
- (3) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in paragraph 4.58(A)(2)(b).

(B) Refrigerated, ready-to-eat, potentially hazardous food prepared in a food establishment and dispensed through a vending machine with an automatic shutoff control shall be discarded if it exceeds a temperature and time combination as specified in paragraph 4.58(A)(2)(b).

SECTION 61. Time as a Public Health Control

(A) Except as specified under paragraph (B) of this section, if time only, rather than time in conjunction with temperature, is used as the public health control for a

working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption:

- (1) The food shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the food is removed from temperature control,
- (2) The food shall be cooked and served, served if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control,
- (3) The food in unmarked containers or packages or marked to exceed a 4 hour limit shall be discarded, and
- (4) Written procedures shall be maintained in the food establishment and made available to the regulatory authority upon request, that ensure compliance with:
 - (a) Subparagraphs (A)(1)-(4) of this section, and
 - (b) 4.56 for food that is prepared, cooked, and refrigerated before time is used as a public health control.

(B) In a food establishment that serves a highly susceptible population, time only, rather than time in conjunction with temperature, may not be used as the public health control for raw eggs.

SECTION 62. Variance Requirement

(A) A food establishment shall obtain a variance from the regulatory authority as specified in 9.1(C)(1) and under 9.1(C)(2) before:

- (1) Smoking food as a method of food preservation rather than as a method of flavor enhancement;
- (2) Curing food;
- (3) Using food additives or adding components such as vinegar:
 - (a) As a method of food preservation rather than as a method of flavor enhancement, or
 - (b) To render a food so that it is not potentially hazardous;

(4) Packaging food using a reduced oxygen packaging method except as specified under 4.63 where a barrier to Clostridium botulinum in addition to refrigeration exists;

(5) Operating a molluscan shellfish life-support system display tank used to store and display shellfish that are offered for human consumption;

(6) Custom processing animals that are for personal use as food and not for sale or service in a food establishment; or

(7) Preparing food by another method that is determined by the regulatory authority to require a variance.

SECTION 63. Clostridium Botulinum Controls, Reduced Oxygen Packaging, Criteria

(A) Except for a food establishment that obtains a variance as specified under 4.62, a food establishment that packages food using a reduced oxygen packaging method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall ensure that there are at least two barriers in place to control the growth and toxin formation of Clostridium botulinum.

(B) A food establishment that packages food using a reduced oxygen packaging method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall have a HACCP plan that contains the information specified under paragraph 9.2(4)(d) and that:

(1) Identifies the food to be packaged;

(2) Limits the food packaged to a food that does not support the growth of Clostridium botulinum because it complies with one of the following:

(a) Has an aw of 0.91 or less,

(b) Has a pH of 4.6 or less,

(c) Is a meat or poultry product cured at a food processing plant regulated by the U.S.D.A. using substances specified in 9 CFR 318.7 Approval of substances for use in the preparation of products and 9 CFR 381.147 restrictions on the use of substances in poultry products and is received in an intact package, or

(d) Is a food with a high level of competing organisms such as raw meat or raw poultry;

(3) Specifies methods for maintaining food at 5°C (41°F) or below;

(4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(a) Maintain the food at 5°C (41°F) or below, and

(b) For food held at refrigeration temperatures, discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;

(5) Limits the refrigerated shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(6) Includes operational procedures that:

(a) Prohibit contacting food with bare hands,

(b) Identify a designated area and the method by which:

(i) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, and

(ii) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, and

(c) Delineate cleaning and sanitization procedures for food-contact surfaces; and

(7) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(a) Concepts required for a safe operation,

(b) Equipment and facilities, and

(c) Procedures specified under Subparagraph (B)(6) of this section and 9.2(d).

(C) Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.

SECTION 64. Accurate Representation

(A) Standards of Identity.

Packaged food shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and Standards of Identity or Composition, and the general requirements in 21 CFR 130 - Food Standards: General and 9 CFR 319 Subpart A - General.

(B) Honestly Presented.

- (1) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.
- (2) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food.

SECTION 65. Labeling

(A) Food Labels.

- (1) Food packaged in a food establishment, shall be labeled as specified in law, including 21 CFR 101 - Food Labeling, and 9 CFR 317 Labeling, Marking Devices, and Containers.
- (2) Label information shall include:
 - (a) The common name of the food, or absent a common name, an adequately descriptive identity statement;
 - (b) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food;
 - (c) An accurate declaration of the quantity of contents;
 - (d) The name and place of business of the manufacturer, packer, or distributor; and
 - (e) Except as exempted in the Federal Food, Drug, and Cosmetic Act ' 403(Q)(3)-(5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.
 - (f) For any salmonid fish containing canthaxanthin as a color additive, the labeling of the bulk fish container, including a list of

ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin.

(3) Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:

- (a) The manufacturer's or processor's label that was provided with the food; or
 - (b) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.
- (4) Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:
- (a) A health, nutrient content, or other claim is not made;
 - (b) There are no state or local laws requiring labeling; and
 - (c) The food is manufactured or prepared on the premises of the food establishment or at another food establishment or a food processing plant that is owned by the same person and is regulated by the food regulatory agency that has jurisdiction.

(B) Other Forms of Information.

- (1) If required by law, consumer warnings shall be provided.
- (2) Food establishment or manufacturers' dating information on foods may not be concealed or altered.
- (3) Disclosure is satisfied when:
 - (a) Items are described, such as:
 - (i) Oysters on the half-shell (raw oysters),
 - (ii) Raw-egg caesar salad, and
 - (iii) Hamburgers (can be cooked to order); or
 - (b) Items are asterisked to a footnote that states that the items:

- (i) Are served raw or undercooked, or
- (ii) Contain (or may contain) raw or undercooked ingredients.

Section 66. Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens

Except as specified in paragraph 4.45(C) and Subparagraph 4.45(D)(3) and under paragraph 4.68(D), if an animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish that is raw, undercooked, or not otherwise processed to eliminate pathogens is offered in a ready-to-eat form as a deli, menu, vended, or other item; or as a raw ingredient in another ready-to-eat food, the permit holder shall inform consumers by brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means of the significantly increased risk associated with certain especially vulnerable consumers eating such foods in raw or undercooked form.

SECTION 67. Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food

- (A) A food that is unsafe, adulterated, or not honestly presented as specified under ' 3-101.11 shall be reconditioned according to an approved procedure or discarded.
- (B) Food that is not from an approved source as specified under 4.1 through 4.7 shall be discarded.
- (C) Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 4.2 shall be discarded.
- (D) Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded.

SECTION 68. Pasteurized Foods, Prohibited Reservice, and Prohibited Food

In a food establishment that serves a highly susceptible population:

- (A) The following criteria apply to juice:
 - (1) For the purposes of this paragraph only, children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care are included as highly susceptible populations;
 - (2) Prepackaged juice or a prepackaged beverage containing juice, that bears a warning label as specified in 21 CFR, Section 101.17(g) Food Labeling, or

packaged juice or beverage containing juice, that bears a warning label as specified under 4.52(B) may not be served or offered for sale; and

(3) Unpackaged juice that is prepared on the premises for service or sale in a ready-to-eat form shall be processed under a HACCP plan that contains the information specified in paragraph 9.8(A)(4)(b), (e) and as specified under 21 CFR PART 120 HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS, Sec. 120.24 Process controls.

(B) Pasteurized shell eggs or pasteurized liquid, frozen, or dry eggs or egg products shall be substituted for raw shell eggs in the preparation of:

- (1) Foods such as caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and egg-fortified beverages, and
- (2) Except as specified in paragraph (E) of this Section, recipes in which more than one egg is broken and the eggs are combined;

(C) Food in an unopened original package may not be re-served; and

(D) The following foods may not be served or offered for sale in a ready-to-eat form:

- (1) Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare,
- (2) A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw shell eggs, and meringue, and
- (3) Raw seed sprouts.

(E) Subparagraph (B)(2) of this section does not apply if:

- (1) The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified under Subparagraph 4.45(A)(1), and served immediately, such as an omelet, soufflé, or scrambled eggs;
- (2) The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread; or
- (3) The preparation of the food is conducted under a HACCP plan that:
 - (a) Identifies the food to be prepared,
 - (b) Prohibits contacting ready-to-eat food with bare hands,

(c) Includes specifications and practices that ensure:

(i) Salmonella Enteritidis growth is controlled before and after cooking, and (ii) Salmonella Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in subparagraph 4.45(A)(2),

(d) Contains the information specified under 9.2(A)(4)(d) including procedures that:

(i) Control cross contamination of ready-to-eat food with raw eggs, and

(ii) Delineate cleaning and sanitization procedures for food-contact surfaces, and

(e) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

CHAPTER 5. EQUIPMENT, UTENSILS, AND LINENS

SECTION 1. Materials for Construction and Repair

(A) Characteristics. Materials that are used in the construction of utensils and food-contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be:

- (1) Safe;
- (2) Durable, corrosion-resistant, and nonabsorbent;
- (3) Sufficient in weight and thickness to withstand repeated warewashing;
- (4) Finished to have a smooth, easily cleanable surface; and
- (5) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

(B) Cast Iron, Use Limitation.

- (1) Except as specified in paragraphs (2) and (3) of this section, cast iron may not be used for utensils or food-contact surfaces of equipment.
- (2) Cast iron may be used as a surface for cooking.

(3) Cast iron may be used in utensils for serving food if the utensils are used only as part of an uninterrupted process from cooking through service.

(C) Lead in Ceramic, China, and Crystal Utensils, Use Limitation. Ceramic, china, crystal utensils, and decorative utensils such as hand painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories:

Utensil Category	Description	Maximum Lead mg/L
Hot Beverage Mugs	Coffee Mugs	0.5
Large Hollowware	Bowls greater than or equal to 1.1 L(1.16 QT)	1
Small Hollowware	Bowls < 1.1 L(1.16 QT)	2.0
Flat Utensils	Plates, Saucers	3.0

(D) Copper, Use Limitation.

(1) Except as specified in paragraph (B) of this section, copper and copper alloys such as brass may not be used in contact with a food that has a pH below 6 such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.

(2) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

(E) Galvanized Metal, Use Limitation. Galvanized metal may not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.

(E) Sponges, Use Limitation. Sponges may not be used in contact with cleaned and sanitized or in-use food-contact surfaces.

(F) Lead in Pewter Alloys, Use Limitation. Pewter alloys containing lead in excess of 0.05% may not be used as a food-contact surface.

(G) Lead in Solder and Flux, Use Limitation. Solder and flux containing lead in excess of 0.2% may not be used as a food-contact surface.

(H) Wood, Use Limitation.

(1) Except as specified in paragraphs (B), (C), and (D) of this Section, wood and wood wicker may not be used as a food-contact surface.

(2) Hard maple or an equivalently hard, close-grained wood may be used for:

(a) Cutting boards; cutting blocks; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and

(b) Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.

(c) Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.

(d) If the nature of the food requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw food may be kept in:

(i) Untreated wood containers; or

(ii) Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for wood.

(I) Nonstick Coatings, Use Limitation. Multiuse kitchenware such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching utensils and cleaning aids.

(J) Nonfood-Contact surfaces. Nonfood-contact surfaces of equipment that are exposed to splash, spillage, or other food soiling or that require frequent cleaning shall be constructed of a corrosion-resistant, nonabsorbent, and smooth material.

(K) Single-Service and Single-Use. Materials that are used to make single-service and single-use articles:

(1) May not:

(a) Allow the migration of deleterious substances, or

(b) Impart colors, odors, or tastes to food; and

(2) Shall be:

(a) Safe, and

(b) Clean.

SECTION 2. Design and Construction

(A) Durability and Strength.

(1) Equipment and Utensils. Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

(2) Food Temperature Measuring Devices. Food temperature measuring device may not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.

(B) Cleanability.

(1) Food-Contact Surfaces. Multiuse food-contact surfaces shall be:

(a) Smooth;

(b) Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections;

(c) Free of sharp internal angles, corners, and crevices;

(d) Finished to have smooth welds and joints; and

(e) Except as specified in paragraph (B) of this section, accessible for cleaning and inspection by one of the following methods:

(i) Without being disassembled,

(ii) By disassembling without the use of tools, or

(iii) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

(2) Subparagraph (1)(e) of this Section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.

(3) CIP Equipment. CIP equipment shall meet the characteristics specified under subparagraph (B) and shall be designed and constructed so that:

(a) Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces, and

(b) The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions; and

(c) CIP equipment that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

(4) "V" Threads, Use Limitation. Except for hot oil cooking or filtering equipment, "V" type threads may not be used on food-contact surfaces.

(5) Hot Oil Filtering Equipment. Hot oil filtering equipment shall meet the characteristics specified under 5.2(B)(1) or 5.2(B)(3) and shall be readily accessible for filter replacement and cleaning of the filter.

(6) Can Openers. Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

(7) Nonfood-Contact Surfaces. Nonfood-contact surfaces shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

(8) Kick Plates, Removable. Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

(a) Removable by one of the methods specified under Subparagraph 5.2(B)(1)(e) or capable of being rotated open; and

(b) Removable or capable of being rotated open without unlocking equipment doors.

(9) Ventilation Hood Systems, Filters. Filters or other grease extracting equipment shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

(C) Accuracy.

(1) Temperature Measuring Devices, Food.

(a) Food temperature measuring device that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to "1°C in the intended range of use.

(b) Food temperature measuring device that are scaled only in Fahrenheit shall be accurate to "2°F in the intended range of use.

(2) Temperature Measuring Devices, Ambient Air, and Water.

(a) Ambient air and water temperature measuring device that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to "1.5°C in the intended range of use.

(b) Ambient air and water temperature measuring device that are scaled only in Fahrenheit shall be accurate to "3°F in the intended range of use.

(3) Pressure Measuring Devices, Mechanical Warewashing Equipment.

Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse shall have increments of 7 kilopascals (1 pounds per square inch) or smaller and shall be accurate to " 14 kilopascals (" 2 pounds per square inch) in the 100-170 kilopascals (15-25 pounds per square inch) range.

(D) Functionality.

(1) Ventilation Hood Systems, Drip Prevention. Exhaust ventilation hood systems in food preparation and warewashing areas including components such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.

(2) Equipment Openings, Closures and Deflectors.

(a) A cover or lid for equipment shall overlap the opening and be sloped to drain.

(b) An opening located within the top of a unit of equipment that is designed for use with a cover or lid shall be flanged upward at least 5 millimeters (two-tenths of an inch).

(c) Except as specified under paragraph (D) of this section, fixed piping, temperature measuring device, rotary shafts, and other parts extending into equipment shall be provided with a watertight joint at the point where the item enters the equipment.

(b) If a watertight joint is not provided:

(i) The piping, temperature measuring device, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the food; and

(2) The opening shall be flanged as specified under paragraph (B) of this section.

(3) Dispensing Equipment, Protection of Equipment and Food. In equipment that dispenses or vends liquid food or ice in unpackaged form:

(A) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food;

(B) The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

(C) The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the equipment is:

(1) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment, or

(2) Available for self-service during hours when it is not under the full-time supervision of a food employee; and

(D) The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

(4) Vending Machine, Vending Stage Closure. The dispensing compartment of a vending machine including a machine that is designed to vend prepackaged snack food that is not potentially hazardous such as chips, party

mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

(A) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(B) Available for self-service during hours when it is not under the full-time supervision of a food employee.

(5) Bearings and Gear Boxes, Leakproof. Equipment containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant can not leak, drip, or be forced into food or onto food-contact surfaces.

(6) Beverage Tubing, Separation. Beverage tubing and cold-plate beverage cooling devices may not be installed in contact with stored ice. This section does not apply to cold plates that are constructed integrally with an ice storage bin.

(7) Ice Units, Separation of Drains. Liquid waste drain lines may not pass through an ice machine or ice storage bin.

(8) Condenser Unit, Separation. If a condenser unit is an integral component of equipment, the condenser unit shall be separated from the food and food storage space by a dustproof barrier.

(9) Can Openers on Vending Machines. Cutting or piercing parts of can openers on vending machines shall be protected from manual contact, dust, insects, rodents, and other contamination.

(10) Molluscan Shellfish Tanks.

(A) Except as specified under paragraph (B) of this section, molluscan shellfish life support system display tanks may not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only.

