Chapter

1 Purpose and Definitions

Parts

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1-1 TITLE, INTENT, SCOPE

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1-101 Title
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Title

1-101.10 Food Code.

These provisions shall be known as the Food Code, hereinafter referred to as "this Code."

Intent

1-102.10 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.

Scope

1-103.10 Statement.

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.

1-2	**DEFINITIONS**	
	Subpart	
	1-201	**Applicability and Terms Defined**

Applicability and Terms Defined	**1-201.10**	**Statement of Application and Listing of Terms.**

(A) The following definitions shall apply in the interpretation and application of this Code.

(B) Terms Defined. As used in this Code, each of the terms listed in ¶ 1-201.10(B) shall have the meaning stated below.

Accredited Program.

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

(2) **"Accredited program"** refers to the certification process and is a designation 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*.

Additive.

(1) **"Food additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1).

(2) **"Color additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).

"Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

"Approved" means acceptable to the REGULATORY AUTHORITY based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Asymptomatic.

(1) **"Asymptomatic"** means without obvious symptoms; not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice.

(2) **"Asymptomatic"** includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

"a_w" 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 A_W.

"Balut" means an embryo inside a fertile EGG that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

"Beverage" means a liquid for drinking, including water.

"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.

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

"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.

"CFR" means CODE OF FEDERAL REGULATIONS. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers, such as 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

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.*

"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.

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.

"Conditional employee" means a potential FOOD EMPLOYEE to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential FOOD EMPLOYEES who may be suffering from a disease that can be transmitted through FOOD and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

"Confirmed disease outbreak" means a FOODBORNE 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.

"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.

"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.

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

"Critical control point" means a point or procedure in a specific FOOD system where loss of control may result in an unacceptable health RISK.

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 *.

"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.

"Disclosure" means a written statement that clearly identifies the animal-derived FOODS which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

Drinking Water.

(1) **"Drinking water"** means water that meets criteria as specified in 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*.

"Dry storage area" means a room or area designated for the storage of PACKAGED or containerized bulk FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) and dry goods such as SINGLE-SERVICE items.

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 in Subparagraph (1) 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.

"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.

Egg.

(1) **"Egg"** means the shell EGG of avian species such as chicken, duck, goose, guinea, quail, RATITES or turkey.

(2) ***"Egg"*** *does not include:*

(a) A BALUT;

(b) The egg of reptile species such as alligator; or

(c) An EGG PRODUCT.

Egg Product.

(1) **"Egg Product"** means all, or a portion of, the contents found inside EGGS separated from the shell and pasteurized in a FOOD PROCESSING PLANT, with or without added ingredients, intended for human consumption, such as dried, frozen or liquid eggs.

(2) ***"Egg Product"*** *does not include FOOD which contains EGGS only in a relatively small proportion such as cake mixes*.

"Employee" means the PERMIT HOLDER, PERSON IN CHARGE, FOOD EMPLOYEE, 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.

"Enterohemorrhagic *Escherichia coli*" (EHEC) means ***E. coli*** which cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. The term is typically used in association with ***E. coli*** that have the capacity to produce Shiga toxins and to cause attaching and effacing lesions in the intestine. EHEC is a subset of STEC, whose members produce additional virulence factors. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Examples of serotypes of EHEC include: ***E. coli*** O157:H7; ***E. coli*** O157:NM; ***E. coli*** O26:H11; ***E. coli*** O145:NM; ***E. coli*** O103:H2; or ***E. coli*** O111:NM. *Also see* SHIGA TOXIN-PRODUCING ***E. COLI.***

"EPA" means the U.S. Environmental Protection Agency.

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 apparatuses 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.*

"Exclude" means to prevent a PERSON from working as an EMPLOYEE in a FOOD ESTABLISHMENT or entering a FOOD ESTABLISHMENT as an EMPLOYEE.

"FDA" means the U.S. Food and Drug Administration.

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.

"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.

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

"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.

"Food employee" means an individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.

Food Establishment.

(1) **"Food establishment"** means an 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.

(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 (TIME/TEMPERATURE CONTROL FOR SAFETY) FOODS*;

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

(c) *A FOOD PROCESSING PLANT;*

(d) *A kitchen in a private home if only FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY) FOOD, 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;*

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

(f) *A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and THE CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; or*

(g) *A private home that receives catered or home-delivered FOOD*.

Food Processing Plant.

(1) **"Food processing plant"** means a commercial operation that manufactures, packages, labels, or stores FOOD for human consumption, and provides FOOD for sale or distribution to other business entities such as FOOD PROCESSING PLANTS or FOOD ESTABLISHMENTS.

(2) ***"Food processing plant"*** *does not include a FOOD ESTABLISHMENT.*

Game Animal.

(1) **"Game animal"** means an animal, the products of which are FOOD, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2 Definitions, or as Poultry, or FISH.

(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*.

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

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

"HACCP plan" means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Handwashing Sink.

(1) **"Handwashing sink"** means a lavatory, a basin or vessel for washing, a wash basin, or a PLUMBING FIXTURE especially placed for use in personal hygiene and designed for the washing of the hands.

(2) **"Handwashing sink"** includes an automatic handwashing facility.

"Hazard" means a biological, chemical, or physical property that may cause an unacceptable CONSUMER health RISK.

"Health practitioner" means a physician licensed to practice medicine, or if allowed by LAW, a nurse practitioner, physician assistant, or similar medical professional.

"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.

"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.

"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.

"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."

Juice.

(1) **"Juice"** means 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.

(2) ***"Juice"*** *does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as BEVERAGES or ingredients of BEVERAGES*.

"Kitchenware" means FOOD preparation and storage UTENSILS.

"Law" means applicable local, state, and federal statutes, regulations, and ordinances.

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

Major Food Allergen.

(1) **"Major food allergen"** means:

(a) Milk, EGG, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(b) A FOOD ingredient that contains protein derived from a FOOD, as specified in Subparagraph (1)(a) of this definition.

(2) ***"Major food allergen"*** *does not include:*

(a) *Any highly refined oil derived from a FOOD specified in Subparagraph (1)(a) of this definition and any ingredient derived from such highly refined oil; or*

(b) *Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282)*.

"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 3-201.17(A)(3) and (4).*

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

"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*.

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.*

"Permit" means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT.

"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 to operate a FOOD ESTABLISHMENT.

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

"Person in charge" means the individual present at a FOOD ESTABLISHMENT who is responsible for the operation at the time of inspection.

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.

"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.

"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.

"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.

"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.

"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.

Potentially Hazardous Food (Time/Temperature Control for Safety Food).

(1) **"Potentially hazardous food (time/temperature control for safety food)"** means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(2) **"Potentially hazardous food (time/temperature control for safety food)"** includes:

(a) An animal FOOD that is raw or heat-treated; a plant FOOD that is heat-treated or consists of raw seed sprouts, cut melons, or garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support pathogenic microorganism growth or toxin formation; and

(b) Except as specified in Subparagraph (3)(d) of this definition, a FOOD that because of the interaction of its A_W and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of pH and A_W for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

A_W values	pH values		
	4.6 or less	> 4.6 - 5.6	> 5.6
≤0.92	non-PHF*/non-TCS FOOD**	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD
> 0.92 - .95	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD	PA***
> 0.95	non-PHF/non-TCS FOOD	PA	PA

* PHF means POTENTIALLY HAZARDOUS FOOD
** TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
*** PA means Product Assessment required

Table B. Interaction of pH and A_W for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED				
A_W values	pH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	non-PHF*/ non-TCS food**	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food
0.88 – 0.90	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA***
> 0.90 – 0.92	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA	PA
> 0.92	non-PHF/ non-TCS food	PA	PA	PA

* PHF means POTENTIALLY HAZARDOUS FOOD
** TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
*** PA means Product Assessment required

(3) ***"Potentially hazardous food (time/temperature control for safety food)"*** *does not include:*

(a) *An air-cooled hard-boiled EGG with shell intact, or an EGG with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable* ***salmonellae****;*

(b) *A FOOD in an unopened* HERMETICALLY SEALED CONTAINER *that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;*

(c) *A FOOD that because of its pH or A_W value, or interaction of A_W and pH values, is designated as a non-PHF/non-TCS FOOD in Table A or B of this definition;*

(d) *A FOOD that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that FOOD is precluded due to:*

(i) *Intrinsic factors including added or natural characteristics of the* FOOD *such as preservatives, antimicrobials, humectants, acidulants, or nutrients,*

(ii) *Extrinsic factors including environmental or operational factors that affect the* FOOD *such as packaging, modified atmosphere such as* REDUCED OXYGEN PACKAGING*, shelf life and use, or temperature range of storage and use, or*

(iii) *A combination of intrinsic and extrinsic factors; or*

(e) *A* FOOD *that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (3)(a) - (3)(d) of this definition even though the* FOOD *may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.*

"Poultry" means:

(1) Any domesticated bird (chickens, turkeys, ducks, geese, guineas, RATITES, or squabs), whether live or dead, as defined in 9 CFR 381.1 Poultry Products Inspection Regulations Definitions, Poultry; and

(2) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1 Voluntary Poultry Inspection Regulations, Definitions.

"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 in Subparagraph (1) 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.

"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.

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

"Ratite" means a flightless bird such as an emu, ostrich, or rhea.

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 one of the following: ¶ 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in ¶ 3-401.11(C); or

(b) Is a raw or partially cooked animal FOOD and the consumer is advised as specified in Subparagraphs 3-401.11(D)(1) and (2); or

(c) Is prepared in accordance with a variance that is granted as specified in Subparagraphs 3-401.11(D) 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 § 3-401.11 or 3-401.12, or frozen as specified under § 3-402.11;

(b) Raw fruits and vegetables that are washed as specified under § 3-302.15;

(c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;

(d) All POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) that is cooked to the temperature and time required for the specific FOOD under Subpart 3-401 and cooled as specified under § 3-501.14;

(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 as specified in 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

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 atmosphere (approximately 21% at sea level); and

(b) A process as specified in Subparagraph (1)(a) of this definition that involves a FOOD for which the HAZARDS ***Clostridium botulinum*** or ***Listeria monocytogenes*** require control 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;

(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;

(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;

(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotrophic pathogens; or

(e) Sous vide PACKAGING, in which raw or partially cooked FOOD is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychotrophic pathogens.

"Refuse" means solid waste not carried by water through the SEWAGE system.

"Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the FOOD ESTABLISHMENT.

"Reminder" means a written statement concerning the health RISK of consuming animal FOODS raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Re-service" means the transfer of FOOD that is unused and returned by a CONSUMER after being served or sold and in the possession of the CONSUMER, to another PERSON.

"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, or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

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

"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.

"Risk" means the likelihood that an adverse health effect will occur within a population as a result of a HAZARD in a FOOD.

"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.

"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.

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

"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.

"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.

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

"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.

"Shellstock" means raw, in-shell MOLLUSCAN SHELLFISH.

"Shiga toxin-producing *Escherichia coli*" (STEC) means any ***E. coli*** capable of producing Shiga toxins (also called verocytotoxins or "Shiga-like" toxins). Examples of serotypes of STEC include both O157 and non-O157 ***E. coli***. *Also see* ENTEROHEMORRHAGIC ***ESCHERICHIA COLI.***

"Shucked shellfish" means MOLLUSCAN SHELLFISH that have one or both shells removed.

"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.

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 §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse UTENSILS.

"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 shrimp.

"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 render it difficult to clean.

"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.

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

"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.

"USDA" means the U.S. Department of Agriculture.

"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.

"Variance" means a written document issued by the REGULATORY AUTHORITY 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.

"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.

"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.

"Warewashing" means the cleaning and SANITIZING of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT.

"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

Parts

2-1 SUPERVISION
2-2 EMPLOYEE HEALTH
2-3 PERSONAL CLEANLINESS
2-4 HYGIENIC PRACTICES

2-1 SUPERVISION

Subparts

2-101 Responsibility
2-102 Knowledge
2-103 Duties

Responsibility

2-101.11 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.

Knowledge

2-102.11 Demonstration.*

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

(A) Complying with this Code by having no violations of CRITICAL ITEMS during the current inspection;

(B) Being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM; or

(C) 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 foodborne disease and the personal hygiene of a FOOD EMPLOYEE;

(2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) and the prevention of foodborne illness;

(5) 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) including MEAT, POULTRY, EGGS, and FISH;

(7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD);

(8) Describing the relationship between the prevention of foodborne 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) Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction.

(10) 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;

(11) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT;

(12) 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;

(13) 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;

(14) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code;

(15) 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 FOOD ESTABLISHMENT;

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

(a) FOOD EMPLOYEE,

(b) CONDITIONAL EMPLOYEE,

(c) PERSON IN CHARGE,

(d) REGULATORY AUTHORITY; and

(17) Explaining how the PERSON IN CHARGE, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION or RESTRICTION of FOOD EMPLOYEES.

2-102.20 Food Protection Manager Certification.

A PERSON IN CHARGE who demonstrates knowledge by being a FOOD protection manager that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs is deemed to comply with ¶ 2-102.11(B).

Duties

2-103.11 Person in Charge.

The PERSON IN CHARGE shall ensure that:

(A) FOOD ESTABLISHMENT operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under § 6-202.111;

(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, unADULTERED, and accurately presented, by routinely monitoring the EMPLOYEES' observations and periodically evaluating FOODS upon their receipt;

(F) EMPLOYEES are properly cooking POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD), being particularly careful in cooking those FOODS known to cause severe foodborne 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 § 4-203.11 and ¶ 4-502.11(B);

(G) EMPLOYEES are using proper methods to rapidly cool POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY 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 § 3-603.11 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 § 3-304.16;

(K) Except when APPROVAL is obtained from the REGULATORY AUTHORITY as specified in ¶ 3-301.11(D), 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;

(L) EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties; and

(M) FOOD EMPLOYEES and CONDITIONAL EMPLOYEES are informed of their responsibility to report in accordance with LAW, to the PERSON IN CHARGE, information about their health and activities as they relate to diseases that are transmissible through FOOD, as specified under ¶ 2-201.11(A).

2-2 EMPLOYEE HEALTH

Subpart

2-201 Responsibilities of Permit Holder, Person in Charge, Food Employees, and Conditional Employees

Responsibilities and Reporting Symptoms and Diagnosis

2-201.11 Responsibility of Permit Holder, Person in Charge, and Conditional Employees.*

(A) The PERMIT HOLDER shall require FOOD EMPLOYEES and CONDITIONAL 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 CONDITIONAL EMPLOYEE shall report the information in a manner that allows the PERSON IN CHARGE to reduce the RISK of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE:

reportable symptoms

(1) Has any of the following symptoms:

(a) Vomiting,

(b) Diarrhea,

(c) Jaundice,

(d) Sore throat with fever, or

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

(i) 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,*

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

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

reportable diagnosis

(2) Has an illness diagnosed by a HEALTH PRACTITIONER due to:

(a) Norovirus,

(b) Hepatitis A virus,

(c) *Shigella* spp.,

(d) ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*, or

(e) *Salmonella* Typhi;

reportable past illness

(3) Had a previous illness, diagnosed by a HEALTH PRACTITIONER, within the past 3 months due to *Salmonella* Typhi, without having received antibiotic therapy, as determined by a HEALTH PRACTITIONER;

reportable history of exposure

(4) Has been exposed to, or is the suspected source of, a CONFIRMED DISEASE OUTBREAK, because the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE consumed or prepared FOOD implicated in the outbreak, or consumed FOOD at an event prepared by a PERSON who is infected or ill with:

(a) Norovirus within the past 48 hours of the last exposure,

(b) ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI, or Shigella* spp. within the past 3 days of the last exposure,

(c) *Salmonella* Typhi within the past 14 days of the last exposure, or

(d) Hepatitis A virus within the past 30 days of the last exposure; or

reportable history of exposure

(5) Has been exposed by attending or working in a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual who works or attends a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(a) Norovirus within the past 48 hours of the last exposure,

(b) ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI, or Shigella* spp. within the past 3 days of the last exposure,

(c) *Salmonella* Typhi within the past 14 days of the last exposure, or

(d) Hepatitis A virus within the past 30 days of the last exposure.

responsibility of person in charge to notify the regulatory authority

(B) The PERSON IN CHARGE shall notify the REGULATORY AUTHORITY when a FOOD EMPLOYEE is:

(1) Jaundiced, or

(2) Diagnosed with an illness due to a pathogen as specified under Subparagraphs (A)(2)(a) - (e) of this section.

responsibility of the person in charge to prohibit a conditional employee from becoming a food

(C) The PERSON IN CHARGE shall ensure that a CONDITIONAL EMPLOYEE:

(1) Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under Subparagraphs

employee

(A)(1) - (3) of this section, is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria for the specific symptoms or diagnosed illness as specified under § 2-201.13; and

(2) Who will work as a FOOD EMPLOYEE in a FOOD ESTABLISHMENT that serves as a HIGHLY SUSCEPTIBLE POPULATION and reports a history of exposure as specified under Subparagraphs (A)(4) – (5), is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria as specified under ¶ 2-201.13(I).

responsibility of the person in charge to exclude or restrict

(D) The PERSON IN CHARGE shall ensure that a FOOD EMPLOYEE who exhibits or reports a symptom, or who reports a diagnosed illness or a history of exposure as specified under Subparagraphs (A)(1) - (5) of this section is:

(1) EXCLUDED as specified under ¶¶ 2-201.12 (A) - (C), and Subparagraphs (D)(1), (E)(1), (F)(1), or (G)(1) and in compliance with the provisions specified under ¶¶ 2-201.13(A) - (G); or

(2) RESTRICTED as specified under Subparagraphs 2-201.12 (D)(2), (E)(2), (F)(2), (G)(2), or ¶¶ 2-201.12(H) or (I) and in compliance with the provisions specified under ¶¶ 2-201.13(D) - (I).

responsibility of food employees and conditional employees to report

(E) A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report to the PERSON IN CHARGE the information as specified under ¶ (A) of this section.

responsibility of food employees to comply

(F) A FOOD EMPLOYEE shall:

(1) Comply with an EXCLUSION as specified under ¶¶ 2-201.12(A) - (C) and Subparagraphs 2-201.12(D)(1), (E)(1), (F)(1), or (G)(1) and with the provisions specified under ¶¶ 2-201.13(A) - (G); or

(2) Comply with a RESTRICTION as specified under Subparagraphs 2-201.12(D)(2), (E)(2), (F)(2), (G)(2), or ¶¶ 2-201.12 (H) or (I) and comply with the provisions specified under ¶¶ 2-201.13(D) - (I).

conditions of exclusion and restriction

2-201.12 Exclusions and Restrictions.*

The PERSON IN CHARGE shall EXCLUDE or RESTRICT a FOOD EMPLOYEE from a FOOD ESTABLISHMENT in accordance with the following:

symptomatic with vomiting or diarrhea

(A) *Except when the symptom is from a noninfectious condition,* EXCLUDE a FOOD EMPLOYEE if the FOOD EMPLOYEE is:

(1) Symptomatic with vomiting or diarrhea; or

(2) Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, *Shigella* spp., or ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *E. COLI*.

jaundiced or diagnosed with hepatitis A infection

(B) EXCLUDE a FOOD EMPLOYEE who is:

(1) Jaundiced and the onset of jaundice occurred within the last 7 calendar days, *unless the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER specifying that the jaundice is not caused by hepatitis A virus or other fecal-orally transmitted infection;*

(2) Diagnosed with an infection from hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within 7 calendar days of the onset of jaundice; or

(3) Diagnosed with an infection from hepatitis A virus without developing symptoms.

diagnosed or reported previous infection due to S. Typhi

(C) EXCLUDE a FOOD EMPLOYEE who is diagnosed with an infection from *Salmonella* Typhi, or reports a previous infection with *Salmonella* Typhi within the past 3 months as specified under Subparagraph 2-201.11(A)(3).

diagnosed with an asymptomatic infection from Norovirus

(D) If a FOOD EMPLOYEE is diagnosed with an infection from Norovirus and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.

diagnosed with Shigella spp. infection and asymptomatic

(E) If a FOOD EMPLOYEE is diagnosed with an infection from *Shigella* spp. and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.

diagnosed with EHEC or STEC and asymptomatic

(F) If a FOOD EMPLOYEE is diagnosed with an infection from ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *E. COLI*, and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.

symptomatic with sore throat with fever

(G) If a FOOD EMPLOYEE is ill with symptoms of acute onset of sore throat with fever:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.

symptomatic with uncovered infected wound or pustular boil

(H) If a FOOD EMPLOYEE is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under Subparagraph 2-201.11(A)(1)(e), RESTRICT the FOOD EMPLOYEE.

exposed to foodborne pathogen and works in food establishment serving HSP

(I) If a FOOD EMPLOYEE is exposed to a foodborne pathogen as specified under Subparagraphs 2-201.11(A)(4) or (5), RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION.

Managing Exclusions and Restrictions

2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions.

The PERSON IN CHARGE may remove, adjust, or retain the EXCLUSION or RESTRICTION of a FOOD EMPLOYEE according to the following conditions:

(A) *Except when a FOOD EMPLOYEE is diagnosed with an infection from hepatitis A virus or Salmonella* Typhi:

removing exclusion for food employee who was symptomatic and not diagnosed

(1) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(1) if the FOOD EMPLOYEE:

(a) Is ASYMPTOMATIC for at least 24 hours; or

(b) Provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the symptom is from a noninfectious condition.

Norovirus diagnosis

(2) If a FOOD EMPLOYEE was diagnosed with an infection from Norovirus and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met; or

retaining exclusion for food employee who was asymptomatic and is now asymptomatic and works in food establishment serving HSP

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met.

Shigella spp. diagnosis

(3) If a FOOD EMPLOYEE was diagnosed with an infection from *Shigella* spp. and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) of this section are met; or

retaining exclusion for food employee who was asymptomatic and is now asymptomatic

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) , or (E)(1) and (3)(a) of this section are met.

EHEC or STEC diagnosis

(4) If a FOOD EMPLOYEE was diagnosed with an infection from ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) of this section are met; or

retaining exclusion for food employee who was symptomatic and is now asymptomatic and works in food establishment serving HSP

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) are met.

hepatitis A virus or jaundice diagnosis - removing exclusions

(B) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(B) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met;

(1) The FOOD EMPLOYEE has been jaundiced for more than 7 calendar days;

(2) The anicteric FOOD EMPLOYEE has been symptomatic with symptoms other than jaundice for more than 14 calendar days; or

(3) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a hepatitis A virus infection.

S. Typhi diagnosis - removing exclusions

(C) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(C) if:

(1) The PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY; and

(2) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the FOOD EMPLOYEE is free from *S.* Typhi infection.

Norovirus diagnosis - removing exclusion or restriction

(D) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (D)(1) who was RESTRICTED under Subparagraph 2-201.12(D)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a Norovirus infection;

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the FOOD EMPLOYEE became ASYMPTOMATIC; or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 48 hours have passed since the FOOD EMPLOYEE was diagnosed.

Shigella spp. diagnosis - removing exclusion or restriction

(E) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (E)(1) or who was RESTRICTED under Subparagraph 2-201.12(E)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Shigella* spp. infection based on test results showing 2 consecutive negative stool specimen cultures that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics, and

(b) At least 24 hours apart;

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC; or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 7 calendar days have passed since the FOOD EMPLOYEE was diagnosed.