(B) Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified in 9.1(C)(1) and a HACCP plan that:

(1) Is submitted by the permit holder and approved as specified under 9.1(C)(2); and

(2) Ensures that:

(i) Water used with fish other than molluscan shellfish does not flow into the molluscan tank,

(ii) The safety and quality of the shellfish as they were received are not compromised by the use of the tank, and

(iii) The identity of the source of the shellstock is retained as specified under 4.19.

(11) Vending Machines, Automatic Shutoff.

(A) A machine vending potentially hazardous food shall have an automatic control that prevents the machine from vending food:

(1) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that can not maintain food temperatures as specified under Chapter 3; and

(2) If a condition specified under Subparagraph (A)(1) of this section occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified under Chapter 3.

(B) When the automatic shutoff within a machine vending potentially hazardous food is activated:

(1) In a refrigerated vending machine, the ambient temperature may not exceed any time/temperature combination as specified under paragraph 4.58(A)(2)(b) for more than 30 minutes immediately after the machine is filled, serviced, or restocked; or

(2) In a hot holding vending machine, the ambient temperature may not be less than 60°C (140°F) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.

(12) Temperature Measuring Devices.

(A) In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.

(B) Except as specified in paragraph (C) of this section, cold or hot holding equipment used for potentially hazardous food shall be designed to include and shall be equipped with at least one temperature measuring device that is located to allow easy viewing of the device's temperature display.

(C) Paragraph (B) of this section does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers, and salad bars.

(D) Temperature measuring devices shall be designed to be easily readable.

(E) Food temperature measuring device and water temperature measuring device on warewashing machines shall have a numerical scale, printed record, or digital readout in increments no greater than 1°C or 2°F in the intended range of use.

(13) Warewashing Machine, Data Plate Operating Specifications. A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operating specifications including the:

(A) Temperatures required for washing, rinsing, and sanitizing;

(B) Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and

(C) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

(14) Warewashing Machines, Internal Baffles. Warewashing machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

(15) Warewashing Machines, Temperature Measuring Devices. A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:

(A) In each wash and rinse tank; and

(B) As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.

(16) Manual Warewashing equipment, Heaters and Baskets. If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be:

(A) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F); and

(B) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

(17) Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers. A warewashing machine that is installed after adoption of this Code by the regulatory authority, shall be designed and equipped to:

(A) Automatically dispense detergents and sanitizers; and

(B) Incorporate a visual means to verify that detergents and sanitizers are delivered or a visual or audible alarm to signal if the detergents and sanitizers are not delivered to the respective washing and sanitizing cycles.

(18) Warewashing Machines, Flow Pressure Device.

(A) Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine; and

(B) If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device shall be mounted in a 6.4 millimeter or one-fourth inch Iron Pipe Size (IPS) valve.

(C) Paragraphs (A) and (B) of this section do not apply to a machine that uses only a pumped or recirculated sanitizing rinse.

(19) Warewashing Sinks and Drainboards, Self-Draining. Sinks and drainboards of warewashing sinks and machines shall be self-draining.

(20) Equipment Compartments, Drainage. Equipment compartments that are subject to accumulation of moisture due to conditions such as condensation, food or beverage drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

(21) Vending Machines, Liquid Waste Products.

(A) Vending machines designed to store beverages that are packaged in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(B) Vending machines that dispense liquid food in bulk shall be:

(1) Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow, or other internal wastes; and

(2) Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(C) Shutoff devices specified under Subparagraph (B)(2) of this section shall prevent water or liquid food from continuously running if there is a failure of a flow control device in the water or liquid food system or waste accumulation that could lead to overflow of the waste receptacle.

(22) Case Lot Handling Equipment, Moveability. Equipment, such as dollies, pallets, racks, and skids used to store and transport large quantities of packaged foods received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available equipment such as hand trucks and forklifts.

(23) Vending Machine Doors and Openings.

(A) Vending machine doors and access opening covers to food and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed

position, is no greater than 1.5 millimeters or one-sixteenth inch by:

- (1) Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than 1.5 millimeters or one-sixteenth inch. Screening of 12 or more mesh to 2.5 centimeters (12 mesh to 1 inch) meets this requirement;
- (2) Being effectively gasketed;
- (3) Having interface surfaces that are at least 13 millimeters or one-half inch wide; or
- (4) Jambs or surfaces used to form an L-shaped entry path to the interface.

(B) Vending machine service connection openings through an exterior wall of a machine shall be closed by sealants, clamps, or grommets so that the openings are no larger than 1.5 millimeters or one-sixteenth inch.

(E) Acceptability.

(1) Food Equipment, Certification and Classification. Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program will be deemed to comply with Parts 5.1 and 5.2 of this chapter.

SECTION 3. Numbers and Capacities

(A) Equipment.

(1) Cooling, Heating, and Holding Capacities. Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity to provide food temperatures as specified under Chapter 3.

(2) Manual Warewashing, Sink Compartment Requirements.

- (a) A sink must have at least 2 compartments and be appropriately designed to effectively provide for manually washing, rinsing, and sanitizing equipment and utensils.
- (b) Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing

machine or alternative equipment as specified in paragraph (C) of this section shall be used.

(c) Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include:

- (i) High-pressure detergent sprayers;
- (ii) Low- or line-pressure spray detergent foamers;
- (iii) Other task-specific cleaning equipment;
- (iv) Brushes or other implements;
- (v) 2-compartment sinks as specified under paragraphs (D) and (E) of this section; or
- (vi) Receptacles that substitute for the compartments of a multi compartment sink.

(d) Before a 2-compartment sink is used:

- (i) The permit holder shall have its use approved; and
- (ii) The permit holder shall limit the number of kitchenware items cleaned and sanitized in the 2-compartment sink, and shall limit warewashing to batch operations for cleaning kitchenware such as between cutting one type of raw meat and another or cleanup at the end of a shift, and shall:
 - (aa) Make up the cleaning and sanitizing solutions immediately before use and drain them immediately after use, and
 - (bb) Use a detergent-sanitizer to sanitize and apply the detergent-sanitizer in accordance with the manufacturer's label instructions and as specified under 5.5(A)(15), or (a) Use a hot water sanitization immersion step as specified under paragraph 5.6(C)(6).

(e) A 2-compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a

continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process.

(3) Drainboards. Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary utensil holding before cleaning and after sanitizing.

(4) Ventilation Hood Systems, Adequacy. Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

(5) Clothes Washers and Dryers.

(A) Except as specified in paragraph (B) of this section, if work clothes or linens are laundered on the premises, a mechanical clothes washer and dryer shall be provided and used.

(B) If on-premises laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under 5.9(B)(2), a mechanical clothes washer and dryer need not be provided.

(B) Utensils, Temperature Measuring Devices, and Testing Devices.

(1) Utensils, Consumer Self-Service. A food dispensing utensil shall be available for each container displayed at a consumer self-service unit such as a buffet or salad bar.

(2) Food Temperature Measuring Devices.

(A) Food temperature measuring device shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under Chapter 3.

(B) A temperature measuring device with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin foods such as meat patties and fish filets.

(C) Unless complete, current and accurate written records are kept, an accurate and regularly calibrated temperature measuring device and a time and temperature of the food process shall be utilized by food establishments.

(3) Temperature Measuring Devices, Manual Warewashing. In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

(4) Sanitizing Solutions, Testing Devices. A test kit or other device that accurately measures the concentration in mg/L of sanitizing solutions shall be provided.

SECTION 4. Location and Installation

(A) Location.

(1) Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

(2) Except as specified in paragraph (B) of this Section, equipment, a cabinet used for the storage of food, or a cabinet that is used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be located:

- (1) In locker rooms;
- (2) In toilet rooms;
- (3) In garbage rooms;
- (4) In mechanical rooms;
- (5) Under sewer lines that are not shielded to intercept potential drips;
- (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
- (7) Under unprotected stairwells; or
- (8) Under other sources of contamination.

(3) A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.

(4) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(B) Installation.

(1) Fixed Equipment, Spacing or Sealing.

(a) Equipment that is fixed because it is not easily movable shall be installed so that it is:

(ii) Spaced to allow access for cleaning along the sides, behind, and above the equipment;

(ii) Spaced from adjoining equipment, walls, and ceilings a distance of not more than 1 millimeter or one thirty-second inch; or

(iii) Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.

(b) Table-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being:

(i) Sealed to the table; or

(ii) Elevated on legs or by other stable means as specified under paragraph 5.2(B)(2)(D).

(2) Fixed Equipment, Elevation or Sealing.

(a) Except as specified in paragraphs (B) and (C) of this section, floor-mounted equipment that is not easily movable shall be sealed to the floor or elevated on legs that provide at least a 15 centimeter (6 inch) clearance between the floor and the equipment.

(b) If no part of the floor under the floor-mounted equipment is more than 15 centimeters (6 inches) from the point of cleaning access, the clearance space may be only 10 centimeters (4 inches).

(c) This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the consumer shopping areas of a retail food store, if the floor under the units is maintained clean.

(d) Except as specified in paragraph (E) of this section, table-mounted or other equipment that is not easily movable shall be elevated on legs or by other stable means that provide at least a 10

centimeter (4 inch) clearance between the table or floor and the equipment.

(e) The clearance space between the table and table-mounted equipment may be:

(i) 7.5 centimeters (3 inches) if the horizontal distance of the table top under the equipment is no more than 50 centimeters (20 inches) from the point of access for cleaning; or

(ii) 5 centimeters (2 inches) if the horizontal distance of the table top under the equipment is no more than 7.5 centimeters (3 inches) from the point of access for cleaning

SECTION 5. Maintenance and Operation

(A) Equipment.

(1) Good Repair and Proper Adjustment.

(a) Equipment shall be maintained in a state of repair and condition that meets the requirements specified under Parts 5.1 and 5.2.

(b) Equipment components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with the manufacturer's or comparable specifications.

(c) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

(2) Cutting Surfaces. Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded if they are not capable of being resurfaced.

(3) Microwave Ovens. Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10.

(4) Warewashing equipment, cleaning frequency. A warewashing machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, or raw foods, or laundering wiping cloths; and

drainboards or other equipment used to substitute for drainboards as specified under 5.3(A)(3) shall be cleaned:

- (a) Before use;
- (b) Throughout the day at a frequency necessary to prevent recontamination of equipment and utensils and to ensure that the equipment performs its intended function; and
- (c) If used, at least every 24 hours.

(5) Warewashing Machines, Manufacturers' Operating Instructions.

- (a) A warewashing machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.
- (b) A warewashing machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

(6) Warewashing Sinks, Use Limitation.

- (a) A warewashing sink may not be used for hand washing as specified under 3.5(E)(2).
- (b) If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink shall be cleaned as specified under 5.5(A)(4) before and after each time it is used to wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified under Part 5.7 before and after using the sink to wash produce or thaw food.

(7) Warewashing Equipment, Cleaning Agents. When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 5.3(A)(2)(C), shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.

(8) Warewashing Equipment, Clean Solutions. The wash, rinse, and sanitize solutions shall be maintained clean.

(9) Manual Warewashing Equipment, Wash Solution Temperature. The temperature of the wash solution in manual warewashing equipment shall be

maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions.

(10) Mechanical Warewashing Equipment, Wash Solution Temperature.

- (a) The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than:
 - (1) For a stationary rack, single temperature machine, 74°C (165°F);
 - (2) For a stationary rack, dual temperature machine, 66°C (150°F);
 - (3) For a single tank, conveyor, dual temperature machine, 71°C (160°F); or
 - (4) For a multitank, conveyor, multi-temperature machine, 66°C (150°F).
- (b) The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than 49°C (120°F).

(11) Manual Warewashing Equipment, Hot Water Sanitization Temperatures. If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above.

(12) Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

- (a) Except as specified in paragraph (B) of this section, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than 90°C (194°F), or less than:
 - (i) For a stationary rack, single temperature machine, 74°C (165°F); or
 - (ii) For all other machines, 82°C (180°F).

(b) The maximum temperature specified under paragraph (A) of this Section, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.

(13) Mechanical Warewashing Equipment, Sanitization Pressure. The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine may not be less than 100 kilopascals (15 pounds per square inch) or more than 170 kilopascals (25 pounds per square inch) as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve.

(14) Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness. A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at exposure times specified under paragraph 5.7(C) shall be listed in 21 CFR 178.1010 sanitizing solutions, shall be used in accordance with the EPA-approved manufacturer's label use instructions, and shall be used as follows:

(a) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;

Minimum Concentration	Minimum Temperature	Minimum Temperature
mg/L	pH 10 or less °C (°F)	pH 8 or less °C (°F)
25	49 (120)	49 (120)
50	38 (100)	24 (75)
100	13 (55)	13 (55)

(b) An iodine solution shall have a:

- (i) Minimum temperature of 24°C (75°F),
- (ii) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, and
- (iii) Concentration between 12.5 mg/L and 25 mg/L;

(c) A quaternary ammonium compound solution shall:

- (i) Have a minimum temperature of 24°C (75°F),
- (ii) Have a concentration as specified under 8.2(D)(1) and as indicated by the manufacturer's use directions included in the labeling, and

(iii) Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;

(d) If another solution of a chemical specified under paragraphs (A)-(C) of this section is used, the permit holder shall demonstrate to the regulatory authority that the solution achieves sanitization and the use of the solution shall be approved; or

(e) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling.

(15) Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers. If a detergent-sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step shall be the same detergent-sanitizer that is used in the washing step.

(16) Warewashing Equipment, Determining Chemical Sanitizer Concentration. Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.

(B) Utensils and Temperature and Pressure Measuring Devices.

(1) Good Repair and Calibration.

(a) Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under Parts 5.1 and 5.2 or shall be discarded.

(b) Food temperature measuring device shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

(c) Ambient air temperature, water pressure, and water temperature measuring device shall be maintained in good repair and be accurate within the intended range of use.

(2) Single-Service and Single-Use Articles, Required Use. A food establishment without facilities specified under Parts 5.6 and 5.7 for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers.

(3) Single-Service and Single-Use Articles, Use Limitation.

- (a) Single-service and single-use articles may not be reused for food service.
- (b) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.
- (c) Single-service plastic containers may be used for non-food service activities, provided that they are first properly cleaned and sterilized and no cross contamination is evident.

(4) Shells, Use Limitation. Mollusk and crustacea shells may not be used more than once as serving containers.

SECTION 6. Cleaning of Equipment and Utensils

(A) Objective.

(1) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.*

- (a) Equipment food-contact surfaces and utensils shall be clean to sight and touch.
- (b) The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.
- (c) Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris.

(B) Frequency.

(1) Equipment Food-Contact Surfaces and Utensils.

(A) Equipment food-contact surfaces and utensils shall be cleaned:

- (i) Except as specified in paragraph (B) of this section, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry;

(ii) Each time there is a change from working with raw foods to working with ready-to-eat foods;

(iii) Between uses with raw fruits and vegetables and with potentially hazardous food;

(iv) Before using or storing a food temperature measuring device; and

(v) At any time during the operation when contamination may have occurred.

(b) Subparagraph (A)(1) of this section does not apply if the food-contact surface or utensil is in contact with a succession of different raw animal foods each requiring a higher cooking temperature as specified under 4.45 than the previous food, such as preparing raw fish followed by cutting raw poultry on the same cutting board.

(c) Except as specified in paragraph (D) of this section, if used with potentially hazardous food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every 4 hours.

(d) Surfaces of utensils and equipment contacting potentially hazardous food may be cleaned less frequently than every 4 hours if:

(i) In storage, containers of potentially hazardous food and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;

(ii) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:

(aa) The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature:

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C - 7.2°C (>41°F - 45°F)	20 hours
>7.2°C - 10.0°C (>45°F - 50°F)	16 hours
>10.0°C - 12.8°C (>50°F - 55°F)	10 hours; and,

(bb) The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment.

(iii) Containers in serving situations such as salad bars, delis, and cafeteria lines hold ready-to-eat potentially hazardous food that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours;

(iv) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under Chapter 3;

(v) Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues;

(vi) The cleaning schedule is approved based on consideration of:

(aa) Characteristics of the equipment and its use,

(bb) The type of food involved,

(cv) The amount of food residue accumulation, and

(dd) The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or

(vii) In-use utensils are intermittently stored in a container of water in which the water is maintained at 60°C (140°F) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

(e) Except when dry cleaning methods are used as specified under 5.6(C)(1), surfaces of utensils and equipment contacting food that is not potentially hazardous shall be cleaned:

(i) At any time when contamination may have occurred;

(ii) At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles;

(iii) Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers; and

(iv) In equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment:

(aa) At a frequency specified by the manufacturer, or

(bb) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

(2) Cooking and Baking Equipment.

(a) The food-contact surfaces of cooking and baking equipment shall be cleaned at least every 24 hours. This section does not

apply to hot oil cooking and filtering equipment if it is cleaned as specified in Subparagraph 5.6(B)(1)(D)(6).

(b) The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

(3) Nonfood-Contact Surfaces. Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

(C) Methods.

(1) Dry Cleaning.

(a) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not potentially hazardous.

(b) Cleaning equipment used in dry cleaning food-contact surfaces may not be used for any other purpose.

(2) Precleaning.

(a) Food debris on equipment and utensils shall be scrapped over a waste disposal unit or garbage receptacle or shall be removed in a warewashing machine with a prewash cycle.

(b) If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked, or scrubbed with abrasives.

(3) Loading of Soiled Items, Warewashing Machines. Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

(a) Exposes the items to the unobstructed spray from all cycles; and

(b) Allows the items to drain.

(4) Wet Cleaning.

(a) Equipment food-contact surfaces and utensils shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid,

alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(b) The washing procedures selected shall be based on the type and purpose of the equipment or utensil, and on the type of soil to be removed.

(5) Washing Procedures for Alternative Manual Warewashing Equipment. If washing in sink compartments or a warewashing machine is impractical such as when the equipment is fixed or the utensils are too large, washing shall be done by using alternative manual warewashing equipment as specified in paragraph 5.3(A)(2)(C) in accordance with the following procedures:

(a) Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts;

(b) Equipment components and utensils shall be scrapped or rough cleaned to remove food particle accumulation; and

(c) Equipment and utensils shall be washed as specified under paragraph 5.6(C)(4)(A).

(6) Rinsing Procedures. Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent sanitizer solution by using one of the following procedures:

(a) Use of a distinct, separate water rinse after washing and before sanitizing if using:

(i) A multi-compartment sink,

(ii) Alternative manual warewashing equipment equivalent to a multi-compartment sink as specified in paragraph 5.3(A)(2)(C), or

(iii) A 3-step washing, rinsing, and sanitizing procedure in a warewashing system for CIP equipment;

(b) Use of a detergent-sanitizer as specified under 5.5(A)(15) if using:

(i) Alternative warewashing equipment as specified in paragraph 5.3(A)(2)(C) that is approved for use with a detergent-sanitizer, or

- (ii) A warewashing system for CIP equipment;
- (c) Use of a nondistinct water rinse that is integrated in the hot water sanitization immersion step of a 2-compartment sink operation or with a hot water and the application of the sanitizing solution;
- (d) If using a warewashing machine that does not recycle the sanitizing solution as specified under paragraph (e) of this section, or alternative manual warewashing equipment such as sprayers, use of a nondistinct water rinse that is:

- (i) Integrated in the application of the sanitizing solution, and

- (ii) Wasted immediately after each application; or

- (e) If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the sanitizing solution.

(7) Returnables, Cleaning for Refilling.

- (a) Except as specified in paragraphs (b) and (c) of this Section, returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.

- (b) A food-specific container for beverages may be refilled at a food establishment if:

- (i) Only a beverage that is not a potentially hazardous food is used as specified under paragraph 4.35(A);

- (ii) The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;

- (iii) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

- (iv) The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and

- (v) The container is refilled by:

- (aa) An employee of the food establishment, or

- (bb) The owner of the container if the beverage system includes a contamination-free transfer process that can not be bypassed by the container owner.

- (c) Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

SECTION 7. Sanitation of Equipment and Utensils

(A) Objective.

- (a) Food-Contact Surfaces and Utensils. Equipment food-contact surfaces and utensils shall be sanitized.

(B) Frequency--Before Use After Cleaning.

- (a) Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning.

(C) Methods--Hot Water and Chemical. After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:

- (a) Hot water manual operations by immersion for at least 30 seconds and as specified under 5.5(A)(11);

- (b) Hot water mechanical operations by being cycled through equipment that is set up as specified under 5.5(A)(5), 5.5(A)(12), and 5.5(A)(13) and achieving a utensil surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator; or

- (c) Chemical manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 5.5(A)(14) by providing:

(i) Except as specified under Subparagraph (C)(2) of this Section, an exposure time of at least 10 seconds for a chlorine solution specified under paragraph 5.5(A)(14)(A),

(ii) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38 degrees C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F),

(iii) An exposure time of at least 30 seconds for other chemical sanitizing solutions, or

(iv) An exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in Subparagraph 1.3(AAAA).

SECTION 8. Laundering

(A) Objective.

(1) Clean Linens. Clean linens shall be free from food residues and other soiling matter.

(B) Frequency.

(1) Specifications.

(a) Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.

(b) Cloth gloves used as specified in paragraph 4.33(D) shall be laundered before being used with a different type of raw animal food such as beef, lamb, pork, and fish.

(c) Linens and napkins that are used as specified under 4.31 and cloth napkins shall be laundered between each use.

(d) Wet wiping cloths shall be laundered daily.

(e) Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

(C) Methods.

(1) Storage of Soiled Linens. Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single-service and single-use articles.

(2) Mechanical Washing.

(a) Except as specified in paragraph (B) of this section, linens shall be mechanically washed.

(b) In food establishments in which only wiping cloths are laundered as specified in paragraph 5.3(D)(5)(B), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a warewashing or food preparation sink that is cleaned as specified under 5.5(A)(4).

(3) Use of Laundry Facilities.

(a) Except as specified in paragraph (B) of this section, laundry facilities on the premises of a food establishment shall be used only for the washing and drying of items used in the operation of the establishment.

(c) Separate laundry facilities located on the premises for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering food establishment items.

SECTION 9. Protection of Clean Items

(A) Drying.

(1) Equipment and Utensils, Air-Drying Required. After cleaning and sanitizing, equipment and utensils:

(a) Shall be air-dried or used after adequate draining as specified in paragraph (a) of 21 CFR 178.1010 sanitizing solutions, before contact with food; and

(b) May not be cloth dried except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

(2) Wiping Cloths, Air-Drying Locations. Wiping cloths laundered in a food establishment that does not have a mechanical clothes dryer as specified in paragraph 5.3(D)(5)(B) shall be air-dried in a location and in a manner that prevents contamination of food, equipment, utensils, linens, and single-service and single-use articles and the wiping cloths. This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified under 5.5(A)(14).

(B) Lubricating and Reassembling.

(1) Food-Contact Surfaces. Lubricants shall be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces.

(2) Equipment. Equipment shall be reassembled so that food-contact surfaces are not contaminated.

(C) Storing.

(1) Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

(a) Except as specified in paragraph (D) of this section, cleaned equipment and utensils, laundered linens, and single-service and single-use articles shall be stored:

- (i) In a clean, dry location;
- (ii) Where they are not exposed to splash, dust, or other contamination; and
- (iii) At least 15 cm (6 inches) above the floor.

(b) Clean equipment and utensils shall be stored as specified under paragraph (A) of this section and shall be stored:

- (i) In a self-draining position that allows air drying; and
- (ii) Covered or inverted.

(c) Single-service and single-use articles shall be stored as specified under paragraph (A) of this section and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(d) Items that are kept in closed packages may be stored less than 15 cm (6 inches) above the floor on dollies, pallets, racks, and skids that are designed as specified under 5.2(D)(22).

(2) Prohibitions.

(a) Except as specified in paragraph (B) of this section, cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be stored:

- (i) In locker rooms;
- (ii) In toilet rooms;
- (iii) In garbage rooms;
- (iv) In mechanical rooms;
- (v) Under sewer lines that are not shielded to intercept potential drips;
- (vi) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
- (vii) Under unprotected stairwells; or
- (viii) Under other sources of contamination.

(b) Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

(D) Handling.

(1) Kitchenware and Tableware.

(a) Single-service and single-use articles and cleaned and sanitized utensils shall be handled, displayed, and dispensed so that contamination of food- and lip-contact surfaces is prevented.

(b) Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by Employees and by Consumers if consumer self-service is provided.

(c) Except as specified under paragraph (B) of this section, single-service articles that are intended for food- or lip-contact shall be furnished for consumer self-service with the original individual wrapper intact or from an approved dispenser.

(2) Soiled and Clean Tableware. Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated.

(3) Preset Tableware. If tableware is preset:

(a) It shall be protected from contamination by being wrapped, covered, or inverted;

(b) Exposed, unused settings shall be removed when a consumer is seated; or

(c) Exposed, unused settings shall be cleaned and sanitized before further use if the settings are not removed when a consumer is seated.

CHAPTER 6. WATER, PLUMBING, AND WASTE

SECTION 1. Water

(A) Source.

(1) Approved System. Drinking water shall be obtained from an approved source that is:

(a) A public water system; or

(b) A nonpublic water system that is constructed, maintained, and operated according to law.

(2) System Flushing and Disinfection. A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

(3) Bottled Drinking Water. Bottled drinking water used or sold in a food establishment shall be obtained from approved sources in accordance with 21 CFR 129- Processing and Bottling of Bottled drinking water.

(B) Quality.

(1) Standards. Except as specified under Section (A)(2):

(a) Water from a public water system shall meet 40 CFR 141 - National Primary Drinking Water Regulations and regulatory authority water quality standards; and

(b) Water from a nonpublic water system shall meet regulatory authority drinking water quality standards.

(2) Nondrinking Water.

(a) A nondrinking water supply shall be used only if its use is approved.

(b) Nondrinking water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, fire protection, and irrigation.

(3) Sampling. Except when used as specified under Section (A) (2), water from a nonpublic water system shall be sampled and tested at least annually and as required by regulatory authority water quality regulations.

(4) Sample Report. The most recent sample report for the nonpublic water system shall be retained on file in the food establishment or the report shall be maintained as specified by the regulatory authority water quality regulations.

(C) Quantity and Availability.

(1) Capacity.

(a) The water source and system shall be of sufficient capacity to meet the peak water demands of the food establishment.

(b) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the food establishment.

(2) Pressure. Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under paragraphs 6.1(D)(a) and (b) to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure.

(D) Distribution, Delivery, and Retention.

(1) System. Water shall be received from the source through the use of:

- (a) An approved public water main; or
- (b) One or more of the following that shall be constructed, maintained, and operated according to law:
 - (i) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances,
 - (ii) Water transport vehicles, and
 - (iii) Water containers.

(2) Alternative Water Supply. Water meeting the requirements specified under Subparts 6.1(A), 6.1(B), and 6.1(C) shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a food establishment with a temporary interruption of its water supply through:

- (a) A supply of containers of commercially bottled drinking water;
- (b) One or more closed portable water containers;
- (c) An enclosed vehicular water tank;
- (d) An on-premises water storage tank; or
- (e) Piping, tubing, or hoses connected to an adjacent approved source.

SECTION 2. Plumbing System

(A) Materials.

(1) Approved.

- (a) A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to law.
- (b) A water filter shall be made of safe materials.

(B) Design, Construction, and Installation.

(1) Approved System and Cleanable Fixtures.

- (a) A plumbing system shall be designed, constructed, and installed according to law.
- (b) A plumbing fixture such as a handwashing facility, toilet, or urinal shall be easily cleanable.

(2) Handwashing Facility, Installation.

- (a) A handwashing lavatory shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet.
- (b) A steam mixing valve may not be used at a handwashing lavatory.
- (c) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.
- (d) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

(3) Backflow Prevention, Air Gap. An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than 25 mm (1 inch).

(4) Backflow Prevention Device, Design Standard. A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device.

(5) Conditioning Device, Design. A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

(C) Numbers and Capacities.

(1) Handwashing Facilities.

(a) Except as specified in paragraphs (B) and (C) of this section, at least 1 handwashing lavatory, a number of handwashing lavatories necessary for their convenient use by employees in areas specified under 6.2(D)(1), and not fewer than the number of handwashing lavatories required by law shall be provided.

(b) If approved and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing lavatories in a food establishment that has at least one handwashing lavatory.

(c) If approved, when food exposure is limited and handwashing lavatories are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing.

(2) Toilets and Urinals. At least 1 toilet and not fewer than the toilets required by law shall be provided within reasonable proximity to the facility. If appropriate, pre-approved by the regulatory agency and as may be authorized by law, urinals may be substituted for toilets.

(3) Service Sink. At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

(4) Backflow Prevention Device, When Required. A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food establishment, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law, by:

(a) Providing an air gap as specified under paragraph (B)(3); or

(b) Installing an approved backflow prevention device as specified under (B)(4).

(5) Backflow Prevention Device, Carbonator.

(a) If not provided with an air gap as specified under paragraph (C)(3), a double check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 25.4mm (100 mesh to 1 inch) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.

(b) A single or double check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified under paragraph (a) of this section.

(D) Location and Placement.

(1) Handwashing Facilities. A handwashing facility shall be located:

(a) To allow convenient on-site use by employees in food preparation, food dispensing, and warewashing areas; and

(b) In, or immediately adjacent to, toilet rooms that are available to employees.

(2) Backflow Prevention Device, Location. A backflow prevention device shall be located so that it may be serviced and maintained.

(3) Conditioning Device, Location. A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

(E) Operation and Maintenance.

(1) Using a Handwashing Facility.

(a) A handwashing facility shall be maintained so that it is accessible at all times for employee use.

(b) A handwashing facility may not be used for purposes other than handwashing.

(c) An automatic handwashing facility shall be used in accordance with manufacturer's instructions.

(2) Prohibiting a Cross Connection.

(a) Except as specified in 9 CFR 308.3(d) for firefighting, a person may not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.

(b) The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.

(3) Scheduling Inspection and Service for a Water System Device. A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge.

(4) Water Reservoir of Fogging Devices, Cleaning.

(a) A reservoir that is used to supply water to a device such as a produce fogger shall be:

(i) Maintained in accordance with manufacturer's specifications; and

(ii) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under paragraph (b) of this Section, whichever is more stringent.

(b) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

(i) Draining and complete disassembly of the water and aerosol contact parts;

(ii) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;

(iii) Flushing the complete system with water to remove the detergent solution and particulate accumulation; and

(iv) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/L hypochlorite solution.

(5) System Maintained in Good Repair. A plumbing system shall be:

(a) Repaired according to law; and

(b) Maintained in good repair.

SECTION 3. Mobile Water Tank and Mobile Food Establishment Water Tank

(A) Materials.

(1) Approved. Materials that are used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances shall be:

(a) Safe;

(b) Durable, corrosion-resistant, and nonabsorbent; and

(c) Finished to have a smooth, easily cleanable surface.

(B) Design and Construction.

(1) Enclosed System, Sloped to Drain. A mobile water tank shall be:

(A) Enclosed from the filling inlet to the discharge outlet; and

(B) Sloped to an outlet that allows complete drainage of the tank.

(2) Inspection and Cleaning Port, Protected and Secured. If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

(A) Flanged upward at least 13 mm (one-half inch); and

(B) Equipped with a port cover assembly that is:

(1) Provided with a gasket and a device for securing the cover in place, and

(2) Flanged to overlap the opening and sloped to drain.

(3) "V" Type Threads, Use Limitation. A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

(4) Tank Vent, Protected. If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

(A) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area; or

(B) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

(5) Inlet and Outlet, Sloped to Drain.

- (a) A water tank and its inlet and outlet shall be sloped to drain.
- (b) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

(6) Hose, Construction and Identification. A hose used for conveying drinking water from a water tank shall be:

- (a) Safe;
- (b) Durable, corrosion-resistant, and nonabsorbent;
- (c) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;
- (d) Finished with a smooth interior surface; and
- (e) Clearly and durably identified as to its use if not permanently attached.

(C) Numbers and Capacities.

(1) Filter, Compressed Air. A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is used to pressurize the water tank system.

(2) Protective Cover or Device. A cap and keeper chain, closed cabinet, closed storage tube, or other approved protective cover or device shall be provided for a water inlet, outlet, and hose.

(3) Mobile Food Establishment Tank Inlet. A mobile food establishment's water tank inlet shall be:

- (a) 19.1 mm (three-fourths inch) in inner diameter or less; and
- (b) Provided with a hose connection of a size or type that will prevent its use for any other service.

(D) Operation and Maintenance.

(1) System Flushing and Disinfection. A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse.

(2) Using a Pump and Hoses, Backflow Prevention. A person shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

(3) Protecting Inlet, Outlet, and Hose Fitting. If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under 6.3(B)(2).

(4) Tank, Pump, and Hoses, Dedication.