EHEC or STEC diagnosis - removing exclusion or restriction

(F) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(A)(2) or (F)(1) or who was RESTRICTED under Subparagraph 2-201.12(F)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of an infection from ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* based on test results that show 2 consecutive negative stool specimen cultures that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics; and

(b) At least 24 hours apart;

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC; or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptomsand more than 7 days have passed since the FOOD EMPLOYEE was diagnosed.

sore throat with fever - removing exclusion or restriction

(G) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(G)(1) or (2) if the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE meets one of the following conditions:

(1) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than 24 hours;

(2) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection; or

(3) Is otherwise determined by a HEALTH PRACTITIONER to be free of a *Streptococcus pyogenes* infection.

uncovered infected wound or pustular boil - removing restriction

(H) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(H) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

(1) An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;

(2) An impermeable cover on the arm if the infected wound or pustular boil is on the arm; or

(3) A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.

exposure to foodborne pathogen and works in food establishment serving HSP – removing restriction

(I) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(I) and was exposed to one of the following pathogens as specified under Subparagraph 2-201.11(A)(4) or (5):

Norovirus

(1) Norovirus and one of the following conditions is met:

(a) More than 48 hours have passed since the last day the FOOD EMPLOYEE was potentially exposed; or

(b) More than 48 hours have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.

Shigella spp., EHEC, or STEC

(2) *Shigella* spp. or ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and one of the following conditions is met:

(a) More than 3 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed; or

(b) More than 3 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.

S. Typhi

(3) *S.* Typhi and one of the following conditions is met:

(a) More than 14 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed; or

(b) More than 14 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.

hepatitis A

(4) Hepatitis A virus and one of the following conditions is met:

(a) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of a prior illness from hepatitis A;

(b) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of vaccination against hepatitis A;

(c) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of IgG administration;

(d) More than 30 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;

(e) More than 30 calendar days have passed since the FOOD EMPLOYEE'S household contact became jaundiced; or

(f) The FOOD EMPLOYEE does not use an alternative procedure that allows bare hand contact with READY-TO-EAT FOOD until at least 30 days after the potential exposure, as specified in Subparagraphs (I)(4)(d) and (e) of this section, and the FOOD EMPLOYEE receives additional training about:

(i) Hepatitis A symptoms and preventing the transmission of infection,

(ii) Proper handwashing procedures, and

(iii) Protecting READY-TO-EAT FOOD from contamination introduced by bare hand contact.

2-3 PERSONAL CLEANLINESS

Subparts

2-301	**Hands and Arms**
2-302	**Fingernails**
2-303	**Jewelry**
2-304	**Outer Clothing**

Hands and Arms

2-301.11 Clean Condition.*

FOOD EMPLOYEES shall keep their hands and exposed portions of their arms clean.

2-301.12 Cleaning Procedure.*

(A) Except as specified in ¶ (D) of this section, FOOD EMPLOYEES shall clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands or arms for at least 20 seconds, using a cleaning compound in a HANDWASHING SINK that is equipped as specified under § 5-202.12 and Subpart 6-301.

(B) FOOD EMPLOYEES shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

(1) Rinse under clean, running warm water;

(2) Apply an amount of cleaning compound recommended by the cleaning compound manufacturer;

(3) Rub together vigorously for at least 10 to 15 seconds while:

(a) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure, and

(b) Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers;

(4) Thoroughly rinse under clean, running warm water; and

(5) Immediately follow the cleaning procedure with thorough drying using a method as specified under § 6-301.12.

(C) *TO avoid recontaminating their hands or surrogate prosthetic devices, FOOD EMPLOYEES may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a HANDWASHING SINK or the handle of a restroom door*.

(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 or surrogate prosthetic devices.*

2-301.13 Special Handwash Procedures.*

Reserved.

2-301.14 When to Wash.*

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 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 ¶ 2-403.11(B);

(D) Except as specified in ¶ 2-401.11(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) Before donning gloves for working with FOOD; and

(I) After engaging in other activities that contaminate the hands.

2-301.15 Where to Wash.

FOOD EMPLOYEES shall clean their hands in a HANDWASHING SINK 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.

2-301.16 Hand Antiseptics.

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

(1) Comply with one of the following:

(a) 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

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

(2) Comply with one of the following:

(a) 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

(b) Comply with and be listed in:

(i) 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

(ii) 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

(3) Be applied only to hands that are cleaned as specified under § 2-301.12.

(B) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:

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

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

(C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 MG/L chlorine.

Fingernails **2-302.11 Maintenance.**

(A) FOOD EMPLOYEES shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.

(B) *Unless wearing intact gloves in good repair*, a FOOD EMPLOYEE may not wear fingernail polish or artificial fingernails when working with exposed FOOD.

Jewelry

2-303.11 Prohibition.

Except for *a plain ring such as a wedding band,* while preparing FOOD, FOOD EMPLOYEES may not wear jewelry including medical information jewelry on their arms and hands.

Outer Clothing

2-304.11 Clean Condition.

FOOD EMPLOYEES shall wear clean outer clothing to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

2-4 HYGIENIC PRACTICES

Subparts

2-401 Food Contamination Prevention
2-402 Hair Restraints
2-403 Animals

Food Contamination Prevention

2-401.11 Eating, Drinking, or Using Tobacco.*

(A) Except as specified in ¶ (B) of this section, an EMPLOYEE shall eat, drink, or use any form 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.*

2-401.12 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.

Hair Restraints

2-402.11 Effectiveness.

(A) Except as provided in ¶ (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*.

Animals

2-403.11 Handling Prohibition.*

(A) Except as specified in ¶ (B) 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 6-501.115(B)(2)-(5).

(B) *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 § 2-301.12 and ¶ 2-301.14(C).*

Chapter

3 Food

Parts

3-1 CHARACTERISTICS
3-2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS
3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING
3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN
3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN
3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING
3-7 CONTAMINATED FOOD
3-8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

3-1 CHARACTERISTICS

Subparts

3-101 Condition

Condition **3-101.11 Safe, Unadulterated, and Honestly Presented.***

FOOD shall be safe, UNADULTERATED, and, as specified under § 3-601.12, honestly presented.

3-2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS

Subparts

3-201 Sources
3-202 Specifications for Receiving
3-203 Original Containers and Records

Sources

3-201.11 Compliance with Food Law.*

(A) FOOD shall be obtained from sources that comply with LAW.

(B) FOOD prepared in 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 §§ 3-202.17 and 3-202.18.

(D) *Fish, other than MOLLUSCAN SHELLFISH, that are intended for consumption in their raw form and allowed as specified in Subparagraph 3-401.11(C)(1) may be offered for sale or service if they are obtained from a supplier that freezes the FISH as specified under § 3-402.11; or frozen on the PREMISES as specified under § 3-402.11 and records are retained as specified under § 3-402.12.*

(E) WHOLE-MUSCLE, INTACT BEEF steaks that are intended for consumption in an undercooked form without a CONSUMER advisory as specified in ¶ 3-401.11(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 (E)(1) of this section or identified as specified in Subparagraph (E)(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 (E)(1) of this section or identified as specified in (E)(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) 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).

3-201.12 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.

3-201.13 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.

3-201.14 Fish.*

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

(1) Commercially and 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.

3-201.15 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.

3-201.16 Wild Mushrooms.*

(A) Except as specified in ¶ (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.*

3-201.17 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 Exotic animals; voluntary inspection or rabbits that are "inspected and certified" in accordance with 9 CFR 354 voluntary inspection of rabbits and edible products thereof;

(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.

(B) A GAME ANIMAL may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 Endangered and threatened wildlife and plants.

Specifications for Receiving

3-202.11 Temperature.*

(A) Except as specified in ¶ (B) of this section, refrigerated, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 (TIME/TEMPERATURE CONTROL FOR SAFETY 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 EGGS shall be received in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less.

(D) POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) that is cooked to a temperature and for a time specified under §§ 3-401.11 - 3-401.13 and received hot shall be at a temperature of 57°C (135°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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be free of evidence of previous temperature abuse.

3-202.12 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 180 Tolerances for pesticides chemicals in food, and exceptions.

3-202.13 Eggs.*

EGGS shall be received clean and sound and may not exceed the restricted EGG tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.200 *et seq*., administered by the Agricultural Marketing Service of USDA.

3-202.14 Eggs and Milk Products, Pasteurized.*

(A) EGG PRODUCTS shall be obtained pasteurized.

(B) Fluid and dry milk and milk products shall:

(1) Be obtained pasteurized; and

(2) Comply with GRADE A STANDARDS as specified in LAW.

(C) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 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.*

3-202.15 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.

3-202.16 Ice.*

Ice for use as a FOOD or a cooling medium shall be made from DRINKING WATER.

3-202.17 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 1.89 L (one-half gallon) or the date shucked for packages with a capacity of 1.89 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 ¶ (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) Molluscan shellfish.

3-202.18 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 ¶ (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 ¶ (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 ¶ (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.*

3-202.19 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.

3-202.110 Juice Treated.

Pre-PACKAGED JUICE shall:

(A) Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120 Hazard Analysis and Critical Control (HACCP) Systems;

(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 Process Controls; or

(C) Bear a warning label as specified in 21 CFR Section 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens.

3-203.11 Molluscan Shellfish, Original Container.

(A) Except as specified in ¶¶ (B) - (D) 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.

Original Containers and Records

(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 § 3-202.18 and recorded as specified under § 3-203.12; 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 § 3-202.17 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.*

(D) *SHUCKED SHELLFISH may be removed from the container in which they were received and repacked in CONSUMER self service containers where allowed by LAW if:*

(1) *The labeling information for the shellfish is on each CONSUMER self service container as specified under § 3-202.17 and ¶¶ 3-602.11(A) and (B)(1) - (5);*

(2) *The labeling information as specified under § 3-202.17 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;*

(3) *The labeling information and dates specified under Subparagraph (D)(2) of this section are maintained for 90 days; and*

(4) *The shellfish are protected from contamination.*

3-203.12 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 dates of harvest:

(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 with different CERTIFICATION NUMBERS; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the CONSUMER.

3-3	PROTECTION FROM CONTAMINATION AFTER RECEIVING
	Subparts
	3-301 Preventing Contamination by Employees
	3-302 Preventing Food and Ingredient Contamination
	3-303 Preventing Contamination from Ice Used as a Coolant
	3-304 Preventing Contamination from Equipment, Utensils, and Linens
	3-305 Preventing Contamination from the Premises
	3-306 Preventing Contamination by Consumers
	3-307 Preventing Contamination from Other Sources

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.*

(A) FOOD EMPLOYEES shall wash their hands as specified under § 2-301.12.