(a) Except as specified in paragraph (b) of this section, a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.

(b) Water tanks, pumps, and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

SECTION 4. Sewage, Other Liquid Waste, and Rainwater

(A) Mobile Holding Tank.

(1) Capacity and Drainage. A sewage holding tank in a mobile food establishment shall be:

- (a) Sized 15 percent larger in capacity than the water supply tank; and
- (b) Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.

(B) Retention, Drainage, and Delivery.

(1) Design, Construction, and Installation.

(a) Establishment Drainage System. Food establishment drainage systems, including grease traps, that convey sewage shall be designed and installed as specified under paragraph 6.2(B)(1)(a).

(b) Backflow Prevention. Except as specified in paragraphs (i) and (ii) of this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.

(i) If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

(ii) If allowed by law, a warewashing or culinary sink may have a direct connection.

(2) Location and Placement.

(a) Grease Trap. If used, a grease trap shall be located to be easily accessible for cleaning.

(3) Operation and Maintenance.

(a) Conveying Sewage. Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law.

(b) Removing Mobile Food Establishment Wastes. Sewage and other liquid wastes shall be removed from a mobile food establishment at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created.

(c) Flushing a Waste Retention Tank. A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

(C) Disposal Facility.

(1) Design and Construction.

(a) Approved Sewage Disposal System. Sewage shall be disposed through an approved facility that is:

(i) A public sewage treatment plant;

(ii) An individual sewage disposal system that is sized, constructed, maintained, and operated according to law; or

(iii) An authorized disposal site.

(b) Other Liquid Wastes and Rainwater. Condensate drainage and other nonsewage liquids and rainwater shall be drained from point of discharge to disposal according to law.

SECTION 5. Refuse, Recyclables, and Returnables

(A) Facilities on the Premises.

(1) Materials, Design, Construction, and Installation.

(a) Indoor Storage Area. If located within the food establishment, a storage area for refuse, recyclables, and returnables shall meet the requirements specified under 7.1(A)(1), 7.2(A)(1) – 7.2(A)(8), 7.2(B)(5), and 7.2(B)(6).

(b) Outdoor Storage Surface. An outdoor storage surface for refuse, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be smooth, durable, and sloped to drain.

(c) Outdoor Enclosure. If used, an outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials.

(d) Receptacles.

(i) Except as specified in paragraph (ii) of this section, receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, and nonabsorbent.

(ii) Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the food establishment, or within closed outside receptacles.

(e) Receptacles in Vending Machines. A refuse receptacle may not be located within a vending machine, except that a receptacle for beverage bottle crown closures may be located within a vending machine.

(f) Outside Receptacles.

(i) Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the food establishment shall be designed and constructed to have tight-fitting lids, doors, or covers.

(ii) Receptacles and waste handling units for refuse and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

(2) Numbers and Capacities.

(a) Storage Areas, Rooms, and Receptacles, Capacity and Availability.

(i) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate.

(ii) A receptacle shall be provided in each area of the food establishment or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.

(iii) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

(b) Toilet Room Receptacle, Covered. An on-premises toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

(c) Cleaning Implements and Supplies.

(i) Except as specified in paragraph (ii) of this section, suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.

(ii) If approved, off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.

(3) Location and Placement.

(a) Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.

(i) An area designated for refuse, recyclables, returnables, and, except as specified in paragraph (B) of this section, a redeeming machine for recyclables or returnables shall be located so that it is separate from food, equipment, utensils, linens, and single-service and single-use articles and a public health hazard or nuisance is not created.

(ii) A redeeming machine may be located in the packaged food storage area or consumer area of a food establishment if food, equipment, utensils, linens, and single-service and single-use articles are not subject to contamination from the machines and a public health hazard or nuisance is not created.

(iii) The location of receptacles and waste handling units for refuse, recyclables, and returnables may not create a public health hazard or nuisance or interfere with the cleaning of adjacent space.

(4) Operation and Maintenance.

(a) Storing Refuse, Recyclables, and Returnables. Refuse, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

(b) Areas, Enclosures, and Receptacles, Good Repair. Storage areas, enclosures, and receptacles for refuse, recyclables, and returnables shall be maintained in good repair.

(c) Outside Storage Prohibitions.

(i) Except as specified in paragraph (ii) of this section, refuse receptacles not meeting the requirements specified under paragraph 6.5(1)(d)(i) such as receptacles that are not rodent-resistant, unprotected

plastic bags and paper bags, or baled units that contain materials with food residue may not be stored outside.

(ii) Cardboard or other packaging material that does not contain food residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.

(d) Covering Receptacles. Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept covered:

(i) Inside the food establishment if the receptacles and units:

(aa) Contain food residue and are not in continuous use; or

(bb) After they are filled; and

(ii) With tight-fitting lids or doors if kept outside the food establishment.

(e) Using Drain Plugs. Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place.

(f) Maintaining Refuse Areas and Enclosures. A storage area and enclosure for refuse, recyclables, or returnables shall be maintained free of unnecessary items, as specified under 7.5(A)(4)(e), and clean.

(g) Cleaning Receptacles.

(i) Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of as specified under 6.4(B)(3)(b).

(ii) Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a

buildup of soil or becoming attractants for insects and rodents.

(B) Removal.

(1) Frequency. Refuse, recyclables, and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

(2) Receptacles or Vehicles. Refuse, recyclables, and returnables shall be removed from the premises by way of:

(a) Portable receptacles that are constructed and maintained according to law; or

(b) A transport vehicle that is constructed, maintained, and operated according to law.

(3) Facilities for Disposal and Recycling.

(a) Community or Individual Facility. Solid waste not disposed of through the sewage system such as through grinders and pulpers shall be recycled or disposed of in an approved public or private community recycling or refuse facility; or solid waste shall be disposed of in an individual refuse facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to law.

CHAPTER 7. PHYSICAL FACILITIES

SECTION 1. Materials for Construction and Repair

(A) Indoor Areas.

(1) Surface Characteristics.

(a) Except as specified in paragraph (b) of this section and 7.2(A)(1), materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

(i) Smooth, durable, and easily cleanable for areas where food establishment operations are conducted, except that anti-slip floor coverings or applications may be used for safety reasons;

(ii) Closely woven and easily cleanable carpet for carpeted areas; and

(iii) Nonabsorbent for areas subject to moisture such as food preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, mobile food establishment servicing areas, and areas subject to flushing or spray cleaning methods.

(b) In a temporary food establishment:

(i) If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other suitable approved materials that are effectively treated to control dust and mud; and

(ii) Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.

(B) Outdoor Areas.

(1) Surface Characteristics.

(a) The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(b) Exterior surfaces of buildings and mobile food establishments shall be of weather-resistant materials and shall comply with law.

(c) Outdoor storage areas for refuse, recyclables, or returnables shall be of materials specified under 6.5(A)(1)(b) and 6.5(A)(1)(c).

SECTION 2. Design, Construction, and Installation

(A) Cleanability.

(1) Floors, Walls, and Ceilings. Except as specified under paragraph (A)(4) if this section, the floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are smooth and easily cleanable, except that antislip floor coverings or applications may be used for safety reasons.

(2) Floors, Walls, and Ceilings, Utility Lines.

(a) Utility service lines and pipes may not be unnecessarily exposed.

(b) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

(c) Exposed horizontal utility service lines and pipes may not be installed on the floor.

(d) Exposed service lines and pipes shall be maintained in a manner that will not cause contamination to food, equipment or employees.

(3) Floor and Wall Junctures, Coved, and Enclosed or Sealed.

(a) In food establishments in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1 mm (one thirty-second inch).

(b) The floors in food establishments in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be covered and sealed.

(4) Floor Carpeting, Restrictions, and Installation.

(a) A floor covering such as carpeting or similar material may not be installed as a floor covering in food preparation areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(b) If carpeting is installed as a floor covering in areas other than those specified under paragraph (a) of this Section, it shall be:

(i) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(ii) Installed tightly against the wall under the coving or installed away from the wall with a space between the

carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

(5) Floor Covering, Mats and Duckboards. Mats and duckboards shall be designed to be removable and easily cleanable.

(6) Wall and Ceiling Coverings and Coatings.

(a) Wall and ceiling covering materials shall be attached so that they are easily cleanable.

(b) Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and sealed to provide a smooth, nonabsorbent, easily cleanable surface.

(7) Walls and Ceilings, Attachments.

(a) Except as specified in paragraph (b) of this section, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be easily cleanable.

(b) In a consumer area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.

(8) Walls and Ceilings, Studs, Joists, and Rafters. Studs, joists, and rafters may not be exposed in areas subject to moisture. This requirement does not apply to temporary food establishments.

(B) Functionality.

(1) Light Bulbs, Protective Shielding.

(a) Except as specified in paragraph (B) of this section, light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed food; clean equipment, utensils, and linens; or unwrapped single-service and single-use articles.

(b) Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages, if:

(i) The integrity of the packages can not be affected by broken glass falling onto them; and

(ii) The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

(c) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

(2) Heating, Ventilating, Air Conditioning System Vents. Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment, or utensils.

(3) Insect Control Devices, Design and Installation.

(a) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

(b) Insect control devices shall be installed so that:

(i) The devices are not located over a food preparation area; and

(ii) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(4) Toilet Rooms, Enclosed. An on-premises toilet room shall be completely enclosed and provided with a tight-fitting and self-closing door except that this requirement does not apply to a toilet room that is located outside a food establishment and does not open directly into the food establishment such as a toilet room that is provided by the management of a shopping mall.

(5) Outer Openings, Protected.

(a) Except as specified in paragraphs (b), (c), and (e) and under paragraph (d) of this section, outer openings of a food establishment shall be protected against the entry of insects and rodents by:

(i) Filling or closing holes and other gaps along floors, walls, and ceilings;

(ii) Closed, tight-fitting windows; and

(iii) Solid, self-closing, tight-fitting doors.

(b) Paragraph (a) of this section does not apply if a food establishment opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.

(c) Exterior doors used as exits need not be self-closing if they are:

(i) Solid and tight-fitting;

(ii) Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the food establishment; and

(iii) Limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.

(d) Except as specified in paragraphs (B) and (E) of this section, if the windows or doors of a food establishment, or of a larger structure within which a food establishment is located, are kept open for ventilation or other purposes or a temporary food establishment is not provided with windows and doors as specified under paragraph (A) of this section, the openings shall be protected against the entry of insects and rodents by:

(i) 16 mesh to 25.4mm (16 mesh to 1 inch) screens;

(ii) Properly designed and installed air curtains to control flying insects; or

(iii) Other effective means.

(e) Paragraph (d) of this section does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting condition.

(6) Exterior Walls and Roofs, Protective Barrier. Perimeter walls and roofs of a food establishment shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.

(7) Outdoor Food Vending Areas, Overhead Protection. If located outside, a machine used to vend food shall be provided with overhead protection except that machines vending canned beverages need not meet this requirement.

(8) Outdoor Servicing Areas, Overhead Protection. Servicing areas shall be provided with overhead protection except that areas used only for the loading of water or the discharge of sewage and other liquid waste, through the use of a closed system of hoses, need not be provided with overhead protection.

(9) Outdoor Walking and Driving Surfaces, Graded to Drain. Exterior walking and driving surfaces shall be graded to drain.

(10) Outdoor Refuse Areas, Curbed and Graded to Drain. Outdoor refuse areas shall be constructed in accordance with law and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the refuse and from cleaning the area and waste receptacles.

(11) Private Homes and Living or Sleeping Quarters, Use Prohibition. An unlicensed area of a private home, a room used as living or sleeping quarters, an area directly opening into a room used as living or sleeping quarters that does not provide controlled access to a licensed area, or any other portion of a private home that is not licensed and is subject to inspected, monitoring, enforcement and other activities authorized under this Code, may not be used as a food establishment.

(12) Living or Sleeping Quarters, Separation. Living or sleeping quarters located on the premises of a food establishment, including those provided for lodging registration clerks or resident managers, shall be separated from rooms and areas used for food establishment operations by complete partitioning and solid self-closing doors.

SECTION 3. Numbers and Capacities

(A) Handwashing Facilities.

(1) Minimum Number. Handwashing facilities shall be provided as specified under section 6.2(C)(1).

(2) Handwashing Cleanser, Availability. Each handwashing lavatory or group of 2 adjacent lavatories shall be provided with a supply of hand cleaning liquid, powder, or bar soap.

(3) Hand Drying Provision. Each handwashing lavatory or group of adjacent lavatories shall be provided with:

- (a) Individual, disposable towels;
- (b) A continuous towel system that supplies the user with a clean towel; or
- (c) A heated-air hand drying device.

(4) Handwashing Aids and Devices, Use restrictions. A sink used for food preparation or utensil washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and devices required for a handwashing lavatory as specified under 7.3(A)(2) and 7.3(A)(3) and paragraph 6.5(A)(2)(a)(iii).

(5) Handwashing Signage. A sign or poster that notifies food employees to wash their hands shall be provided at all handwashing lavatories used by food employees and shall be clearly visible to food employees.

(6) Disposable Towels, Waste Receptacle. A handwashing lavatory or group of adjacent lavatories that is provided with disposable towels shall be provided with a waste receptacle as specified under paragraph 6.5(A)(2)(a)(iii).

(B) Toilets and Urinal.

(1) Minimum Number. Toilets and urinals shall be provided as specified under 6.2(C)(2).

(2) Toilet Tissue, Availability. A supply of toilet tissue shall be available at each toilet.

(C) Lighting Intensity. The light intensity shall be:

(1) At least 110 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry food storage areas and in other areas and rooms during periods of cleaning;

(2) At least 220 lux (20 foot candles):

(a) At a surface where food is provided for consumer self-service such as buffets and salad bars or where fresh produce or packaged foods are sold or offered for consumption;

(b) Inside equipment such as reach-in and under-counter refrigerators;

(c) At a distance of 75 cm (30 inches) above the floor in areas used for handwashing, warewashing, and equipment and utensil storage, and in toilet rooms; and

(3) At least 540 lux (50 foot candles) at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders, or saws where employee safety is a factor.

(D) Ventilation.

(1) Mechanical. If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.

(E) Dressing Areas and Lockers Designation.

(1) Dressing rooms or dressing areas shall be designated if employees routinely change their clothes in the establishment.

(2) Lockers, hangers or other suitable facilities shall be provided for the orderly storage of employees' clothing and other possessions.

(F) Service Sinks Availability. A service sink or curbed cleaning facility shall be provided as specified under 6.2(C)(3).

SECTION 4. Location and Placement

(A) Handwashing Facilities Conveniently Located. Handwashing facilities shall be conveniently located as specified under 6.2(D)(1).

(B) Toilet Rooms Convenience and Accessibility. Toilet rooms shall be conveniently located and accessible to employees during all hours of operation.

(C) Employee Accommodations Designated Areas.

(1) If applicable, areas designated for employees to eat, drink, and use tobacco shall be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.

(2) Lockers, clothes hangers or other suitable facilities shall be located in a designated room or area where contamination of food, equipment, utensils, linens, and single-service and single-use articles can not occur.

(D) Distressed Merchandise Segregation and Location. Products that are held by the permit holder for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are

separated from food, equipment, utensils, linens, and single-service and single-use articles.

(E) Refuse, Recyclables, and Returnables Receptacles, Waste Handling Units and Designated Storage Areas. Units, receptacles, and areas designated for storage of refuse and recyclable and returnable containers shall be located as specified under 6.5(A)(3)(a).

SECTION 5. Maintenance and Operation

(A) Repairing. The physical facilities shall be maintained in good repair.

(B) Cleaning, Frequency and Restrictions.

(1) The physical facilities shall be cleaned as often as necessary to keep them clean.

(2) Cleaning shall be done during periods when the least amount of food is exposed such as after closing. This requirement does not apply to cleaning that is necessary due to a spill or other accident.

(C) Cleaning Floors, Dustless Methods.

(1) Except as specified in paragraph (2) of this section, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.

(2) Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:

(a) Without the use of dust-arresting compounds; and

(b) In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.

(D) Cleaning Ventilation Systems, Nuisance, and Discharge Prohibition.

(1) Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

(2) If vented to the outside, ventilation systems may not create a public health hazard or nuisance or unlawful discharge.

(E) Cleaning Maintenance Tools, Preventing Contamination. Food preparation sinks, handwashing lavatories, and warewashing equipment may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.

(F) Drying Mops. After use, mops shall be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies.

(G) Absorbent Materials on Floors, Use Limitation. Except as specified in paragraph 7.5(C)(2), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

(H) Maintaining and Using Handwashing Facilities. Handwashing facilities shall be kept clean, and maintained and used as specified under 6.2(E)(1).

(I) Closing Toilet Room Doors. Toilet room doors as specified under 7.2(B)(4) shall be kept closed except during cleaning and maintenance operations.

(J) Using Dressing Rooms and Lockers.

(1) Dressing rooms or other designated areas shall be used by employees if the employees regularly change their clothes in the establishment.

(2) Lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.

(K) Controlling Pests. The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by:

(1) Routinely inspecting incoming shipments of food and supplies;

(2) Routinely inspecting the premises for evidence of pests;

(3) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under 8.2(B)(2), 8.2(F)(2), and 8.2(F)(3); and

(4) Eliminating harborage conditions.

(L) Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests. Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

(M) Storing Maintenance Tools. Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

(1) Stored so they do not contaminate food, equipment, utensils, linens, and single-service and single-use articles; and

(2) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

(N) Maintaining Premises, Unnecessary Items and Litter. The premises shall be free of:

(1) Items that are unnecessary to the operation or maintenance of the establishment such as equipment that is nonfunctional or no longer used; and

(2) Litter.

(O) Prohibiting Animals.

(1) Except as specified in paragraphs (2) and (3) of this section, live animals may not be allowed on the premises of a food establishment.

(2) Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result:

(a) Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

(b) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

(c) In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person, if a health or safety hazard will not result from the presence or activities of the service animal;

(d) Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:

(i) Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas,

(ii) Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present, and

(iii) Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and

(e) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals.

(3) Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result.

CHAPTER 8. POISONOUS OR TOXIC MATERIALS

SECTION 1. Labeling and Identification

(A) Original Containers.

(1) Identifying Information, Prominence. Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label.

(B) Working Containers Common Name. Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies shall be clearly and individually identified with the common name of the material.

SECTION 2. Operational Supplies and Applications

(A) Storage Separation. Poisonous or toxic materials shall be stored so they can not contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

(1) Separating the poisonous or toxic materials by spacing or partitioning; and

(2) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This paragraph does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

(B) Presence and Use.

(1) Restriction.

(a) Only those poisonous or toxic materials that are required for the operation and maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a food establishment.

(b) Part (a) of this section does not apply to packaged poisonous or toxic materials that are for retail sale.

(2) Conditions of Use. Poisonous or toxic materials shall be:

(a) Used according to:

(i) Law and this Code,

(ii) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food establishment,

(iii) The conditions of certification, if certification is required, for use of the pest control materials, and

(iv) Additional conditions that may be established by the regulatory authority; and

(b) Applied so that:

(i) A hazard to employees or other persons is not constituted, and

(ii) Contamination including toxic residues due to drip, drain, fog, splash or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted use pesticide, this is achieved by:

(aa) Removing the items,

(bb) Covering the items with impermeable covers, or

(cc) Taking other appropriate preventive actions, and

(dd) Cleaning and sanitizing equipment and utensils after the application.

(c) A restricted use pesticide shall be applied only by an applicator certified as defined in 7 USC 136(e) Certified Applicator, of the Federal Insecticide, Fungicide and Rodenticide Act, or a person under the direct supervision of a certified applicator.

(C) Container Prohibitions of Poisonous or Toxic Material Containers. A container previously used to store poisonous or toxic materials may not be used to store, transport, or dispense food.

(D) Chemicals.

(1) Sanitizers, Criteria. Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010 sanitizing solutions.

(2) Chemicals for Washing Fruits and Vegetables, Criteria. Chemicals used to wash or peel raw, whole fruits, and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.

(3) Boiler Water Additives, Criteria. Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310 Boiler Water Additives.

(4) Drying Agents, Criteria. Drying agents used in conjunction with sanitization shall:

(a) Contain only components that are listed as one of the following:

(i) Generally recognized as safe for use in food as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe,

(ii) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe,

(iii) Approved for use as a drying agent under a prior sanction specified in 21 CFR 181 - Prior-Sanctioned Food Ingredients,

(iv) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175-178, or

(v) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; and

(b) When sanitization is with chemicals, the approval required under Subparagraph (A)(3) or (A)(5) of this section or the regulation as an indirect food additive required under Subparagraph (A)(4) of this section, shall be specifically for use with chemical sanitizing solutions.

(E) Lubricants, Incidental Food Contact, Criteria. Lubricants shall meet the requirements specified in 21 CFR 178.3570 Lubricants with incidental food contact, if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces.

(F) Pesticides.

(1) Restricted Use Pesticides, Criteria. Restricted use pesticides specified under paragraph 8.2(B)(2)(c) shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.

(2) Rodent Bait Stations. Rodent bait shall be contained in a covered, tamper-resistant bait station.

(3) Tracking Powders, Pest Control and Monitoring.

(a) A tracking powder pesticide may not be used in a food establishment.

(b) If used, a nontoxic tracking powder such as talcum or flour may not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

(G) Medicines.

(1) Restriction and Storage.

(a) Only those medicines that are necessary for the health of employees shall be allowed in a food establishment. This section does not apply to medicines that are stored or displayed for retail sale.

(b) Medicines that are in a food establishment for the employees' use shall be labeled as specified under 8.1(A)(1) and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.

(2) Refrigerated Medicines, Storage. Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

(a) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; and

(b) Located so they are inaccessible to children.

(H) First Aid Supplies, Storage. First aid supplies that are in a food establishment for the Employees' use shall be:

(1) Labeled as specified under 8.1(A)(1); and

(2) Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and linens, and single-service and single-use articles.

(I) Other Personal Care Items, Storage. Except as specified under 8.2(G)(2) and 8.2(H), employees shall store their personal care items in facilities as specified under paragraph 7.3(E)(2).

SECTION 3. Stock and Retail Sale

(A) Storage and Display, Separation. Poisonous or toxic materials shall be stored and displayed for retail sale so they can not contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

(1) Separating the poisonous or toxic materials by spacing or partitioning; and

(2) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.

CHAPTER 9 COMPLIANCE AND ENFORCEMENT

SECTION 1. Code Applicability

(A) Use for Intended Purpose, Public Health Protection.

(1) The regulatory authority shall apply this Code to promote its underlying purpose, as specified in 1.1, of safeguarding public health and ensuring that food is safe, unadulterated, and honestly presented when offered to the consumer.

(2) In enforcing the provisions of this Code, the Regulatory authority shall assess existing facilities or equipment that were in use before the effective date of this Code based on the following considerations:

- (a) Whether the facilities or equipment are in good repair and capable of being maintained in a sanitary condition;
- (b) Whether food-contact surfaces comply with Subpart 5.1(A)-(J);
- (c) Whether the capacities of cooling, heating, and holding equipment are sufficient to comply with 5.3(A)(1); and
- (d) The existence of a documented agreement with the permit holder that the facilities or equipment will be replaced as specified under paragraph 9.3(D)(2)(g) or upgraded or replaced as specified under paragraph 9.3(D)(2)(h).

(B) Additional Requirements, Preventing Health Hazards, Provision for Conditions Not Addressed.

- (1) If necessary to protect against public health hazards or nuisances, the regulatory authority may impose specific requirements in addition to the requirements contained in this Code that are authorized by law.
- (2) The Regulatory authority shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the permit applicant or permit holder and a copy shall be maintained in the Regulatory authority's file for the food establishment.

(C) Variations.

(1) Modifications and Waivers. The regulatory authority may grant a variance by modifying or waiving the requirements of this Code if in the opinion of the regulatory authority a health hazard or nuisance will not result from the variance. If a variance is granted, the regulatory authority shall retain the information specified under 9.1(C)(2) in its records for the food establishment.

(2) Documentation of Proposed Variance and Justification. Before a variance from a requirement of this Code is approved, the information that shall be provided by the person requesting the variance and retained in the regulatory authority's file on the food establishment includes:

- (a) A statement of the proposed variance of the Code requirement citing relevant Code section numbers;
- (b) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and
- (c) A HACCP plan if required as specified under paragraph 9.2(A)(3)(a) that includes the information specified under 9.2(A)(4) as it is relevant to the variance requested.

(3) Conformance with Approved Procedures. If the regulatory authority grants a variance as specified in 9.1(A)(1), or a HACCP plan is otherwise required as specified under 9.1(A)(3), the permit holder shall:

- (a) Comply with the HACCP plans and procedures that are submitted as specified under 9.2(A)(4) and approved as a basis for the modification or waiver; and
- (b) Maintain and provide to the regulatory authority, upon request, records specified under paragraphs 9.2(A)(4) (d) and (e) that demonstrate that the following are routinely employed;
 - (i) Procedures for monitoring critical control points,
 - (ii) Monitoring of the critical control points,
 - (iii) Verification of the effectiveness of an operation or process, and
 - (iv) Necessary corrective actions if there is failure at a critical control point.

SECTION 2. Plan Submission and Approval

(A) Facility and Operating Plans.

(1) When Plans Are Required. A permit applicant or permit holder shall submit to the regulatory authority properly prepared plans and specifications for review and approval before:

- (a) The construction of a food establishment;
- (b) The conversion of an existing structure for use as a food establishment; or
- (c) The remodeling of a food establishment or a change of type of food establishment or food operation as specified under paragraph 9.3(B)(4)(c) if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this Code.

(2) Contents of the Plans and Specifications. The plans and specifications for a food establishment, including a food establishment specified under 9.2(A)(3), shall include, as required by the Regulatory authority based on the type of operation, type of food preparation, and foods prepared, the following information to demonstrate conformance with Code provisions:

- (a) Intended menu;
- (b) Anticipated volume of food to be stored, prepared, and sold or served;
- (c) Proposed layout, mechanical schematics, construction materials, and finish schedules;
- (d) Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
- (e) Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed; and
- (f) Other information that may be required by the regulatory authority for the proper review of the proposed construction, conversion or modification, and procedures for operating a food establishment.

(3) When a HACCP Plan is Required.

(a) Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as specified under 9.2(A)(4) and the relevant provisions of this Code if:

- (i) Submission of a HACCP plan is required according to law;
- (ii) A variance is required as specified under 4.62, paragraph 5.2(D)(10)(B), or Subparagraph 4.45D(3); or
- (iii) The regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal specified under 9.2(A)(2), an inspectional finding, or a variance request.

(b) A permit applicant or permit holder shall have a properly prepared HACCP plan as specified under 4.62.

(4) Contents of a HACCP Plan. For a food establishment that is required under 9.3(A)(3) to have a HACCP plan, the plan and specifications shall indicate:

- (a) A categorization of the types of potentially hazardous foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority;
- (b) A flow diagram by specific food or category type identifying critical control points and providing information on the following:
 - (i) Ingredients, materials, and equipment used in the preparation of that food, and
 - (ii) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
- (c) Food employee and supervisory training plan that addresses the food safety issues of concern;
- (d) A statement of standard operating procedures for the plan under consideration including clearly identifying:

- (i) Each critical control point,
 - (ii) The critical limits for each critical control point,
 - (iii) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge,
 - (iv) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points,
 - (v) Action to be taken by the person in charge if the critical limits for each critical control point are not met, and
 - (vi) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed; and
- (e) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.

(B) Confidentiality, Trade Secrets. The regulatory authority shall treat as confidential in accordance with law, information that meets the criteria specified in law for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified under 9.2(A)(2) and 9.2(A)(4).

(C) Construction Inspection and Approval, Pre-operational Inspections. The regulatory authority shall conduct one or more pre-operational inspections to verify that the food establishment is constructed and equipped in accordance with the approved plans and approved modifications of those plans, has established standard operating procedures as specified under paragraph 9.2(A)(2)(e), and is in compliance with law and this Code.

SECTION 3. Permit to Operate

(A) Requirement, Prerequisite for Operation. A person may not operate a food establishment under the Tribes authority without a valid permit or license to operate issued by the regulatory authority.

(B) Application Procedure.

(1) Submission 30 Calendar Days Before Proposed Opening. An applicant shall submit an application for a permit at least 30 calendar days before the date planned for opening a food establishment or the expiration date of the current permit for an existing facility.

(2) Form of Submission. A person desiring to operate a food establishment shall submit to the regulatory authority a written application for a permit on a form provided by the regulatory authority.

(3) Qualifications and Responsibilities of Applicants. To qualify for a permit, an applicant shall:

- (a) Be an owner of the food establishment or an officer of the legal ownership;
- (b) Comply with the requirements of this Code;
- (c) As specified under 9.4(B)(1), agree to allow access to the food establishment and to provide required information; and
- (d) Pay the applicable permit fees at the time the application is submitted.

(4) Contents of the Application. The application may include the following information:

- (a) The name, birth date, mailing address, telephone number, and signature of the person applying for the permit and the name, mailing address, and location of the food establishment;
- (b) Information specifying whether the food establishment is owned by an association, corporation, individual, partnership, or other legal entity;
- (c) A statement specifying whether the food establishment:

- (i) Is mobile or stationary and temporary or permanent, and
- (ii) Is an operation that includes one or more of the following:
 - (aa) Prepares, offers for sale, or serves potentially hazardous food:

- (bb) Only to order upon a consumer's request,
- (cc) In advance in quantities based on projected consumer demand and discards food that is not sold or served at an approved frequency, or
- (dd) Using time as the public health control as specified under 4.61,
- (ee) Prepares potentially hazardous food in advance using a food preparation method that involves two or more steps which may include combining potentially hazardous ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,
- (ff) Prepares food as specified under Subparagraph (C)(2)(b) of this section for delivery to and consumption at a location off the premises of the food establishment where it is prepared,
- (gg) Prepares food as specified under Subparagraph (C)(2)(b) of this section for service to a highly susceptible population,
- (hh) Prepares only food that is not potentially hazardous, or
- (ii) Does not prepare, but offers for sale only prepackaged food that is not potentially hazardous;
- (d) The name, title, address, and telephone number of the person directly responsible for the food establishment;
- (e) The name, title, address, and telephone number of the person who functions as the immediate supervisor of the person specified under paragraph (D) of this section such as the zone, district, or regional supervisor;

(f) The names, titles, and addresses of:

(i) The persons comprising the legal ownership as specified under paragraph (B) of this section including the owners and officers, and

(ii) The local resident agent if one is required based on the type of legal ownership;

(g) A statement signed by the applicant that:

(i) Attests to the accuracy of the information provided in the application, and

(ii) Affirms that the applicant will:

(aa) Comply with this Code, and

(bb) Allow the Regulatory authority access to the establishment as specified under 9.4(B)(1) and to the records specified under 4.61 and 6.2(E)(3) and Subparagraph 9.2(A)(4)(d)(vi); and (h) Other information required by the regulatory authority.

(C) Issuance.

(1) New, Converted, or Remodeled Establishments. For food establishments that submit plans as specified under 9.2(A)(1), the regulatory authority shall issue a permit to the applicant after:

(a) A properly completed application is submitted;

(b) The required plans, specifications, and information are reviewed and approved; and

(c) A pre-operational inspection as specified in 9.2(C) shows that the establishment is built or remodeled in accordance with the approved plans and specifications and that the establishment is in compliance with this Code.

(2) Existing Establishments, Permit Renewal, and Change of Ownership. The regulatory authority may renew a permit for an existing food establishment or may issue a permit to a new owner of an existing food establishment after a properly completed application is submitted, reviewed,

payment of proper fees, and an inspection shows that the establishment is in compliance with this Code.

(3) Denial of Application for Permit, Notice. If an application for a permit to operate is denied, the regulatory authority shall provide the applicant with a notice that includes:

- (a) The specific reasons and Code citations for the permit denial;
- (b) The actions, if any, that the applicant must take to qualify for a permit; and
- (c) Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in law.

(D) Conditions of Retention.

(1) Responsibilities of the Regulatory Authority.

- (a) At the time a permit is first issued, the regulatory authority shall provide to the permit holder a copy of this Code so that the permit holder is notified of the compliance requirements and the conditions of retention, as specified under 9.3(D)(2), that are applicable to the permit.
- (b) Failure to provide the information specified in paragraph (A) of this section does not prevent the regulatory authority from taking authorized action or seeking remedies if the permit holder fails to comply with this Code or an order, warning, or directive of the regulatory authority.