(B) *Except when washing fruits and vegetables as specified under § 3-302.15 or as specified in ¶ (D) of this section,* 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.[s]

(D) *FOOD EMPLOYEES not serving a HIGHLY SUSCEPTIBLE POPULATION may contact exposed, READY-TO-EAT FOOD with their bare hands if:*

(1) *The PERMIT HOLDER obtains prior APPROVAL from the REGULATORY AUTHORITY;*

(2) *Written procedures are maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that include:*

(a) *For each bare hand contact procedure, a listing of the specific READY-TO-EAT FOODS that are touched by bare hands,*

(b) *Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under §§ 5-203.11, 5-204.11, 5-205.11, 6-301.11, 6-301.12, and 6-301.14, are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;*

(3) *A written* EMPLOYEE *health policy that details how the* FOOD ESTABLISHMENT *complies with §§ 2-201.11, 2-201.12, and 2-201.13 including*:

(a) *Documentation that* FOOD EMPLOYEES *and* CONDITIONAL EMPLOYEES *acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through* FOOD *as specified under ¶ 2-201.11(A)*,

(b) *Documentation that* FOOD EMPLOYEES *and* CONDITIONAL EMPLOYEES *acknowledge their responsibilities as specified under ¶ 2-201.11(E) and (F), and*

(c) *Documentation that the* PERSON IN CHARGE *acknowledges the responsibilities as specified under ¶¶ 2-201.11(B), (C) and (D), and §§ 2-201.12 and 2-201.13*;

(4) *Documentation that* FOOD EMPLOYEES *acknowledge that they have received training in*:

(a) *The* RISKS *of contacting the specific* READY-TO-EAT FOODS *with bare hands*,

(b) *Proper handwashing as specified under § 2-301.12*,

(c) *When to wash their hands as specified under § 2-301.14*,

(d) *Where to wash their hands as specified under § 2-301.15*,

(e) *Proper fingernail maintenance as specified under § 2-302.11*,

(f) *Prohibition of jewelry as specified under § 2-303.11, and*

(g) *Good hygienic practices as specified under §§2-401.11 and 2-401.12;*

(5) *Documentation that hands are washed before* FOOD *preparation and as necessary to prevent cross contamination by* FOOD EMPLOYEES *as specified under §§ 2-301.11, 2-301.12, 2-301.14, and 2-301.15 during all hours of operation when the specific* READY-TO-EAT FOODS *are prepared*;

(6) *Documentation that* FOOD EMPLOYEES *contacting* READY-TO-EAT FOOD *with bare hands use two or more of the following control measures to provide additional safeguards to* HAZARDS *associated with bare hand contact*:

(a) *Double handwashing,*

(b) *Nail brushes,*

(c) *A hand antiseptic after handwashing as specified under § 2-301.16,*

(d) *Incentive programs such as paid sick leave that assist or encourage* FOOD EMPLOYEES *not to work when they are ill, or*

(e) *Other control measures* APPROVED *by the* REGULATORY AUTHORITY*; and*

(7) *Documentation that corrective action is taken when Subparagraphs (D)(1) - (6) of this section are not followed*.

3-301.12 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.

Preventing Food and Ingredient Contamination

3-302.11 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 fruits and 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 ¶ 4-602.11(A) and SANITIZING as specified under § 4-703.11;

(4) Except as specified under Subparagraph 3-501.15(B)(2) and in ¶ (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 § 6-404.11; and

(8) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 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 3-501.15(B)(2); or*

(5) *SHELLSTOCK*.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Except for containers holding FOOD that can be readily and unmistakably recognized such as dry pasta, 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.

3-302.13 Pasteurized Eggs, Substitute for Raw Eggs for Certain Recipes.*

Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and EGG-fortified BEVERAGES that are not:

(A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2); or

(B) Included in ¶ 3-401.11(D).

3-302.14 Protection from Unapproved Additives.*

(A) FOOD shall be protected from contamination that may result from the addition of, as specified in § 3-202.12:

(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 B_1; or

(2) *Except for grapes,* serve or sell FOOD specified under Subparagraph (B)(1) of this section that is treated with sulfiting agents before receipt by the FOOD ESTABLISHMENT.

3-302.15 Washing Fruits and Vegetables.

(A) *Except as specified in ¶ (B) of this section and except for whole,* raw *fruits and vegetables that are intended for washing by the* CONSUMER *before consumption,* 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.

(B) *Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12.*

Preventing Contamination from Ice Used as a Coolant

3-303.11 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, PACKAGED FOODS such as canned BEVERAGES, or cooling coils and tubes of EQUIPMENT, ice may not be used as FOOD.

3-303.12 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 ¶¶ (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 poultry 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.*

Preventing Contamination from Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.*

FOOD shall only contact surfaces of:

(A) EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code; or

(B) SINGLE-SERVICE and SINGLE-USE ARTICLES.

3-304.12 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 ¶ (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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) 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 §§ 4-602.11 and 4-702.11;

(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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD); or

(F) In a container of water if the water is maintained at a temperature of at least 57°C (135°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

3-304.13 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*.

3-304.14 Wiping Cloths, Use Limitation.

(A) Cloths in-use for wiping FOOD spills from TABLEWARE and carry-out containers that occur as FOOD is being served shall be:

(1) Maintained dry; and

(2) Used for no other purpose.

(B) Cloths in-use for wiping counters and other EQUIPMENT surfaces shall be:

(1) Held between uses in a chemical sanitizer solution at a concentration specified under § 4-501.114; and

(2) Laundered daily as specified under ¶ 4-802.11(D).

(C) Cloths in-use for wiping surfaces in contact with raw animal FOODS shall be kept separate from cloths used for other purposes.

(D) Dry wiping cloths and the chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be free of FOOD debris and visible soil.

(E) Containers of chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES.

(F) SINGLE-USE disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer's label use instructions.

3-304.15 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 ¶ (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 Part 3-4 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 Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT*.

3-304.16 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 ¶ (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 ¶¶ 4-204.13(A), (B), and (D)*.

3-304.17 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD).

(B) Except as specified in ¶ (C), a take-home FOOD container refilled with FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be cleaned as specified under ¶ 4-603.17(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 ¶¶ 4-204.13(A), (B), and (D)*.

Preventing Contamination from the Premises

3-305.11 Food Storage.

(A) Except as specified in ¶¶ (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 § 4-204.122*.

(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*.

3-305.12 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 open stairwells; or

(I) Under other sources of contamination.

3-305.13 Vended Potentially Hazardous Food (Time/Temperature Control for Safety Food), Original Container.

POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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.

3-305.14 Food Preparation.

During preparation, unPACKAGED FOOD shall be protected from environmental sources of contamination.

Preventing Contamination by Consumers

3-306.11 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.

3-306.12 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.

3-306.13 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. *This paragraph does not apply to:*

(1) *CONSUMER self-service of READY-TO-EAT FOODS at buffets or salad bars that serve FOODS such as sushi or raw shellfish;*

(2) *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*

(3) *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.[N]

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures.[N]

3-306.14 Returned Food and Re-Service of Food.*

(A) Except as specified in ¶ (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 ¶ 3-801.11(G), *a container of FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) may be RE-SERVED 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*.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

FOOD shall be protected from contamination that may result from a factor or source not specified under Subparts 3-301 - 3-306.

3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

3-401 Cooking
3-402 Freezing
3-403 Reheating
3-404 Other Methods

Cooking

3-401.11 Raw Animal Foods.*

(A) Except as specified under ¶ (B) and in ¶¶ (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 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 (A)(3) and ¶ (B), and in ¶ (C) of this section, FISH and MEAT including GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(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 3-201.17(A)(1), and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(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, BALUTS, wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed RATITES, or stuffing containing FISH, MEAT, POULTRY, or RATITES.

(B) Whole MEAT roasts including beef, corned beef, lamb, pork, 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) or More
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity[1]	121°C (250°F) or less	121°C (250°F) or less

[1] 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[1] in Minutes**	**Temperature °C (°F)**	**Time[1] 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		
[1]*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 ¶ 3-201.11(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 ¶ (C) of this section, may be served or offered for sale upon CONSUMER request or selection in a READY-TO-EAT form if:*

(1) *As specified under ¶¶ 3-801.11(C)(1) and (2), the FOOD ESTABLISHMENT serves a population that is not a HIGHLY SUSCEPTIBLE POPULATION; and*

(2) *The* CONSUMER *is informed as specified under § 3-603.11 that to ensure its safety, the* FOOD *should be cooked as specified under ¶ (A) or (B) of this section; or*

(3) *The* REGULATORY AUTHORITY *grants a* VARIANCE *from ¶ (A) or (B) of this section as specified in § 8-103.10 based on a HACCP* PLAN *that:*

(a) *Is submitted by the* PERMIT HOLDER *and* APPROVED *as specified under § 8-103.11,*

(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*.*

3-401.12 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.

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 57°C (135°F).

Freezing

3-402.11 Parasite Destruction.*

(A) Except as specified in ¶ (B) of this section, before service or sale in READY-TO-EAT form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH shall be:

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

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

(3) Frozen at -35°C (-31°F) or below until solid and stored at -20°C (-4°F) or below for a minimum of 24 hours.

(B) *Paragraph (A) of this section does not apply to*:

(1) *MOLLUSCAN SHELLFISH*;

(2) *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); or*

(3) *Aquacultured FISH, such as salmon, that*:

(a) *If raised in open water, are raised in net-pens, or*

(b) *Are raised in land-based operations such as ponds or tanks, and*

(c) *Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured FISH*.

3-402.12 Records, Creation and Retention.

(A) Except as specified in ¶ 3-402.11(B) and ¶ (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 § 3-402.11 may substitute for the records specified under ¶ (A) of this section.*

(C) If raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in READY-TO-EAT form, and the FISH are raised and fed as specified in Subparagraph 3-402.11(B)(3), a written agreement or statement from the supplier or aquaculturist stipulating that the FISH were raised and fed as specified in Subparagraph 3-402.11(B)(3) shall be obtained by the PERSON IN CHARGE and retained in the records of the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH.

3-403.10 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.

Reheating

3-403.11 Reheating for Hot Holding.*

(A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 ¶ (C) of this section, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 57°C (135°F) for hot holding.

(D) Reheating for hot holding as specified under ¶¶ (A) - (C) of this section shall be done rapidly and the time the FOOD is between the temperature specified under Subparagraph 3-501.16(A)(2) and the temperatures specified under ¶¶ (A) - (C) of this section may not exceed 2 hours.

(E) *Remaining unsliced portions of MEAT roasts that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

Other Methods

3-404.11 Treating Juice.

JUICE PACKAGED in a FOOD ESTABLISHMENT shall be:

(A) Treated under a HACCP PLAN as specified in ¶¶ 8-201.12(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 § 3-602.11, and

(2) As specified in 21 CFR 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "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."

3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

3-501 Temperature and Time Control
3-502 Specialized Processing Methods

Temperature and Time Control

3-501.11 Frozen Food.

Stored frozen FOODS shall be maintained frozen.

3-501.12 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Slacking.

Frozen POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 Subparagraph 3-501.16(A)(2); or

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

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 Subparagraph 3-501.16(A)(2); 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 Subparagraph 3-501.16(A)(2), or

(4) For a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), or 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2), 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 Subparagraph 3-501.16(A)(2);

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

(1) Cooked as specified under ¶ 3-401.11(A) or (B) or § 3-401.12, 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.*

3-501.14 Cooling.*

(A) Cooked POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be cooled:

(1) Within 2 hours from 57ºC (135ºF) to 21ºC (70°F); and

(2) Within a total of 6 hours from 57ºC (135ºF) to 5ºC (41°F) or less, or to 7ºC (45°F) or less as specified under Subparagraph 3-501.16(A)(2)(b).

(B) POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be cooled within 4 hours to 5°C (41°F) or

less, or to 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2)(b) if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna.

(C) Except as specified under ¶ (D) of this section, a POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2)(b).

(D) Raw EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.

3-501.15 Cooling Methods.

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under § 3-501.14 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

3-305.11(A)(2), during the cooling period to facilitate heat transfer from the surface of the FOOD.

3-501.16 Potentially Hazardous Food (Time/Temperature Control for Safety 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 § 3-501.19,* and except as specified under ¶ (B) of this section, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be maintained:

(1) At 57°C (135°F) or above, *except that roasts cooked to a temperature and for a time specified in ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F) or above*; or

(2) At a temperature specified in the following:

(a) 5°C (41°F) or less; or

(b) 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) 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 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

(B) 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.

3-501.17 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.*

on-premises preparation
• prepare and hold cold

(A) Except when PACKAGING FOOD using a REDUCED OXYGEN PACKAGING method as specified under § 3-502.12, and except as specified in ¶¶ (D) and (E) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 below. The day of preparation shall be counted as Day 1.