(2) Responsibilities of the Permit Holder. Upon acceptance of the permit issued by the regulatory authority, the permit holder in order to retain the permit shall:

- (a) Post the permit in a location in the food establishment that is conspicuous to consumers;
- (b) Comply with the provisions of this Code including the conditions of a granted variance as specified under 9.1(A)(3), and approved plans as specified under 9.2(A)(2);
- (c) If a food establishment is required under 9.2(A)(3) to operate under a HACCP plan, comply with the plan as specified under 9.1(A)(3);

(d) Immediately contact the regulatory authority to report an illness of a food employee as specified under 9.2(A)(5);

(e) Immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist as specified under 9.4(B)(1);

(f) Allow representatives of the regulatory authority access to the food establishment as specified under 9.4(B)(1);

(g) Except as specified under paragraph (h) of this section, replace existing facilities and equipment specified in '9.1(A)(1) with facilities and equipment that comply with this Code if:

(i) The regulatory authority directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted,

(ii) The regulatory authority directs the replacement of the facilities and equipment because of a change of ownership, or

(iii) The facilities and equipment are replaced in the normal course of operation;

(h) Upgrade or replace refrigeration equipment as specified under paragraph 4.58(A)(2)(b), if the circumstances specified under Subparagraphs (G)(1)-(3) of this section do not occur first, and 2 years pass after the regulatory authority adopts this Code;

(i) Comply with directives of the regulatory authority including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the regulatory authority in regard to the permit holder's food establishment or in response to community emergencies;

(j) Accept notices issued and served by the regulatory authority according to law; and

(k) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this Code or a directive of the regulatory authority, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

(3) Permits Not Transferable. A permit may not be transferred from one person to another person, from one food establishment to another, or from one type of operation to another if the food operation changes from the type of operation specified in the application as specified under paragraph 9.3(B)(4)(c) and the change in operation is not approved.

SECTION 4. Inspection and Correction of Violations

(A) Frequency.

(1) Establishing Inspection Interval.

(a) Except as specified in paragraphs (b) and (c) of this section, the regulatory authority shall inspect a food establishment at least once every 6 months.

(b) The regulatory authority may increase the interval between inspections beyond 6 months if:

(i) The food establishment is fully operating under an approved and validated HACCP plan as specified under 9.2(A)(4) and paragraphs 9.1(A)(3)(a) and (b);

(ii) The food establishment is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every 6 months the establishment is contacted by telephone or other means by the regulatory authority to ensure that the establishment manager and the nature of food operation are not changed; or

(iii) The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not potentially hazardous such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.

(c) The regulatory authority shall periodically inspect throughout its permit period a temporary food establishment that prepares, sells, or serves unpackaged potentially hazardous food and that:

(i) Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food

temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or

(ii) Has inexperienced food employees.

(2) Performance- and Risk-Based. Within the parameters specified in 9.4(A)(1), the regulatory authority shall prioritize, and conduct more frequent inspections based upon its assessment of a food establishment's history of compliance with this Code and the establishment's potential as a vector of foodborne illness by evaluating:

(a) Past performance, for nonconformance with Code or HACCP plan requirements that are critical;

(b) Past performance, for numerous or repeat violations of Code or HACCP plan requirements that are noncritical;

(c) Past performance, for complaints investigated and found to be valid;

(d) The hazards associated with the particular foods that are prepared, stored, or served;

(e) The type of operation including the methods and extent of food storage, preparation, and service;

(f) The number of people served; and

(g) Whether the population served is a highly susceptible population.

(B) Access.

(1) Allowed at Reasonable Times after Due Notice. After the regulatory authority presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the regulatory authority to determine if the food establishment is in compliance with this Code by allowing access to the establishment, allowing inspection, and providing information and records specified in this Code and to which the regulatory authority is entitled according to law, during the food establishment's hours of operation and other reasonable times.

(2) Refusal, Notification of Right to Access, and Final Request for Access. If a person denies access to the regulatory authority, the regulatory authority shall:

(a) Inform the person that:

(i) The permit holder is required to allow access to the regulatory authority as specified under 9.4(B)(1) of this Code,

(ii) Access is a condition of the acceptance and retention of a food establishment permit to operate as specified under paragraph 9.3(D)(2)(f), and

(iii) If access is denied, an order issued by the appropriate authority allowing access, hereinafter referred to as an inspection order, may be obtained according to law; and

(b) Make a final request for access.

(3) Refusal, Reporting. If after the regulatory authority presents credentials and provides notice as specified under 9.4(B)(1), explains the authority upon which access is requested, and makes a final request for access as specified in 9.4(B)(2), the person in charge continues to refuse access, the regulatory authority shall provide details of the denial of access on an inspection report form.

(4) Inspection Order to Gain Access. If denied access to a food establishment for an authorized purpose and after complying with 9.4(B)(2), the regulatory authority may issue, or apply for the issuance of, an inspection order to gain access as provided in law.

(C) Report of Findings.

(1) Documenting Information and Observations. The regulatory authority shall document on an inspection report form:

(a) Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation as specified under paragraph 9.3(B)(4)(c), inspection date, and other information such as type of water supply and sewage disposal, status of the permit, and personnel certificates that may be required; and

(b) Specific factual observations of violative conditions or other deviations from this Code that require correction by the permit holder including:

(i) Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this Code specified under 2.2,

(ii) Failure of food employees and the person in charge to demonstrate their knowledge of their responsibility to report a disease or medical condition as specified under 3.4 and 3.5,

(iii) Nonconformance with critical items of this Code,

(iv) Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the regulatory authority as specified under 9.1(A)(3),

(v) Failure of the person in charge to provide records required by the regulatory authority for determining conformance with a HACCP plan as specified under Subparagraph 9.2(A)(4)(d)(vi), and

(vi) Nonconformance with critical limits of a HACCP plan.

(2) Specifying Time Frame for Corrections. The regulatory authority shall specify on the inspection report form the time frame for correction of the violations as specified under 9.4(D)(1), 9.4(E)(1), and 9.4(F).

(3) Issuing Report and Obtaining Acknowledgment of Receipt.

At the conclusion of the inspection and according to law, the regulatory authority shall provide a copy of the completed inspection report and the notice to correct violations to the permit holder or to the person in charge, and request a signed acknowledgment of receipt.

(4) Refusal to Sign Acknowledgment. The regulatory authority shall:

(a) Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in 9.4(C)(3) that:

(i) An acknowledgment of receipt is not an agreement with findings,

(ii) Refusal to sign an acknowledgment of receipt will not affect the permit holder's obligation to correct the

violations noted in the inspection report within the time frames specified, and

(iii) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the Regulatory authority's historical record for the food establishment; and

(b) Make a final request that the person in charge sign an acknowledgment receipt of inspectional findings.

(5) Public Information. Except as specified in 9.2(B), the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it as provided in law.

(D) Imminent Health Hazard.

(1) Ceasing Operations and Reporting.

(a) Except as specified in paragraph (b) of this section, a permit holder shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger public health.

(b) A permit holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

(2) Resumption of Operations. If operations are discontinued as specified under 9.4(D)(1) or otherwise according to law, the permit holder shall obtain approval from the Regulatory authority before resuming operations.

(E) Critical Violation.

(1) Timely Correction.

(a) Except as specified in paragraph (b) of this section, a permit holder shall at the time of inspection correct a critical violation of this Code and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.

(b) Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame, not to exceed 10 calendar days after the inspection, for the permit holder to correct critical Code violations or HACCP plan deviations.

(2) Verification and Documentation of Correction.

(a) After observing at the time of inspection a correction of a critical violation or deviation, the regulatory authority shall enter the violation and information about the corrective action on the inspection report.

(b) As specified under paragraph 9.4(E)(1)(b), after receiving notification that the permit holder has corrected a critical violation or HACCP plan deviation, or at the end of the specified period of time, the regulatory authority shall verify correction of the violation, document the information on an inspection report, and enter the report in the regulatory authority's records.

(F) Noncritical Violation, Time Frame for Correction.

(1) Except as specified in paragraph (2) of this section, the permit holder shall correct noncritical violations by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.

(2) The regulatory authority may approve a compliance schedule that extends beyond the time limits specified under paragraph (A) of this section if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance.

SECTION 5. Prevention of Foodborne Disease Transmission by Employees

(A) Investigation and Control.

(1) Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis. The regulatory authority shall act when it has reasonable cause to believe that a food employee has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through food; may be a carrier of infectious agents that cause a disease that is transmissible through food; or is affected with a boil, an infected wound, or acute respiratory infection, by:

(a) Securing a confidential medical history of the employee suspected of transmitting disease or making other investigations as deemed appropriate; and

(b) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected employee and other employees.

(2) Restriction or Exclusion of Food Employee, or Summary Suspension of Permit. Based on the findings of an investigation related to a food employee who is suspected of being infected or diseased, the regulatory authority may issue an order to the suspected food employee or permit holder instituting one or more of the following control measures:

(a) Restricting the food employee;

(b) Excluding the food employee; or

(c) Closing the food establishment by summarily suspending a permit to operate in accordance with law.

(3) Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order. Based on the findings of the investigation as specified in 9.5(A)(1) and to control disease transmission, the regulatory authority may issue an order of restriction or exclusion to a suspected food employee or the permit holder without prior warning, notice of a hearing, or a hearing if the order:

(a) States the reasons for the restriction or exclusion that is ordered;

(b) States the evidence that the food employee or permit holder shall provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated;

(c) States that the suspected food employee or the permit holder may request an appeal hearing by submitting a timely request as provided in law; and

(d) Provides the name and address of the regulatory authority representative to whom a request for an appeal hearing may be made.

(4) Release of Food employee from Restriction or Exclusion. The regulatory authority shall release a food employee from restriction or exclusion according to law and the following conditions:

(a) A food employee who was infected with Salmonella Typhi if the food employee's stools are negative for S. Typhi based on testing of at least 3 consecutive stool specimen cultures that are taken:

(i) Not earlier than 1 month after onset,

(ii) At least 48 hours after discontinuance of antibiotics, and

(iii) At least 24 hours apart; and

(b) If one of the cultures taken as specified in paragraph (A) of this section is positive, repeat cultures are taken at intervals of 1 month until at least 3 consecutive negative stool specimen cultures are obtained.

(c) A food employee who was infected with Shigella spp. or Shiga toxin-producing Escherichia coli if the employee's stools are negative for Shigella spp. or Shiga toxin-producing Escherichia coli based on testing of 2 consecutive stool specimen cultures that are taken:

(i) Not earlier than 48 hours after discontinuance of antibiotics; and

(ii) At least 24 hours apart.

(d) A food employee who was infected with hepatitis A virus if:

(i) Symptoms cease; or

(ii) At least 2 blood tests show falling liver enzymes.

APPENDIX A.
HACCP TRAINING AND
IMPLEMENTATION GUIDELINES
(Adapted from FDA Food Code)

CONTENTS

1. INTRODUCTION
2. HACCP PRINCIPLES
3. SUMMARY
4. OTHER SOURCES OF HACCP INFORMATION

SECTION 1. Introduction

HACCP (Hazard Analysis and Critical Control Point) is a systematic approach in 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.

A HACCP system is a preventive system of hazard control rather than a reactive one. HACCP systems are designed to prevent the occurrence of potential food safety problems. This is achieved by assessing the inherent hazards attributable to a product or a process, determining the necessary steps that will control the identified hazards, and implementing active managerial control practices to ensure that the hazards are eliminated or minimized.

Essentially, HACCP is a system that identifies and monitors specific foodborne hazards biological, chemical, or physical properties that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs). CCPs identify those points in the process that must be controlled to ensure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to ensure that potential hazards are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan. Seven principles have been developed which provide guidance on the development of an effective HACCP plan. HACCP represents an important food protection tool supported by Standard Operating Procedures, employee training and other prerequisite programs that small independent businesses as well as national companies can implement to achieve active managerial control of hazards associated with foods. Employee training is key to successful implementation. Employees must learn which control points are critical in an operation and what the critical limits are at these points, for each preparation step they perform. Establishment management must also follow through by routinely monitoring the food operation to verify that employees are keeping the process under control by complying with the critical limits.

Local jurisdictions can effectively promote the industry's use of HACCP and apply the concepts during inspections. The implementation of HACCP continues to evolve as hazards and their control measures are more clearly defined. To meet the challenges presented by advances in food research, product development, and their impact at retail, regulatory personnel must keep themselves informed. Food protection publications issued by the food industry, professional organizations, and other groups and continuing education programs can be particularly helpful in providing an understanding of food operations and how the application of HACCP can bring a focus to food safety that traditional inspection methods have lacked.

This Guide recognizes that there are differences between using a HACCP plan in food manufacturing plants. By incorporating the seven principles of HACCP, a good set of Standard Operating Procedures, and using a process approach, this Guide sets up a framework for the retail food industry to develop and implement a sound food safety management system. The Agency recognizes that this document has areas that need to be further clarified, developed with broader input, and based on industry's experiences with the practicalities of integrating the HACCP approach in their operations.

(A) Definitions.

Many terms are used in discussion of HACCP that must be clearly understood to effectively develop and implement a plan. The following definitions are provided for clarity:

- (1) "Acceptable level" means the presence of a hazard which does not pose the likelihood of causing an unacceptable health risk.
- (2) "Control point" means any point in a specific food system at which loss of control does not lead to an unacceptable health risk.
- (3) "Critical control point," as defined in the Food Code, means a point at which loss of control may result in an unacceptable health risk.
- (4) "Critical limit," as defined in the Food Code, means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.
- (5) "Deviation" means failure to meet a required critical limit for a critical control point.
- (6) "HACCP plan," as defined in the Food Code, means a written document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

(7) "Hazard," as defined in the Food Code, means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

(8) "Monitoring" means a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.

(9) "Preventive measure" means an action to exclude, destroy, eliminate, or reduce a hazard and prevent re-contamination through effective means.

(10) "Risk" means an estimate of the likely occurrence of a hazard.

(11) "Sensitive ingredient" means any ingredient historically associated with a known microbiological hazard that causes or contributes to production of a potentially hazardous food as defined in the Food Code.

(12) "Verification" means methods, procedures, and tests used to determine if the HACCP system in use is in compliance with the HACCP plan.

(B) History.

The application of HACCP to food production was pioneered by the Pillsbury Company with the cooperation and participation of the National Aeronautic and Space Administration (NASA), Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group.

Application of the system in the early 1960's created food for the United State's space program that approached 100% assurance against contamination by bacterial and viral pathogens, toxins, and chemical or physical hazards that could cause illness or injury to astronauts. HACCP replaced end-product testing to provide food safety assurance and provided a preventive system for producing safe food that had universal application.

In the succeeding years, the HACCP system has been recognized worldwide as an effective system of controls. The system has undergone considerable analysis, refinement, and testing and is widely accepted in the United States and internationally.

(C) Advantages of HACCP.

FDA is recommending the implementation of HACCP in food establishments because it is a system of preventive controls that is the most effective and efficient way to ensure that food products are safe. A HACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies the food establishment as the final party responsible for ensuring the safety of the food it produces. HACCP requires the food establishment to analyze its preparation methods in a rational, scientific manner in order to identify critical control points and to establish critical limits and monitoring procedures. A vital aspect of the establishment's responsibility is to establish and maintain records that document adherence to the critical limits that relate to the identified critical control points, thus resulting in continuous self-inspection. Secondly, a HACCP system allows the regulatory agency to more comprehensively determine an establishment's level of compliance. A food establishment's use of HACCP requires development of a plan to prepare safe food. This plan must be shared with the regulatory agency because it must have access to CCP monitoring records and other data necessary to verify that the HACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection which provide a "snapshot" of conditions at the moment of the inspection. However, by adopting a HACCP approach, both current and past conditions can be determined. When regulatory agencies review HACCP records, they have, in effect, a look back through time. Therefore, the regulatory agency can better ensure that processes are under control. Traditional inspection is relatively resource-intensive and inefficient and is reactive rather than preventive compared to the HACCP approach for ensuring food safety. Regulatory agencies are challenged to find new approaches to food safety that enable them to become more focused and efficient and to minimize costs wherever possible. Thus, the advantages of HACCP-based inspections are becoming increasingly acknowledged by the regulatory community. Examples of the successful implementation of HACCP by food establishments may be found throughout the food industry. During the past several years, FDA and a number of state and local jurisdictions have worked with two national voluntary pilot projects for retail food stores and restaurants. These projects involved more than 20 food establishments and demonstrated that HACCP is a viable and practical option to improve food safety. FDA believes that HACCP concepts have matured to the point at which they can be formally implemented for all food products on an industry-wide basis.

SECTION 2. HACCP Principles

(A) Background of NACMCF. Established in 1988, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and comprised of participants from the USDA (Food Safety and Inspection Service), Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry and state employees. NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.

(B) Development of HACCP Principles. In November 1992, NACMCF defined seven widely accepted HACCP principles that were to be considered when developing a HACCP plan. In 1997, the NACMCF reconvened the HACCP Working Group to review the Committee's November 1992 HACCP document and to compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene. From this committee, HACCP was defined as a systematic approach to the identification, evaluation and control of food safety hazards based on the following seven principles:

(1) Conduct a hazard analysis.

(a) Purposes.

The hazard analysis process accomplishes three purposes:

- (i) Hazards of significance are identified;
- (ii) The hazard analysis provides a risk basis for selecting likely hazards;
- (iii) Identified hazards can be used to develop preventive measures for a process or product to ensure or improve food safety.

Before beginning to develop a HACCP plan, a team should be assembled that is familiar with the overall food operation and the specific production processes to be included in the plan. The team's goal and each member's responsibilities in reaching that goal must be clearly defined.

The first step in the development of a HACCP plan for a food operation is identification of hazards associated with the product. A hazard may be a biological, chemical, or physical property that can cause a food to be unsafe. The analysis of hazards requires the assessment of two factors with respect to any identified hazard, i.e., the likelihood that the hazard will occur and the severity if it does occur. Hazard analysis also involves establishment of preventive measures for control. Hazards that involve low risk and that are not likely to occur need not be considered for the purposes of HACCP.

To be effectively addressed, hazards must be such that their prevention, elimination, or reduction to acceptable levels is attained.

Numerous issues have to be considered during hazard analysis. These relate to factors such as ingredients, processing, distribution, and the intended use of the product. These issues include whether a food contains sensitive ingredients that can create microbiological, chemical, or physical hazards; or whether sanitation practices that are used can introduce these hazards to the food that is being prepared or processed. An example is whether the finished food will be heated by the consumer, if it is consumed off the premises. Even factors beyond the immediate control of the food establishment, such as how the food will be treated if taken out by the consumer and how it will be consumed, must be considered because these factors could influence how food should be prepared or processed in the establishment.

(b) Flow Diagram.

Consequently, a flow diagram that delineates the steps in the process from receipt to sale or service forms the foundation for applying the seven principles. The significant hazards associated with each step in the flow diagram should be listed along with preventative measures proposed to control the hazards. This tabulation will be used under Principle 2 to determine the CCPs. The flow diagram should be constructed by a HACCP team that has knowledge and expertise on the product, process, and the likely hazards. Each step in a process should be identified and observed to accurately construct the flow diagram. Some examples of flow diagrams are found at the end of this Annex.

(c) Biological Hazards.

Foodborne biological hazards include bacterial, viral, and parasitic organisms. These organisms are commonly associated with humans and with raw products entering the food establishment. Many of these pathogens occur naturally in the environment where foods are grown. Most are killed or inactivated by adequate cooking and numbers are kept to a minimum by adequate cooling during distribution and storage.

Bacterial pathogens comprise the majority of reported foodborne disease outbreaks and cases. A certain level of the pathogens can be expected with some raw foods. Temperature abuse, such as improper hot or cold holding temperatures, can significantly magnify this number. Cooked food which has been subject to cross-contamination with pathogens often provides a fertile medium for their rapid and progressive growth.

Enteric viruses can be foodborne, waterborne, or transmitted from a person or from animals. Unlike bacteria, a virus cannot multiply outside of a living cell. Hepatitis A and Norwalk viruses are examples of viral hazards associated with ready-to-eat foods.

Parasites are most often animal host-specific and can include humans in their life cycles.

Parasitic infections are commonly associated with undercooking meat products or cross contamination of ready-to-eat food.

Fishborne parasites in products that are intended to be eaten raw, marinated, or partially cooked can be killed by effective freezing techniques.

The following table provides an assessment of severity of the biological hazards which may be associated with food being prepared, served, or sold in food establishments.

TABLE 1. Hazardous Microorganisms and Parasites Grouped on the Basis of Risk Severity

Severe Hazards: <i>Clostridium botulinum</i> types A, B, E, and F <i>Shigella dysenteriae</i> <i>Salmonella</i> Typhi; paratyphi A, B Hepatitis A and E <i>Brucella abortus</i> ; <i>B. suis</i> <i>Vibrio cholerae</i> 01 <i>Vibrio vulnificus</i> <i>Taenia solium</i> <i>Trichinella spiralis</i>
Moderate Hazards: Potentially Extensive Spread <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Shigella</i> spp. Enterovirulent <i>Escherichia coli</i> (EEC) <i>Streptococcus pyogenes</i> Rotavirus Norwalk virus group <i>Entamoeba histolytica</i> <i>Diphyllobothrium latum</i> <i>Ascaris lumbricoides</i> <i>Cryptosporidium parvum</i>
Moderate Hazards: Limited Spread <i>Bacillus cereus</i> <i>Campylobacter jejuni</i> <i>Clostridium perfringens</i> <i>Staphylococcus aureus</i> <i>Vibrio cholerae</i> , non-01 <i>Vibrio parahaemolyticus</i> <i>Yersinia enterocolitica</i> <i>Giardia lamblia</i> <i>Taenia saginata</i>

Fn. Adapted from International Commission on Microbiological Specifications for Food (ICMSF) (1986). Used with permission, "HACCP Principles, and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

Fn. Although classified as moderate hazards, complications and sequelae may be severe in certain susceptible populations.

(d) Chemical Hazards.

Chemical hazards in foods should be considered during a hazard analysis. Chemical contaminants may be naturally occurring or may be added during the processing of food.

Harmful chemicals at very high levels have been associated with acute cases of foodborne illnesses and can be responsible for chronic illness at lower levels.

The following table provides some examples of chemical hazards found within the naturally occurring and added chemical categories. The Code of Federal Regulations, Title 21, provides guidance on naturally occurring toxic substances and allowable limits for many of the chemicals added during processing (food additives). The FDA Compliance Policy Guidelines also provide information on other naturally occurring chemicals.

Table 2. Types of Chemical Hazards and Examples

Naturally Occurring Chemicals Mycotoxins (e.g., aflatoxin) from mold Scombrotoxin (histamine) from protein Decomposition Ciguatera toxin from marine dinoflagellates Toxic mushroom species Shellfish toxins (from marine dinoflagellates) Paralytic shellfish poisoning (PSP) Diarrhetic shellfish poisoning (DSP) Neurotoxic shellfish poisoning (NSP) Amnesic shellfish poisoning (ASP) Plant toxins Pyrrolizidine alkaloids Phytohemagglutinin
Added Chemicals Agricultural chemicals: Pesticides, fungicides, fertilizers, insecticides, antibiotics and growth hormones Polychlorinated biphenyls (PCBs) Industrial chemicals Prohibited substances (21 CFR 189) Direct/Indirect Toxic elements and compounds: Lead, zinc, arsenic, mercury, and cyanide

Fn. Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY and adapted.

Food additives: Direct - allowable limits under GMPs
 Preservatives (nitrite and sulfating agents) Flavor enhancers
 (monosodium glutamate) Nutritional additives (niacin) Color
 additives

Food Additives: Secondary direct and indirect Chemicals used in
 establishments (e.g.,
 lubricants, cleaners, sanitizers, cleaning compounds, coatings, and
 paints) Poisonous or toxic
 chemicals intentionally added (sabotage)

(e) Food Allergens.

Each year the Food & Drug Administration (FDA) receives reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially involving the production of allergen-specific IgE antibodies, to naturally occurring proteins in certain foods that most individuals can eat safely. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label.

To combat this problem, the agency issued a letter titled "Notice to Manufacturers," dated June 10, 1996, which addressed labeling issues and Good Manufacturing Practices (GMPs). This letter is available on FDA's website, www.cfsan.fda.gov/~lrd/allerg7.html.

FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies: Peanuts, Soybeans, Milk, Eggs, Fish, Crustacea, Tree nuts, and Wheat.

Current FDA policy, as reflected in FDA Compliance Policy Guide (CPG) 555.250 with regard to direct addition as ingredients or sub-ingredients, is:

Products which contain an allergenic ingredient by design must comply with 21 U.S.C. 343(i)(2). Where substances that are, bear, or contain allergens are added as ingredients or sub-ingredients (including rework), the Federal Food, Drug, and Cosmetic Act (the Act) requires a complete listing of the food ingredients (section 403(i)(2); 21 U.S.C. 343(i)(2); 21 C.F.R.101.4) unless a labeling exemption applies.

FDA's Regulations (21 CFR 101.100(a)(3)), provide that incidental additives, such as processing aids, which are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food are exempt from ingredient declaration. Some manufacturers have asserted to FDA that some allergens used as processing aids qualify for this exemption. FDA, however, does not consider food allergens eligible for this exemption. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts; therefore, the presence of an allergen must be declared in accordance with 21 CFR 101.4.

Allergens may be unintentionally added to food as a result of practices such as improper rework addition, product carry-over due to use of common equipment and production sequencing, or the presence of an allergenic product above exposed product lines. Such practices with respect to allergenic substances can be unsanitary conditions that may render the food injurious to health and adulterate the product under section 402(a)(4) of the Act [21 U.S.C. 342(a)(4)].

(f) Physical Hazards.

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment. As establishments develop their HACCP programs, the following table can be used to further identify sources of potential physical risks to the food being prepared, served, or sold.

Table 3. Main Materials of Concern as Physical Hazards and Common Sources

Material	Injury Potential	Source
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light, 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	Fields, buildings, machinery, fields, wire, employees

	require surgery to remove	
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>a Adapted from Corlett (1991). b Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.</p>		

(f) Determining Level of Risk.

The potential significance or risk of each hazard should be assessed by considering its likelihood of occurrence and severity. The estimate of risk for a hazard occurring is based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if it were to become an actuality.

Hazard identification in conjunction with risk estimation provides a rational basis for determining which hazards are significant and must be addressed in the HACCP plan. To determine risk during the hazard analysis, safety concerns must be differentiated from quality concerns. A food safety hazard is a biological, chemical, or physical property that may cause a food to be unsafe.

There may be differences of opinion, even among experts, as to the risk of a hazard. The food establishment must rely upon the expert opinion published in peer reviewed literature or experts who actively assist in the development of the HACCP plan.

The hazards must at least include those that are commonly associated with a specific product. If a hazard that is commonly associated is dismissed from the plan, the basis for rejecting it

must be clearly stated in the hazard analysis so that it is understood and agreed to by the regulatory authority reviewing the HACCP plan.

(g) Hazard Analysis Process.

This point in hazard analysis consists of asking a series of questions which are appropriate to each step in the flow diagram. The hazard analysis should question the effect of a variety of factors upon the safety of the food.

(i) Ingredients. Does the food contain any sensitive ingredients that are likely to present microbiological hazards (e.g., *Salmonella*, *Staphylococcus aureus*), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide residues) or physical hazards (stones, glass, bone, metal)?

(ii) Intrinsic factors of food. Physical characteristics and composition (e.g., pH, type of acids, fermentable carbohydrate, water activity, preservatives) of the food during and after preparation can cause or prevent a hazard.

Which intrinsic factors of the food must be controlled in order to ensure food safety?

Does the food permit survival or multiplication of pathogens and/or toxin formation in the food before or during preparation?

Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?

Are there other similar products in the market place? What has been the safety record for these products?

(iii) Procedures used for preparation/processing.

Does the preparation procedure or process include a controllable step that destroys

pathogens or their toxins? Consider both vegetative cells and spores.

Is the product subject to recontamination between the preparation step (e.g., cooking) and packaging?

(iv) Microbial Content of the Food.

Is the food commercially sterile (i.e., low acid canned food)?

Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?

What is the normal microbial content of the food stored under proper conditions?

Does the microbial population change during the time the food is stored before consumption?

Does that change in microbial population alter the safety of the food?

(v) Facility design.

Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods?

Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

Is the traffic pattern for people and moving equipment a potentially significant source of contamination?

(vi) Equipment design.

Will the equipment provide the time/temperature control that is necessary for safe food?

Is the equipment properly sized for the volume of food that will be prepared?

Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?

Is the equipment reliable or is it prone to frequent breakdowns?

Is the equipment designed so that it can be cleaned and sanitized?

Is there a chance for product contamination with hazardous substances, e.g., glass?

What product safety devices such as time/temperature integrators are used to enhance consumer safety?

(vii) Packaging.

Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?

Is the package clearly labeled "Keep Refrigerated" if this is required for safety?

Does the package include instructions for the safe handling and preparation of the food by the consumer?

Are tamper-evident packaging features used?

Is each package legibly and accurately coded to indicate production lot?

Does each package contain the proper label?

(viii) Sanitation.

Can the sanitation practices that are employed impact upon the safety of the food that is being prepared?

Can the facility be cleaned and sanitized to permit the safe handling of food?

Is it possible to provide sanitary conditions consistently and adequately to ensure safe foods?

(ix) Employee health, hygiene, and education.

Can employee health or personal hygiene practices impact the safety of the food being prepared?

Do the employees understand the food preparation process and the factors they must control to ensure safe foods?

Will the employees inform management of a problem which could impact food safety?

(x) Conditions of storage between packaging and the consumer.

What is the likelihood that the food will be improperly stored at the wrong temperature?

Would storage at improper temperatures lead to a microbiologically unsafe food?

(xi) Intended use.

Will the food be heated by the consumer?

Will there likely be leftovers?

(xii) Intended consumer.

Is the food intended for the general public, i.e., a population that does not have an increased risk of becoming ill?

Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the elderly, the infirm, and immunocompromised individuals)?

(h) Developing Preventive Measures.

The preventive measures procedure identifies the steps in the process at which hazards can be controlled.

After identifying the hazards the food establishment must then consider what preventive measures, if any, can be applied for each hazard. Preventive measures are physical, chemical, or other factors that can be used to control an identified health hazard. More than one preventive measure may be required to control a specific hazard and more than one hazard may be controlled by a specified preventive measure.

For example, if a HACCP team were to conduct a hazard analysis for the preparation of hamburgers from frozen beef patties, enteric pathogens on the incoming raw meat would be identified as a potential hazard. Cooking is a preventive measure which can be used to eliminate this hazard. Thus, cooking, the preventive measure, would be listed along with the hazard (i.e., enteric pathogens) as follows:

Step	Identified Hazard	Preventive Measures
Cooking	Enteric pathogens	Cooking sufficiently to kill enteric pathogens

(2) Determine the critical control points (“CCPs”).

A CCP is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Points in food preparation that may be CCPs include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene.

For example, cooking that must occur at a specific temperature and for a specified time in order to destroy microbiological pathogens is a critical control point. Likewise, refrigeration or the adjustment of a food's pH to a

level required to prevent hazardous microorganisms from multiplying or toxins from forming are also CCPs.

Many points in food preparation may be considered control points, but very few are actually critical control points. A control point is any point, step, or procedure at which biological, physical, or chemical factors can be controlled. Concerns that do not impact food safety may be addressed at control points; however, since these control points do not relate to food safety, they are not included in the HACCP plan.

Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCPs. This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is used. Generic HACCP plans can serve as useful guides; however, it is essential that the unique conditions within each facility be considered during the development of a HACCP plan.

CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. The following decision tree is helpful in verifying which of the food preparation steps should be designated as CCPs.

(3) Establish critical limits.

Associated with Each Identified Critical Control Point. This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Critical limits can be thought of as boundaries of safety for each CCP and may be set for preventive measures such as temperature, time, physical dimensions, aw, pH, and available chlorine. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and consultation with experts.

Criteria Most Frequently Used for Critical Limits include:
- Time
- Temperature
- Humidity
- aw
- pH
- Titratable acidity
- Preservatives
- Salt concentration
- Available chlorine
- Viscosity

(a) Critical Limit. A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to ensure prevention, elimination, or reduction of hazards to acceptable levels. The food establishment is responsible for using competent authorities to validate that the critical limits chosen will control the identified hazard.

(b) Target Level. In some cases, variables involved in food preparation may require certain target levels to ensure that critical limits are not exceeded. For example, a preventive measure and critical limit may be an internal product temperature of 71°C (160°F) during one stage of a process. The oven temperature, however, may be 71 °3°C (160°F); thus an oven target temperature would have to be greater than 74°C (165°F) so that no product receives a cook of less than 71°C (160°F).