(1) 5°C (41°F) or less for a maximum of 7 days; or

(2) 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) 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:

(a) The EQUIPMENT is in place and in use in the FOOD ESTABLISHMENT, and

(b) Within 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

commercially processed food
• open and hold cold

(B) Except as specified in ¶¶ (D) - (F) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 ¶ (A) of this section 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) ingredient or a portion of a refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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.

(D) *A date marking system that meets the criteria stated in ¶¶ (A) and (B) of this section may include*:

(1) *Using a method APPROVED by the REGULATORY AUTHORITY for refrigerated, READY-TO-EAT POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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;*

(2) *Marking the date or day of preparation, with a procedure to discard the FOOD or on before the last date or day by which the FOOD must be consumed on the premises, sold, or discarded as specified under ¶ (A) of this section;*

(3) *Marking the date or day the original container is opened in a FOOD ESTABLISHMENT, with a procedure to discard the FOOD on or before the last date or day by which the FOOD must be consumed on the premises, sold, or discarded as specified under ¶ (B) of this section; or*

(4) *Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the REGULATORY AUTHORITY upon request.*

(E) *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*.

(F) *Paragraph (B) of this section does not apply to the following FOODS prepared and PACKAGED by a FOOD PROCESSING PLANT inspected by a REGULATORY AUTHORITY*:

(1) *Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR 110 Current good manufacturing practice in manufacturing, packing, or holding human food;*

(2) *Hard cheeses containing not more than 39% moisture as defined in 21 CFR 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;*

(3) *Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;*

(4) *Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as yogurt, sour cream, and buttermilk;*

(5) *Preserved FISH products, such as pickled herring and dried or salted cod, and other acidified FISH products defined in 21 CFR 114 Acidified foods;*

(6) *Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami that are not labeled "Keep Refrigerated" as specified in 9 CFR 317 Labeling, marking devices, and containers, and which retain the original CASING on the product; and*

(7) *Shelf stable salt-cured products such as prosciutto and Parma (ham) that are not labeled "Keep Refrigerated" as specified in 9 CFR 317 Labeling, marking devices, and containers*.

3-501.18 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Disposition.*

(A) A FOOD specified in ¶ 3-501.17(A) or (B) shall be discarded if it:

(1) Exceeds either of the temperature and time combinations specified in ¶ 3-501.17(A), 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 ¶ 3-501.17(A).

(B) Refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 ¶ 3-501.17(A).

3-501.19 Time as a Public Health Control.*

(A) Except as specified under ¶ (D) of this section, if time only is used as the public health control for a working supply of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) before cooking, or for READY-TO-EAT POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) that is displayed or held for service for immediate consumption:

(1) Written procedures shall be prepared in advance, maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that specify:

(a) Methods of compliance with Subparagraphs (B)(1)-(3) or (C)(1)-(5) of this section; and

(b) Methods of compliance with § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control.

Time – maximum up to 4 hours

(B) If time only, rather than time in conjunction with temperature control, up to a maximum of 4 hours, is used as the public health control:

(1) The FOOD shall have an initial temperature of 5ºC (41ºF) or less if removed from cold holding temperature control, or 57°C (135°F) or greater if removed from hot holding temperature control;

(2) 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;

(3) 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; and

(4) The FOOD in unmarked containers or PACKAGES, or marked to exceed a 4-hour limit shall be discarded.

Time – maximum up to 6 hours

(C) If time only, rather than time in conjunction with temperature control, up to a maximum of 6 hours, is used as the public health control:

(1) The FOOD shall have an initial temperature of 5ºC (41ºF) or less when removed from temperature control and the FOOD temperature may not exceed 21ºC (70ºF) within a maximum time period of 6 hours;

(2) The FOOD shall be monitored to ensure the warmest portion of the FOOD does not exceed 21ºC (70ºF) during the 6-hour period, *unless an ambient air temperature is maintained that ensures the FOOD does not exceed 21ºC (70ºF) during the 6-hour holding period*;

(3) The FOOD shall be marked or otherwise identified to indicate:

(a) The time when the FOOD is removed from 5ºC (41ºF) or less cold holding temperature control, and

(b) The time that is 6 hours past the point in time when the FOOD is removed from cold holding temperature control;

(4) The FOOD shall be:

(a) Discarded if the temperature of the FOOD exceeds 21°C (70°F), or

(b) Cooked and served, served if READY-TO-EAT, or discarded within a maximum of 6 hours from the point in time when the FOOD is removed from 5ºC (41ºF) or less cold holding temperature control; and

(5) The FOOD in unmarked containers or PACKAGES, or marked with a time that exceeds the 6-hour limit shall be discarded.

(D) A FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION may not use time as specified under ¶¶ (A), (B) or (C)

of this section as the public health control for raw EGGS.

Specialized Processing Methods

3-502.11 Variance Requirement.*

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before:

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;

(B) Curing FOOD;

(C) Using FOOD ADDITIVES or adding components such as vinegar:

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, or

(2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD);

(D) Packaging FOOD using a REDUCED OXYGEN PACKAGING method *except as specified under § 3-502.12 where a barrier to* ***Clostridium botulinum*** *in addition to refrigeration exists*;

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

(F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT;

(G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; or

(H) Sprouting seeds or beans.

Clostridium botulinum and Listeria monocytogenes Controls

3-502.12 Reduced Oxygen Packaging, Criteria.*

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11 and except as specified under ¶¶ (C) and (E) and as specified in ¶ (D) of this section, a FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall ensure that there are at least two barriers in place to control the growth and toxin formation of ***Clostridium botulinum*** and the growth of ***Listeria monocytogenes***.

(B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:

(1) Identifies the FOOD to be PACKAGED;

(2) Except as specified under ¶¶ (C) and (E) and as specified in ¶ (D) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria:

(a) Has an A_W 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 USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, 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) Describes how the PACKAGE 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) 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;

(4) Limits the refrigerated shelf life to no more than 14 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(5) Includes operational procedures that:

(a) Prohibit contacting FOOD with bare hands,

(b) Identify a designated work 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

(6) 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)(5) of this section and ¶ 8-201.14(D).

Fish

(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.

Cook-Chill or Sous Vide

(D) Except as specified under ¶ (C) of this section, *a FOOD ESTABLISHMENT may package FOOD using a cook-chill or sous vide process without obtaining a VARIANCE if:*

(1) *The FOOD ESTABLISHMENT implements a HACCP PLAN that*

contains the information as specified under ¶ 8-201.14(D);

(2) *The* FOOD *is:*

(a) *Prepared and consumed on the* PREMISES*, or prepared and consumed off the* PREMISES *but within the same business entity with no distribution or sale of the bagged product to another business entity or the* CONSUMER*,*

(b) *Cooked to heat all parts of the* FOOD *to a temperature and for a time as specified under § 3-401.11,*

(c) *Protected from contamination after cooking as specified under Part 3-3,*

(d) *Placed in a package or bag with an oxygen barrier before cooking, or placed in a* PACKAGE *or bag immediately after cooking and before reaching a temperature below 57°C (135°F),*

(e) *Except for frozen* FOOD *that is not shelf life restricted, cooled to 5°C (41°F) in the* PACKAGE *or bag as specified under § 3-501.14 and then cooled to 1°C (34°F) or less within 48 hours of reaching 5°C (41°F), and:*

(i) *Held at 1°C (34°F) and consumed or discarded within 30 days after the date of preparation, or*

(ii) *If removed from a storage unit that maintains a 1°C (34°F)* FOOD *temperature, held at 5°C (41°F) or less for no more than 72 hours before consumption.*

(f) *Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,*

(g) *If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and*

(h) *Labeled with the product name and the date* PACKAGED; and

(3) *The records required to confirm that cooling and cold*

holding refrigeration time/temperature parameters are required as part of the HACCP PLAN*, are maintained and are:*

(a) *Made available to the* REGULATORY AUTHORITY *upon request, and*

(b) *Held for 6 months; and*

(4) *Written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section are implemented*.

Cheese

(E) *A* FOOD ESTABLISHMENT *may* PACKAGE *cheese using a* REDUCED OXYGEN PACKAGING *method without obtaining a* VARIANCE *if it*:

(1) Limits the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;

(2) Has a HACCP PLAN that contains the information specified under ¶ 8-201.14(D);

(3) Except as specified under Subparagraphs (B)(2), (B)(3)(b), and (B)(4), complies with ¶ (B) of this section;

(4) Labels the PACKAGE on the principal display panel with a “use by” date that does not exceed 30 days or the original manufacturer’s “sell by” or “use by” date, whichever occurs first; and

(5) Discards the REDUCED OXYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.

3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING

Subparts

3-601	**Accurate Representation**
3-602	**Labeling**
3-603	**Consumer Advisory**

Accurate Representation

3-601.11 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.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) 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.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) 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;

(3) An accurate declaration of the quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient (Effective January 1, 2006).

(6) 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.

(7) 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.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

(1) The manufacturer's or processor's label that was provided with the FOOD; or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

(1) *A health, nutrient content, or other claim is not made;*

(2) *There are no state or local LAWS requiring labeling; and*

(3) *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.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

Consumer Advisory

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.*

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(3) and under ¶ 3-801.11(D), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order);" or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request;

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.

3-7 CONTAMINATED FOOD

Subpart

3-701 Disposition

Disposition

3-701.11 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 discarded or reconditioned according to an APPROVED procedure.

(B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 - .17 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 § 2-201.12 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.

3-8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

Subpart

3-801 Additional Safeguards

Additional Safeguards

3-801.11 Pasteurized Foods, Prohibited Re-Service, 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, 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a PACKAGED JUICE or BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(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 under ¶¶ 8-201.14(B) - (E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls.

(B) Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of:

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, EGGnog, ice cream, and EGG-fortified BEVERAGES, and

(2) Except as specified in ¶ (F) of this section, recipes in which more than one EGG is broken and the EGGS are combined;

(C) 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 EGGS, and meringue; and

(3) Raw seed sprouts.

(D) FOOD EMPLOYEES may not contact READY-TO-EAT FOOD as specified under ¶¶ 3-301.11(B) and (D).

(E) Time only, as the public health control as specified under § 3-501.19(D), may not be used for raw EGGS.

(F) *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 3-401.11(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 3-401.11(A)(2),*

(d) *Contains the information specified under ¶ 8-201.14(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*.

Re-service of Food

(G) Except as specified in paragraph (H) of this section, FOOD may be re-served as specified under Subparagraph 3-306.14(B)(1) and (2).

Prohibited Re-service of Food

(H) *FOOD may not be re-served under the following conditions:*

(1) *Any* FOOD *served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside*.

(2) *Packages of* FOOD *from any patients, clients, or other* CONSUMERS *should not be re-served to* PERSONS *in protective environment isolation*.

Chapter

4 Equipment, Utensils, and Linens

Parts

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR
4-2 DESIGN AND CONSTRUCTION
4-3 NUMBERS AND CAPACITIES
4-4 LOCATION AND INSTALLATION
4-5 MAINTENANCE AND OPERATION
4-6 CLEANING OF EQUIPMENT AND UTENSILS
4-7 SANITIZATION OF EQUIPMENT AND UTENSILS
4-8 LAUNDERING
4-9 PROTECTION OF CLEAN ITEMS

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

4-101 Multiuse
4-102 Single-Service and Single-Use

Multiuse

4-101.11 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:

(A) Safe;

(B) Durable, CORROSION-RESISTANT, and nonabsorbent;[N]

(C) Sufficient in weight and thickness to withstand repeated WAREWASHING;[N]

(D) Finished to have a SMOOTH, EASILY CLEANABLE surface;[N] and

(E) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.[N]

4-101.12 Cast Iron, Use Limitation.

(A) Except as specified in ¶¶ (B) and (C) of this section, cast iron may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.

(B) *Cast iron may be used as a surface for cooking.*

(C) *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.*

4-101.13 Lead, Use Limitation.

(A) Ceramic, china, and 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	Ceramic Article Description	Maximum Lead MG/L
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls ≥ 1.1 Liter (1.16 Quart)	1
Small Hollowware (excluding cups & mugs)	Bowls < 1.1 Liter (1.16 Quart)	2.0
Flat TABLEWARE	Plates, Saucers	3.0

(B) Pewter alloys containing lead in excess of 0.05% may not be used as a FOOD-CONTACT SURFACE.

(C) Solder and flux containing lead in excess of 0.2% may not be used as a FOOD-CONTACT SURFACE.

4-101.14 Copper, Use Limitation.*

(A) Except as specified in ¶ (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.

(B) *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.*

4-101.15 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.

4-101.16 Sponges, Use Limitation.

Sponges may not be used in contact with cleaned and SANITIZED or in-use FOOD-CONTACT SURFACES.

4-101.17 Wood, Use Limitation.

(A) Except as specified in ¶¶ (B), (C), and (D) of this section, wood and wood wicker may not be used as a FOOD-CONTACT SURFACE.

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

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

(2) *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:*

(1) *Untreated wood containers; or*

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

4-101.18 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.

4-101.19 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.

Single-Service and Single-Use

4-102.11 Characteristics.*

Materials that are used to make SINGLE-SERVICE and SINGLE-USE ARTICLES:

(A) May not:

(1) Allow the migration of deleterious substances, or

(2) Impart colors, odors, or tastes to FOOD;[N] and

(B) Shall be:

(1) Safe, and

(2) Clean.[N]

4-2	**DESIGN AND CONSTRUCTION**	
	Subparts	
	4-201	**Durability and Strength**
	4-202	**Cleanability**
	4-203	**Accuracy**
	4-204	**Functionality**
	4-205	**Acceptability**

Durability and Strength

4-201.11 Equipment and Utensils.

EQUIPMENT and UTENSILS shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

4-201.12 Food Temperature Measuring Devices.*

FOOD TEMPERATURE MEASURING DEVICES 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*.

Cleanability

4-202.11 Food-Contact Surfaces.*

(A) Multiuse FOOD-CONTACT SURFACES shall be:

(1) SMOOTH;

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

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

(4) Finished to have SMOOTH welds and joints; and

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

(a) Without being disassembled,

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

(c) 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.

(B) *Subparagraph (A)(5) of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or* BEVERAGE *syrup lines or tubes*.

4-202.12 CIP Equipment.

(A) CIP EQUIPMENT shall meet the characteristics specified under § 4-202.11 and shall be designed and constructed so that:

(1) Cleaning and SANITIZING solutions circulate throughout a fixed system and contact all interior FOOD-CONTACT SURFACES, and

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

(B) 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.

4-202.13 "V" Threads, Use Limitation.

Except for hot oil cooking or filtering EQUIPMENT, "V" type threads may not be used on FOOD-CONTACT SURFACES.

4-202.14 Hot Oil Filtering Equipment.

Hot oil filtering EQUIPMENT shall meet the characteristics specified under § 4-202.11 or § 4-202.12 and shall be readily accessible for filter replacement and cleaning of the filter.

4-202.15 Can Openers.

Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

4-202.16 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.

4-202.17 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 4-202.11(A)(5) or capable of being rotated open; and

(B) Removable or capable of being rotated open without unlocking EQUIPMENT doors.

4-202.18 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.

Accuracy

4-203.11 Temperature Measuring Devices, Food.

(A) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to $\pm 1^{o}$C in the intended range of use.

(B) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to ±2°F in the intended range of use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

(A) Ambient air and water TEMPERATURE MEASURING DEVICES 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 DEVICES that are scaled only in Fahrenheit shall be accurate to ±3°F in the intended range of use.

4-203.13 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.

Functionality

4-204.11 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.

4-204.12 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 ¶ (D) of this section, fixed piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending into EQUIPMENT shall be provided with a watertight joint at the point where the item enters the EQUIPMENT.

(D) If a watertight joint is not provided:

(1) The piping, TEMPERATURE MEASURING DEVICES, 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 ¶ (B) of this section.

4-204.13 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.

4-204.14 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) 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.

4-204.15 Bearings and Gear Boxes, Leakproof.

EQUIPMENT containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant cannot leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

4-204.16 Beverage Tubing, Separation.

Except for cold plates that are constructed integrally with an ice storage bin, BEVERAGE tubing and cold-plate BEVERAGE cooling devices may not be installed in contact with stored ice.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines may not pass through an ice machine or ice storage bin.

4-204.18 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.

4-204.19 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.

4-204.110 Molluscan Shellfish Tanks.

(A) Except as specified under ¶ (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 § 8-103.10 and a HACCP PLAN that:

(1) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11; and

(2) Ensures that:

(a) Water used with FISH other than MOLLUSCAN SHELLFISH does not flow into the molluscan tank,

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

(c) The identity of the source of the SHELLSTOCK is retained as specified under § 3-203.12.

4-204.111 Vending Machines, Automatic Shutoff.*

(A) A machine vending POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 cannot 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) is activated:

(1) In a refrigerated VENDING MACHINE, the ambient temperature may not exceed any time/temperature combination as specified under Subparagraph 3-501.16(A)(2) 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 57°C (135°F) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.

4-204.112 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 ¶ (C) of this section, cold or hot holding EQUIPMENT used for POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be designed to include and shall be equipped with at least one integral or permanently affixed 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 DEVICES and water TEMPERATURE MEASURING DEVICES 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.

4-204.113 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 operation 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.

4-204.114 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.

4-204.115 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.

4-204.116 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.

4-204.117 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 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.

4-204.118 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.*

4-204.119 Warewashing Sinks and Drainboards, Self-Draining.

Sinks and drainboards of WAREWASHING sinks and machines shall be self-draining.

4-204.120 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.

4-204.121 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.

4-204.122 Case Lot Handling Apparatuses, Moveability.

Apparatuses, 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 apparatuses such as hand trucks and forklifts.

4-204.123 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.

Acceptability **4-205.10 Food Equipment, Certification and Classification.**

FOOD EQUIPMENT that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.

4-3 NUMBERS AND CAPACITIES

Subparts

4-301 Equipment
4-302 Utensils, Temperature Measuring Devices, and Testing Devices

Equipment **4-301.11 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.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

(A) Except as specified in ¶ (C) of this section, a sink with at least 3 compartments shall be provided 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 ¶ (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:*

(1) *High-pressure detergent sprayers;*

(2) *Low- or line-pressure spray detergent foamers;*

(3) *Other task-specific cleaning* EQUIPMENT*;*

(4) *Brushes or other implements;*

(5) *2-compartment sinks as specified under ¶¶ (D) and (E) of this section; or*

(6) *Receptacles that substitute for the compartments of a multicompartment sink.*

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

(1) The PERMIT HOLDER shall have its use APPROVED; and

(2) 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:

(a) Make up the cleaning and SANITIZING solutions immediately before use and drain them immediately after use, and

(b) Use a detergent-SANITIZER to SANITIZE and apply the detergent-SANITIZER in accordance with the manufacturer's label instructions and as specified under § 4-501.115, or

(c) Use a hot water SANITIZATION immersion step as specified under ¶ 4-603.16(C).

(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.

4-301.13 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.

4-301.14 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.

4-301.15 Clothes Washers and Dryers.

(A) Except as specified in ¶ (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 § 4-901.12, a mechanical clothes washer and dryer need not be provided.*

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 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.

4-302.12 Food Temperature Measuring Devices.

(A) FOOD TEMPERATURE MEASURING DEVICES 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.

4-302.13 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.

4-302.14 Sanitizing Solutions, Testing Devices.

A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided.

4-4 LOCATION AND INSTALLATION

Subparts

4-401 Location
4-402 Installation

Location

4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

(A) Except as specified in ¶ (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 open stairwells; or

(8) Under other sources of contamination.

(B) *A storage cabinet used for* LINENS *or* SINGLE-SERVICE *or* SINGLE-USE ARTICLES *may be stored in a locker room.*

(C) 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.

Installation

4-402.11 Fixed Equipment, Spacing or Sealing.

(A) EQUIPMENT that is fixed because it is not EASILY MOVABLE shall be installed so that it is:

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

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

(3) SEALED to adjoining EQUIPMENT or walls, if the EQUIPMENT is exposed to spillage or seepage.

(B) COUNTER-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:

(1) SEALED; or

(2) Elevated on legs as specified under ¶ 4-402.12(D).

4-402.12 Fixed Equipment, Elevation or Sealing.

(A) Except as specified in ¶¶ (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 ¶ (E) of this section, COUNTER-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be elevated on legs that provide at least a 10 centimeter (4 inch) clearance between the table and the EQUIPMENT.

(E) *The clearance space between the table and COUNTER-MOUNTED EQUIPMENT may be*:

(1) *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*

(2) *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*

4-5 MAINTENANCE AND OPERATION

Subparts

4-501 Equipment
4-502 Utensils and Temperature and Pressure Measuring Devices

Equipment

4-501.11 Good Repair and Proper Adjustment.

(A) EQUIPMENT shall be maintained in a state of repair and condition that meets the requirements specified under Parts 4-1 and 4-2.

(B) EQUIPMENT components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's 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.

4-501.12 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.

4-501.13 Microwave Ovens.

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 Microwave ovens.

4-501.14 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 § 4-301.13 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.

4-501.15 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.

4-501.16 Warewashing Sinks, Use Limitation.

(A) A WAREWASHING sink may not be used for handwashing as specified under § 2-301.15.

(B) If a WAREWASHING sink is used to wash wiping cloths, wash produce, or thaw FOOD, the sink shall be cleaned as specified under § 4-501.14 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 4-7 before and after using the sink to wash produce or thaw FOOD.

4-501.17 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 ¶ 4-301.12(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.

4-501.18 Warewashing Equipment, Clean Solutions.

The wash, rinse, and SANITIZE solutions shall be maintained clean.

4-501.19 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.

4-501.110 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, multitemperature 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).

4-501.111 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.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(A) Except as specified in ¶ (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:

(1) For a stationary rack, single temperature machine, 74°C (165°F); or

(2) For all other machines, 82°C (180°F).

(B) *The maximum temperature specified under ¶ (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.*

4-501.113 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.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.*

A chemical SANITIZER used in a SANITZING solution for a manual or mechanical operation at exposure times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 Sanitizers, Criteria, 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	
MG/L	PH 10 or less ^{o}C (^{o}F)	PH 8 or less ^{o}C (^{o}F)
25	49 (120)	49 (120)
50	38 (100)	24 (75)
100	13 (55)	13 (55)

(B) An iodine solution shall have a:

(1) Minimum temperature of 24°C (75°F),

(2) PH of 5.0 or less or a PH no higher than the level for which the manufacturer specifies the solution is effective, and

(3) Concentration between 12.5 MG/L and 25 MG/L;

(C) A quaternary ammonium compound solution shall:

(1) Have a minimum temperature of 24°C (75°F),

(2) Have a concentration as specified under § 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and

(3) 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 ¶¶ (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.

4-501.115 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.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device.

Utensils and Temperature and Pressure Measuring Devices

4-502.11 Good Repair and Calibration.

(A) UTENSILS shall be maintained in a state of repair or condition that complies with the requirements specified under Parts 4-1 and 4-2 or shall be discarded.

(B) FOOD TEMPERATURE MEASURING DEVICES 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 DEVICES shall be maintained in good repair and be accurate within the intended range of use.