(c) Application Example. An example for Principle 3 is the cooking of beef patties. The process should be designed to eliminate the most heat-resistant vegetative pathogen which could reasonably be expected to be in the product. Criteria may be required for factors such as temperature, time, and meat patty thickness. Technical development of the appropriate critical limits requires accurate information on the probable maximum numbers of these microorganisms in the meat and their heat resistance. The relationship between the CCP and its critical limits for the meat patty example is shown below:

Process Step	CCP	Critical Limits
Cooking	YES	Minimum internal temperature of patty: 68°C / 155°F Broiler temperature: _____°C / _____°F Time; rate of heating/cooling (e.g., conveyer belt speed in): cm/min: _____ ft/min _____ Patty thickness: _____ cm / _____ in Patty composition: e.g., % Fat, % Filler Oven humidity: _____ % RH

(4) Establish monitoring procedures.

(a) Observations and Measurements. Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification procedures. There are three main purposes for monitoring:

(i) It tracks the system's operation so that a trend toward a loss of control can be recognized and corrective action can be taken to bring the process back into control before a deviation occurs;

(ii) It indicates when loss of control and a deviation have actually occurred, and corrective action must be taken; and

(iii) It provides written documentation for use in verification of the HACCP plan.

Examples of Measurements for Monitoring
- Visual observations
- Temperature
- Time
- pH
- aw

(b) **Continuous Monitoring.** An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical defect, monitoring procedures must be effective.

Continuous monitoring is always preferred when feasible and continuous monitoring is possible with many types of physical and chemical methods. For example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the batch must be recorded as a process deviation and reprocessed or discarded.

Instrumentation used by the food establishment for measuring critical limits must be carefully calibrated for accuracy. Records of calibrations must be maintained as a part of the HACCP plan documentation.

(c) **Monitoring Procedures.** When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish that the monitoring interval will be reliable enough to indicate that the hazard is under control.

Statistically designed data collection or sampling systems lend themselves to this purpose. When statistical process control is used, it is important to recognize that violations of critical limits

must not occur. For example, when a temperature of 68°C (155°F) or higher is required for product safety, the minimum temperature of the product may be set at a target that is above this temperature to compensate for variation.

Most monitoring procedures for CCPs will need to be done rapidly because the time frame between food preparation and consumption does not allow for lengthy analytical testing.

Microbiological testing is seldom effective for monitoring CCPs because of its time-consuming nature. Therefore, physical and chemical measurements are preferred because they may be done rapidly and can indicate whether microbiological control is occurring.

Assignment of responsibility for monitoring is an important consideration for each CCP within the operation. Specific assignments will depend on the number of CCPs, preventive measures, and the complexity of monitoring. The most appropriate employees for such assignments are often directly associated with the operation, such as the person in charge of the food establishment, chefs, and departmental supervisors.

Individuals monitoring CCPs must be trained in the monitoring technique, completely understand the purpose and importance of monitoring, and be unbiased in monitoring and reporting so that monitoring is accurately recorded. The designated individuals must have ready access to the CCP being monitored and to the calibrated instrumentation designated in the HACCP plan.

The person responsible for monitoring must also record a food operation or product that does not meet critical limits and ensure that immediate corrective action can be taken. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

Random checks may be useful in supplementing the monitoring of certain CCPs. They may be used to check incoming ingredients, serve as a check for compliance where ingredients are recertified as meeting certain standards, and assess factors such as equipment. Random checks are also advisable for monitoring environmental factors such as airborne contamination, and cleaning and sanitizing gloves.

With some foods containing microbiologically sensitive ingredients, there may not be an alternative to microbiological

testing. However, it is important to recognize that a sampling frequency which is adequate for reliable detection of low levels of pathogens is seldom possible because of the large number of samples needed. For this reason, microbiological testing has limitations in a HACCP system, but is valuable as a means of establishing and verifying the effectiveness of control at CCPs (such as through challenge tests, random testing, or testing that focuses on isolating the source of a problem).

(5) Establish corrective actions.

(a) Purpose of Corrective Action Plan. Although the HACCP system is intended to prevent deviations from occurring, perfection is rarely, if ever, achievable. Thus, there must be a corrective action plan in place to:

- (i) Determine the disposition of any food that was produced when a deviation was occurring;
- (ii) Correct the cause of the deviation and ensure that the critical control point is under control; and
- (iii) Maintain records of corrective actions.

(b) Aspects of Corrective Action Plan.

Because of the variations in CCPs for different food operations and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control. Individuals who have a thorough understanding of the operation, product, and HACCP plan must be assigned responsibility for taking corrective action. Corrective action procedures must be documented in the HACCP plan.

Food establishments covered by the Food Code will usually be concerned with food which has a limited shelf-life and distribution. Primary focus for the application of this HACCP principle will be on the correction of the procedure or condition which led to the noncompliance. More frequent monitoring may be temporarily required to ensure that the deviation from the established critical limit is not continuing when the operation is resumed.

If a deviation should occur in food operations that are traditionally considered food processing operations, such as cook-chill, curing

and smoking, or reduced oxygen packaging, the food establishment must place the product on hold pending completion of appropriate corrective actions and analyses. As appropriate, scientific experts and regulatory agencies must be consulted regarding additional testing or disposition of the product. Identification of deviant lots and corrective actions taken to ensure safety of these lots must be noted in the HACCP record. This record must remain on file for a reasonable period after the expiration date or expected shelf life of the product.

(6) Establish verification procedures.

(a) Establishing Verification Procedures.

(i) The first phase of the process is the scientific or technical verification that critical limits at CCPs are satisfactory. This can be complex and may require intensive involvement of highly skilled professionals from a variety of disciplines capable of doing focused studies and analyses. A review of the critical limits is necessary to verify that the limits are adequate to control the hazards that are likely to occur.

(ii) The second phase of verification ensures that the facility's HACCP plan is functioning effectively. A functioning HACCP system requires little end-product sampling, since appropriate safeguards are built in early in the food preparation. Therefore, rather than relying on end-product sampling, food establishments must rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate risk management decisions and product dispositions are made when preparation deviations occur.

(iii) The third phase consists of documented periodic revalidations, independent of audits or other verification procedures, that must be performed to ensure the accuracy of the HACCP plan. Revalidations are performed by a HACCP team on a regular basis and/or whenever significant product, preparation, or packaging changes require modification of the HACCP plan. The revalidation includes a documented on-site review and verification of all flow diagrams and CCPs in the HACCP plan. The HACCP team modifies the HACCP plan as necessary.

(iv) The fourth phase of verification deals with the regulatory agency's responsibility and actions to ensure that the establishment's HACCP system is functioning satisfactorily.

(b) The following are some examples of HACCP plan verification activities which should be used as a part of a HACCP program:

(i) Verification procedures may include:

(aa) Establishment of appropriate verification inspection schedules;

(bb) Review of the HACCP plan;

(cc) Review of CCP records;

(dd) Review of deviations and their resolution, including the disposition of food;

(ee) Visual inspections of operations to observe if CCPs are under control;

(ff) Random sample collection and analysis;

(gg) Review of critical limits to verify that they are adequate to control hazards;

(hh) Review of written record of verification inspections which certifies compliance with the HACCP plan or deviations from the plan and the corrective actions taken;

(ii) Validation of HACCP plan, including on-site review and verification of flow diagrams and CCPs; and

(jj) Review of modifications of the HACCP plan.

(ii) Verification inspections should be conducted:

(aa) Routinely or on an unannounced basis, to ensure that selected CCPs are under control;

(bb) When it is determined that intensive coverage of a specific food is needed because of new information concerning food safety;

(cc) When foods prepared at the establishment have been implicated as a vehicle of foodborne disease;

(dd) When requested on a consultative basis and resources allow accommodating the request;

(ee) When established criteria have not been met; and

(ff) To verify that changes have been implemented correctly after a HACCP plan has been modified.

(iii) Verification reports should include information about:

(aa) Existence of a HACCP plan and the person(s) responsible for administering and updating the HACCP plan;

(bb) The status of records associated with CCP monitoring;

(cc) Direct monitoring data of the CCP while in operation; Certification that monitoring equipment is properly calibrated and in working order;

(dd) Deviations and corrective actions;

(ee) Any samples analyzed to verify that CCPs are under control. Analyses may involve physical, chemical, microbiological, or organoleptic methods;

(ff) Modifications to the HACCP plan; and

(gg) Training and knowledge of individuals responsible for monitoring CCPs.

(c) Training and Knowledge.

(i) Focus and Objective. Training and knowledge are very important in making HACCP successful in any food establishment. HACCP works best when it is integrated into each employee's normal duties rather than added as something extra.

The depth and breadth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the HACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as product cooking temperatures and cooling times. The training plan should be specific to the establishment's operation rather than attempt to develop HACCP expertise for broad application.

The food employee's training should provide an overview of HACCP's prevention philosophy while focusing on the specifics of the employee's normal functions. The CCPs such as proper handwashing and use of utensils or gloves for working with ready-to-eat food should be stressed. The use of recipes or Standard Operating Procedures (SOPs) which include the critical limits of cooking times and temperatures, with a final cooking time and temperature measurement step, should be included.

For all employees, the fundamental training goal should be to make them proficient in the specific tasks which the HACCP plan requires them to perform. This includes the development of a level of competency in their decision making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

(ii) Reinforcement. Training reinforcement is also needed for continued motivation of the food establishment employees. Some examples might include:

(aa) A HACCP video training program such as the Pennsylvania Department of Environmental Regulation's Foodborne Illness: It's Your Business;

(bb) Changing reminders about HACCP critical limits such as "HANDWASHING PAYS BIG DIVIDENDS" printed on employee's time cards or checks; and

(cc) Work station reminders such as pictorials on how and when to take food temperatures.

Every time there is a change in a product or food operation within the establishment, the ACCP training needs should be evaluated. For example, when a food establishment substitutes a frozen seafood product for a fresh one, proper thawing critical limits should be taught and then monitored for implementation. The employees should be made sensitive to how the changes will affect food safety.

The HACCP plan should include a feedback loop for employees to suggest what additional training is needed. All employees should be made a part of the continuous food safety improvement cycle because the old statement is very true, "The customer's health is in their hands". This helps maintain their active awareness and involvement in the importance of each job to the safety of the food provided by their establishment.

(7) Establish record-keeping and documentation procedures.

(a) Written HACCP Plan. This principle requires the preparation and maintenance of a written HACCP plan by the food establishment. The plan must detail the hazards of each individual or categorical product covered by the plan. It must clearly identify the CCPs and critical limits for each CCP. CCP monitoring and record keeping procedures must be shown in the establishment's HACCP plan. HACCP plan implementation strategy should be provided as a part of the food establishment's documentation.

(b) Record Keeping. The principle requires the maintenance of records generated during the operation of the plan. The record keeping associated with HACCP procedures ultimately makes the system work. One conclusion of a study of HACCP performed by

the U.S. Department of Commerce is that correcting problems without record keeping almost guarantees that problems will recur. The requirement to record events at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences that are discovered as CCPs are monitored or that otherwise come to light must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation. A sous vidé process or cook-chill operation for a large institution would require more record keeping than a limited menu cook-serve operation. The simplest effective record keeping system that lends itself well to integration within the existing operation is best.

(c) Contents of the Plan and Records. The approved HACCP plan and associated records must be on file at the food establishment. Generally, the following are examples of documents that can be included in the total HACCP system:

- (i) Listing of the HACCP team and assigned responsibilities;
- (ii) Description of the product and its intended use;
- (iii) Flow diagram food preparation indicating CCPs;
- (iv) Hazards associated with each CCP and preventive measures;
- (v) Critical limits;
- (vi) Monitoring system;
- (vii) Corrective action plans for deviations from critical limits;
- (viii) Record keeping procedures; and
- (ix) Procedures for verification of HACCP system.

(d) Format for HACCP Information. In addition to listing the HACCP team, product description and uses, and providing a flow diagram, other information in the HACCP plan can be tabulated to include:

- (i) Process Step
- (ii) CCP
- (iii) Chemical Physical Biological Hazards
- (iv) Critical Limit
- (v) Monitoring Procedures
- (vi) Frequency
- (vii) Persons Responsible
- (ix) Corrective Action(s)
- (ix) HACCP Records
- (x) Verification Procedures

The following chart is an example of a HACCP plan documentation for a product cooling step in a retail level food establishment.

PROCESS STEP	COOLING
CCP	Critical Control Point #8 Criteria or Critical Limit Cool Foods Rapidly in Small Quantities to 5°C(41°F)
Establish Monitoring	Department Personnel Break Down Food into Small Quantities and Monitor The Cooling Process
Corrective/Preventive Action	Modify Cooling Procedures/ Discard
HACCP Records	Deli Cooking/Cooling Log
HACCP System Verification	Deli Safety Audit by Store Manager

(e) Examples of Records obtained during the operation of the plan:

- (i) Ingredients.

(aa) Supplier certification documenting compliance with establishment's specifications.

(bb) Establishment audit records verifying supplier compliance.

(cc) Storage temperature record for temperature-sensitive ingredients.

(dd) Storage time records of limited shelf-life ingredients.

(ii) Preparation.

(aa) Records from all monitored CCPs.

(bb) Records verifying the continued adequacy of the food preparation procedures.

(iii) Packaging.

(aa) Records indicating compliance with specifications of packaging materials.

(bb) Records indicating compliance with sealing specifications.

(iv) Finished product.

(aa) Sufficient data and records to establish the efficacy of barriers in maintaining product safety.

(bb) Sufficient data and records establishing the safe shelf-life of the product; if age of product can affect safety.

(cc) Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

(v) Storage and distribution.

(aa) Temperature records.

(bb) Records showing no product shipped after shelf life date on temperature-sensitive products.

(vi) Deviation and corrective action. Validation records and modification to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

(vii) Employee training. Records indicating that food employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures. Refer to the discussion regarding Training and Knowledge under Principle (7).

SECTION 3. Summary

HACCP is a systematic approach to food safety which will dramatically improve the level of food safety. The NACMCF has developed the seven HACCP principles discussed within this Appendix.

The FDA recommends the implementation of a HACCP system throughout the food industry using these NACMCF recommendations.

An effective national food safety program from food production to consumer is enhanced by the implementation of HACCP. The statistics from foodborne surveillance reveal that retail level food establishments can have a significant impact on the health of consumers.

Implementation of HACCP programs by the establishments will profoundly enhance their role in the protection of public health beyond the traditional emphasis on facility and equipment design and maintenance and adherence to the principles of sanitation, good manufacturing, and food preparation practices. The education and training of all personnel are critical to the success and effectiveness of any HACCP program. The Food Code stresses the application to HACCP principles and the knowledge and responsibilities of establishment management and employees.

Specific HACCP plans for the products prepared and sold by the retail food establishment should be developed and implemented for optimal food safety management. HACCP systems are recommended for use as a tool for regulatory inspections. The regulatory official should incorporate procedures in the inspection process that ensure record reviews and active monitoring.

Because the retail food establishment industry is composed of large, small, chain, and independent establishments, the level of food safety expertise varies widely and is not necessarily linked to size or affiliation. Regardless of the size and sophistication of the establishment, a HACCP plan for safe food preparation and sales needs to be designed, implemented, and verified.

Studies have shown that a significant level of illness and mortality from foodborne disease in institutional feeding operations such as hospitals, nursing homes, and

prisons is related to preventable causes. For populations that may be more vulnerable to foodborne disease, FDA and the NACMCF recommend that HACCP systems be immediately implemented by establishments and institutions preparing foods for these susceptible individuals.

Food processing operations at retail food establishments such as reduced oxygen packaging and curing and smoking under the Food Code are required to develop and implement a HACCP plan for that part of the operation. Additionally, any establishment seeking a variance from the requirements of the Code must submit a HACCP plan. This HACCP attachment can serve to guide these establishments in this process.

Food establishments have the primary responsibility for food safety. The development and implementation of HACCP programs is a reliable and responsible step to help ensure the safety of food offered for consumption.

SECTION 4. Other Sources of HACCP Information

FDA CFSAN Web Page. A Free On-Line Draft, "Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level" (<http://www.cfsan.fda.gov/~dms/hret-toc.html>), FDA, 200 C Street SW - HFS-676, Washington, D.C. 20204-0001

PA DEPARTMENT of ENVIRONMENTAL RESOURCES, 1992. *Foodborne Illness: It's your business* (HACCP video). Division of Food Protection, Food Facilities Section, Harrisburg, PA. (Note: Two Typical HACCP Flow Diagrams are available on the FDA website.)