4-502.12 Single-Service and Single-Use Articles, Required Use.*

A FOOD ESTABLISHMENT without facilities specified under Parts 4-6 and 4-7 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.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES may not be reused.

(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.

4-502.14 Shells, Use Limitation.

Mollusk and crustacea shells may not be used more than once as serving containers.

4-6 CLEANING OF EQUIPMENT AND UTENSILS

Subparts

4-601 Objective
4-602 Frequency
4-603 Methods

Objective

4-601.11 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.[N]

(C) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be kept free of an accumulation of dust, dirt, FOOD residue, and other debris.[N]

Frequency

4-602.11 Equipment Food-Contact Surfaces and Utensils.*

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned:

(1) Except as specified in ¶ (B) of this section, before each use with a different type of raw animal FOOD such as beef, FISH, lamb, pork, or POULTRY;

(2) Each time there is a change from working with raw FOODS to working with READY-TO-EAT FOODS;

(3) Between uses with raw fruits and vegetables and with POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD);

(4) Before using or storing a FOOD TEMPERATURE MEASURING DEVICE; and

(5) 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 § 3-401.11 than the previous FOOD, such as preparing raw FISH followed by cutting raw poultry on the same cutting board*.

(C) Except as specified in ¶ (D) of this section, if used with POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) *may be cleaned less frequently than every 4 hours if:*

(1) *In storage, containers of* POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) *and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;*

(2) *U*TENSILS *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:*

(a) *The* UTENSILS *and* EQUIPMENT *are cleaned at the frequency in the following chart that corresponds to the temperature; and*

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

(b) *The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the* FOOD ESTABLISHMENT.

(3) *Containers in serving situations such as salad bars, delis, and cafeteria lines hold* READY-TO-EAT POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY 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;*

(4) *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;*

(5) *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;*

(6) *The cleaning schedule is APPROVED based on consideration of:*

(a) *Characteristics of the EQUIPMENT and its use,*

(b) *The type of FOOD involved,*

(c) *The amount of FOOD residue accumulation, and*

(d) *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*

(7) In-use UTENSILS are intermittently stored in a container of water in which the water is maintained at 57°C (135°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 § 4-603.11*, surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be cleaned:[N]

(1) At any time when contamination may have occurred;

(2) At least every 24 hours for iced tea dispensers and CONSUMER self-service UTENSILS such as tongs, scoops, or ladles;

(3) Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers and display containers; and

(4) 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:

(a) At a frequency specified by the manufacturer, or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

4-602.12 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 4-602.11(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.

4-602.13 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

Methods

4-603.11 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD).

(B) Cleaning EQUIPMENT used in dry cleaning FOOD-CONTACT SURFACES may not be used for any other purpose.

4-603.12 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.

4-603.13 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.

4-603.14 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.

4-603.15 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 ¶ 4-301.12(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 ¶ 4-603.14(A).

4-603.16 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-santizer solution by using one of the following procedures:

(A) Use of a distinct, separate water rinse after washing and before SANITIZING if using:

(1) A 3-compartment sink,

(2) Alternative manual WAREWASHING EQUIPMENT equivalent to a 3-compartment sink as specified in ¶ 4-301.12(C), or

(3) A 3-step washing, rinsing, and SANITIZING procedure in a WAREWASHING system for CIP EQUIPMENT;

(B) Use of a detergent-SANITIZER as specified under § 4-501.115 if using:

(1) Alternative WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) that is APPROVED for use with a detergent-SANITIZER, or

(2) 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;

(D) If using a WAREWASHING machine that does not recycle the SANITIZING solution as specified under ¶ (E) of this section, or alternative manual WAREWASHING EQUIPMENT such as sprayers, use of a nondistinct water rinse that is:

(1) Integrated in the application of the SANITIZING solution, and

(2) 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.

4-603.17 Returnables, Cleaning for Refilling.*

(A) Except as specified in ¶¶ (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:*

(1) *Only a BEVERAGE that is not a POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) is used as specified under ¶ 3-304.17(A);*

(2) *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;*

(3) *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;*

(4) *The CONSUMER-owned container returned to the FOOD ESTABLISHMENT for refilling is refilled for sale or service only to the same CONSUMER; and*

(5) *The container is refilled by:*

(a) *An EMPLOYEE of the FOOD ESTABLISHMENT, or*

(b) *The owner of the container if the* BEVERAGE *system includes a contamination-free transfer process that cannot 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.*

4-7	**SANITIZATION OF EQUIPMENT AND UTENSILS**	
	Subparts	
	4-701	**Objective**
	4-702	**Frequency**
	4-703	**Methods**

Objective **4-701.10 Food-Contact Surfaces and Utensils.**

EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED.

Frequency **4-702.11 Before Use After Cleaning.***

UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT shall be SANITIZED before use after cleaning.

Methods **4-703.11 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 § 4-501.111;

(B) Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 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 § 4-501.114 by providing:

(1) Except as specified under Subparagraph (C)(2) of this section, an exposure time of at least 10 seconds for a chlorine solution specified under ¶ 4-501.114(A),

(2) 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°C (100°F) or a PH of 8 or less and a temperature of at least 24°C (75°F),

(3) An exposure time of at least 30 seconds for other chemical SANITIZING solutions, or

(4) 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 1-201.10(B).

4-8 LAUNDERING

Subparts

4-801 Objective
4-802 Frequency
4-803 Methods

Objective **4-801.11 Clean Linens.**

Clean LINENS shall be free from FOOD residues and other soiling matter.

Frequency **4-802.11 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 ¶ 3-304.15(D) shall be laundered before being used with a different type of raw animal FOOD such as beef, FISH, lamb, pork or POULTRY.

(C) LINENS and napkins that are used as specified under § 3-304.13 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.

Methods

4-803.11 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.

4-803.12 Mechanical Washing.

(A) Except as specified in ¶ (B) of this section, LINENS shall be mechanically washed.

(B) *In FOOD ESTABLISHMENTS in which only wiping cloths are laundered as specified in ¶ 4-301.15(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 § 4-501.14.*

4-803.13 Use of Laundry Facilities.

(A) Except as specified in ¶ (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.

(B) *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.*

4-9 PROTECTION OF CLEAN ITEMS

Subparts

4-901	**Drying**
4-902	**Lubricating and Reassembling**
4-903	**Storing**
4-904	**Preventing Contamination**

Drying

4-901.11 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 the first paragraph of 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface 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*.

4-901.12 Wiping Cloths, Air-Drying Locations.

Wiping cloths laundered in a FOOD ESTABLISHMENT that does not have a mechanical clothes dryer as specified in ¶ 4-301.15(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 § 4-501.114.*

Lubricating and Reassembling

4-902.11 Food-Contact Surfaces.

Lubricants as specified under § 7-205.11 shall be applied to FOOD-CONTACT SURFACES that require lubrication in a manner that does not contaminate FOOD-CONTACT SURFACES.

4-902.12 Equipment.

EQUIPMENT shall be reassembled so that FOOD-CONTACT SURFACES are not contaminated.

Storing

4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

(A) Except as specified in ¶ (D) of this section, cleaned EQUIPMENT and UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored:

(1) In a clean, dry location;

(2) Where they are not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) Clean EQUIPMENT and UTENSILS shall be stored as specified under ¶ (A) of this section and shall be stored:

(1) In a self-draining position that allows air drying; and

(2) Covered or inverted.

(C) SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored as specified under ¶ (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 § 4-204.122.*

4-903.12 Prohibitions.

(A) Except as specified in ¶ (B) of this section, cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be stored:

(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 open stairwells; or

(8) 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.*

Preventing Contamination

4-904.11 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 ¶ (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.

4-904.12 Soiled and Clean Tableware.

Soiled TABLEWARE shall be removed from CONSUMER eating and drinking areas and handled so that clean TABLEWARE is not contaminated.

4-904.13 Preset Tableware.

(A) TABLEWARE that is preset shall be protected from contamination by being wrapped, covered, or inverted.

(B) When TABLEWARE is preset, exposed, unused settings shall be:

(1) Removed when a CONSUMER is seated; or

(2) Cleaned and SANITIZED before further use if the settings are not removed when a CONSUMER is seated.

Chapter

5 Water, Plumbing, and Waste

Parts

5-1 WATER
5-2 PLUMBING SYSTEM
5-3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT WATER TANK
5-4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER
5-5 REFUSE, RECYCLABLES, AND RETURNABLES

5-1 WATER

Subparts

5-101 Source
5-102 Quality
5-103 Quantity and Availability
5-104 Distribution, Delivery, and Retention

Source **5-101.11 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.

5-101.12 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.

5-101.13 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.

Quality

5-102.11 Standards.*

Except as specified under § 5-102.12:

(A) Water from a PUBLIC WATER SYSTEM shall meet 40 CFR 141 - National Primary Drinking Water Regulations and state DRINKING WATER quality standards; and

(B) Water from a nonPUBLIC WATER SYSTEM shall meet state DRINKING WATER quality standards.

5-102.12 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.

5-102.13 Sampling.

Except when used as specified under § 5-102.12, water from a nonPUBLIC WATER SYSTEM shall be sampled and tested at least annually and as required by state water quality regulations.

5-102.14 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 state water quality regulations.

Quantity and Availability

5-103.11 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.

5-103.12 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 ¶¶ 5-104.12(A) and (B) to a TEMPORARY FOOD ESTABLISHMENT or in response to a temporary interruption of a water supply need not be under pressure*.

Distribution, Delivery, and Retention

5-104.11 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:

(1) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances,

(2) Water transport vehicles, or

(3) Water containers.

5-104.12 Alternative Water Supply.

Water meeting the requirements specified under Subparts 5-101, 5-102, and 5-103 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.

5-2 PLUMBING SYSTEM

Subparts

5-201 Materials
5-202 Design, Construction, and Installation
5-203 Numbers and Capacities
5-204 Location and Placement
5-205 Operation and Maintenance

Materials

5-201.11 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.

Design, Construction, and Installation

5-202.11 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 SINK, toilet, or urinal shall be EASILY CLEANABLE.[N]

5-202.12 Handwashing Sink, Installation.

(A) A HANDWASHING SINK 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 SINK.

(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.

5-202.13 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).

5-202.14 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.

5-202.15 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.

Numbers and Capacities

5-203.11 Handwashing Sinks.*

(A) Except as specified in ¶¶ (B) and (C) of this section, at least 1 HANDWASHING SINK, a number of HANDWASHING SINKS necessary for their convenient use by EMPLOYEES in areas specified under § 5-204.11, and not fewer than the number of HANDWASHING SINKS 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 SINKS in a FOOD ESTABLISHMENT that has at least one HANDWASHING SINK.*

(C) *If APPROVED, when FOOD exposure is limited and HANDWASHING SINKS 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.*

5-203.12 Toilets and Urinals.*

At least 1 toilet and not fewer than the toilets required by LAW shall be provided. If authorized by LAW and urinals are substituted for toilets, the substitution shall be done as specified in LAW.

5-203.13 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.

5-203.14 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 § 5-202.13; or

(B) Installing an APPROVED backflow prevention device as specified under § 5-202.14.

5-203.15 Backflow Prevention Device, Carbonator.*

(A) If not provided with an air gap as specified under § 5-202.13, a double check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 25.4 mm (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 ¶ (A) of this section.*

Location and Placement

5-204.11 Handwashing Sinks.*

A HANDWASHING SINK shall be located:

(A) To allow convenient use by EMPLOYEES in FOOD preparation, FOOD dispensing, and WAREWASHING areas; and

(B) In, or immediately adjacent to, toilet rooms.

5-204.12 Backflow Prevention Device, Location.

A backflow prevention device shall be located so that it may be serviced and maintained.

5-204.13 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.

Operation and Maintenance

5-205.11 Using a Handwashing Sink.

(A) A HANDWASHING SINK shall be maintained so that it is accessible at all times for EMPLOYEE use.

(B) A HANDWASHING SINK may not be used for purposes other than handwashing.

(C) An automatic handwashing facility shall be used in accordance with manufacturer's instructions.

5-205.12 Prohibiting a Cross Connection.*

(A) 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.[N]

5-205.13 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.

5-205.14 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:

(1) Maintained in accordance with manufacturer's specifications; and

(2) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under ¶ (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:

(1) Draining and complete disassembly of the water and aerosol contact parts;

(2) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;

(3) Flushing the complete system with water to remove the detergent solution and particulate accumulation; and

(4) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 MG/L hypochlorite solution.

5-205.15 System Maintained in Good Repair.*

A PLUMBING SYSTEM shall be:

(A) Repaired according to LAW; and

(B) Maintained in good repair.[s]

5-3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT WATER TANK

Subparts

5-301 Materials
5-302 Design and Construction
5-303 Numbers and Capacities
5-304 Operation and Maintenance

Materials

5-301.11 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.

Design and Construction

5-302.11 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.

5-302.12 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.

5-302.13 "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.

5-302.14 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.

5-302.15 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.

5-302.16 Hose, Construction and Identification.

A hose used for conveying DRINKING WATER from a water tank shall be:

(A) Safe;

(B) Durable, CORROSION-RESISTANT, and nonaborbent;

(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.

Numbers and Capacities

5-303.11 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.

5-303.12 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.

5-303.13 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.

Operation and Maintenance

5-304.11 System Flushing and Sanitization.*

A water tank, pump, and hoses shall be flushed and SANITIZED before being placed in service after construction, repair, modification, and periods of nonuse.

5-304.12 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.

5-304.13 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 § 5-303.12.

5-304.14 Tank, Pump, and Hoses, Dedication.

(A) Except as specified in ¶ (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.*

5-4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER

Subparts

5-401 Mobile Holding Tank
5-402 Retention, Drainage, and Delivery
5-403 Disposal Facility

Mobile Holding Tank

5-401.11 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.

Retention, Drainage, and Delivery

design, construction, and installation

5-402.10 Establishment Drainage System.

FOOD ESTABLISHMENT drainage systems, including grease traps, that convey SEWAGE shall be designed and installed as specified under ¶ 5-202.11(A).

5-402.11 Backflow Prevention.*

(A) Except as specified in ¶¶ (B), (C), and (D) 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.

(B) *Paragraph (A) of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building*.

(C) *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.*

(D) *If allowed by LAW, a WAREWASHING or culinary sink may have a direct connection*.

location and placement

5-402.12 Grease Trap.

If used, a grease trap shall be located to be easily accessible for cleaning.

operation and maintenance

5-402.13 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.

5-402.14 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.

5-402.15 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.

Disposal Facility

design and construction

5-403.11 Approved Sewage Disposal System.*

SEWAGE shall be disposed through an APPROVED facility that is:

(A) A public SEWAGE treatment plant; or

(B) An individual SEWAGE disposal system that is sized, constructed, maintained, and operated according to LAW.

5-403.12 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.

5-5 REFUSE, RECYCLABLES, AND RETURNABLES

Subparts

5-501 Facilities on the Premises
5-502 Removal
5-503 Facilities for Disposal and Recycling

Facilities on the Premises
materials, design, construction, and installation

5-501.10 Indoor Storage Area.

If located within the FOOD ESTABLISHMENT, a storage area for REFUSE, recyclables, and returnables shall meet the requirements specified under §§ 6-101.11, 6-201.11 - 6-201.18, 6-202.15, and 6-202.16.

5-501.11 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.

5-501.12 Outdoor Enclosure.

If used, an outdoor enclosure for REFUSE, recyclables, and returnables shall be constructed of durable and cleanable materials.

5-501.13 Receptacles.

(A) Except as specified in ¶ (B) 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.

(B) *Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the FOOD ESTABLISHMENT, or within closed outside receptacles.*

5-501.14 Receptacles in Vending Machines.

Except for a receptacle for BEVERAGE *bottle crown closures,* a REFUSE receptacle may not be located within a VENDING MACHINE.

5-501.15 Outside Receptacles.

(A) 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.

(B) 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.

numbers and capacities

5-501.16 Storage Areas, Rooms, and Receptacles, Capacity and Availability.

(A) 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.

(B) 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.

(C) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

5-501.17 Toilet Room Receptacle, Covered.

A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

5-501.18 Cleaning Implements and Supplies.

(A) Except as specified in ¶ (B) 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.

(B) *If APPROVED, off-PREMISES-based cleaning services may be used if on-PREMISES cleaning implements and supplies are not provided.*

location and placement

5-501.19 Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.

(A) An area designated for REFUSE, recyclables, returnables, and, except as specified in ¶ (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.

(B) *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.*

(C) 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.

operation and maintenance

5-501.110 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.

5-501.111 Areas, Enclosures, and Receptacles, Good Repair.

Storage areas, enclosures, and receptacles for REFUSE, recyclables, and returnables shall be maintained in good repair.

5-501.112 Outside Storage Prohibitions.

(A) Except as specified in ¶ (B) of this section, REFUSE receptacles not meeting the requirements specified under ¶ 5-501.13(A) 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.

(B) *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.*

5-501.113 Covering Receptacles.

Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be kept covered:

(A) Inside the FOOD ESTABLISHMENT if the receptacles and units:

(1) Contain FOOD residue and are not in continuous use; or

(2) After they are filled; and

(B) With tight-fitting lids or doors if kept outside the FOOD ESTABLISHMENT.

5-501.114 Using Drain Plugs.

Drains in receptacles and waste handling units for REFUSE, recyclables, and returnables shall have drain plugs in place.

5-501.115 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 § 6-501.114, and clean.

5-501.116 Cleaning Receptacles.

(A) 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 § 5-402.13.

(B) 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.

Removal

5-502.11 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.

5-502.12 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.

Facilities for Disposal and Recycling

5-503.11 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

6 Physical Facilities

Parts

6-1 MATERIALS FOR CONSTRUCTION AND REPAIR
6-2 DESIGN, CONSTRUCTION, AND INSTALLATION
6-3 NUMBERS AND CAPACITIES
6-4 LOCATION AND PLACEMENT
6-5 MAINTENANCE AND OPERATION

6-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

6-101 Indoor Areas
6-102 Outdoor Areas

Indoor Areas

6-101.11 Surface Characteristics.

(A) Except as specified in ¶ (B) of this section, materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

(1) SMOOTH, durable, and EASILY CLEANABLE for areas where FOOD ESTABLISHMENT operations are conducted;

(2) Closely woven and EASILY CLEANABLE carpet for carpeted areas; and

(3) 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:*

(1) *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 APPROVED materials that are effectively treated to control dust and mud; and*

(2) *Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.*

Outdoor Areas

6-102.11 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 §§ 5-501.11 and 5-501.12.

6-2 DESIGN, CONSTRUCTION, AND INSTALLATION

Subparts

6-201 Cleanability
6-202 Functionality

Cleanability

6-201.11 Floors, Walls, and Ceilings.

Except as specified under § 6-201.14 and *except for antislip floor coverings or applications that may be used for safety reasons,* floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are SMOOTH and EASILY CLEANABLE.

6-201.12 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.

6-201.13 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 coved and SEALED.

6-201.14 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 ¶ (A) of this section, it shall be:

(1) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(2) 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.

6-201.15 Floor Covering, Mats and Duckboards.

Mats and duckboards shall be designed to be removable and EASILY CLEANABLE.

6-201.16 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.

6-201.17 Walls and Ceilings, Attachments.

(A) Except as specified in ¶ (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.*

6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Except for TEMPORARY FOOD ESTABLISHMENTS, studs, joists, and rafters may not be exposed in areas subject to moisture.

Functionality

6-202.11 Light Bulbs, Protective Shielding.

(A) Except as specified in ¶ (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*:

(1) *The integrity of the packages cannot be affected by broken glass falling onto them; and*

(2) *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.

6-202.12 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.

6-202.13 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:

(1) The devices are not located over a FOOD preparation area; and

(2) 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.

6-202.14 Toilet Rooms, Enclosed.

Except where a toilet room 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, a toilet room located on the PREMISES shall be completely enclosed and provided with a tight-fitting and self-closing door.

6-202.15 Outer Openings, Protected.

(A) Except as specified in ¶¶ (B), (C), and (E) and under ¶ (D) of this section, outer openings of a FOOD ESTABLISHMENT shall be protected against the entry of insects and rodents by:

(1) Filling or closing holes and other gaps along floors, walls, and ceilings;

(2) Closed, tight-fitting windows; and

(3) 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:*

(1*) Solid and tight-fitting;*

(2) *Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the* FOOD ESTABLISHMENT*; and*

(3) *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 ¶¶ (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 ¶ (A) of this section, the openings shall be protected against the entry of insects and rodents by:

(1) 16 mesh to 25.4 mm (16 mesh to 1 inch) screens;

(2) Properly designed and installed air curtains to control flying insects; or

(3) 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.*

6-202.16 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.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

Except for machines that vend canned BEVERAGES, if located outside, a machine used to vend FOOD shall be provided with overhead protection.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Except for 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, SERVICING AREAS shall be provided with overhead protection.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

Exterior walking and driving surfaces shall be graded to drain.

6-202.110 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.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibition.

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting FOOD ESTABLISHMENT operations.

6-202.112 Living or Sleeping Quarters, Separation.

Living or sleeping quarters located on the PREMISES of a FOOD ESTABLISHMENT such as 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.

6-3 NUMBERS AND CAPACITIES

Subparts

6-301 Handwashing Sinks
6-302 Toilets and Urinals
6-303 Lighting
6-304 Ventilation
6-305 Dressing Areas and Lockers
6-306 Service Sinks

Handwashing Sinks

6-301.10 Minimum Number.

HANDWASHING SINKS shall be provided as specified under § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Each HANDWASHING SINK or group of 2 adjacent HANDWASHING SINKS shall be provided with a supply of hand cleaning liquid, powder, or bar soap.

6-301.12 Hand Drying Provision.

Each HANDWASHING SINK or group of adjacent HANDWASHING SINKS 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.

6-301.13 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 SINK as specified under §§ 6-301.11 and 6-301.12 and ¶ 5-501.16(C).

6-301.14 Handwashing Signage.

A sign or poster that notifies FOOD EMPLOYEES to wash their hands shall be provided at all HANDWASHING SINKS used by FOOD EMPLOYEES and shall be clearly visible to FOOD EMPLOYEES.

6-301.20 Disposable Towels, Waste Receptacle.

A HANDWASHING SINK or group of adjacent HANDWASHING SINKS that is provided with disposable towels shall be provided with a waste receptacle as specified under ¶ 5-501.16(C).

Toilets and Urinals

6-302.10 Minimum Number.

Toilets and urinals shall be provided as specified under § 5-203.12.

6-302.11 Toilet Tissue, Availability.

A supply of toilet tissue shall be available at each toilet.

Lighting

6-303.11 Intensity.

The light intensity shall be:

(A) At least 108 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;

(B) At least 215 lux (20 foot candles):

(1) 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,

(2) Inside EQUIPMENT such as reach-in and under-counter refrigerators; and

(3) 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

(C) 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.

Ventilation

6-304.11 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.

Dressing Areas and Lockers

6-305.11 Designation.

(A) Dressing rooms or dressing areas shall be designated if EMPLOYEES routinely change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be provided for the orderly storage of EMPLOYEES' clothing and other possessions.

Service Sinks

6-306.10 Availability.

A service sink or curbed cleaning facility shall be provided as specified under § 5-203.13.

6-4 LOCATION AND PLACEMENT

Subparts

6-401 Handwashing Sinks
6-402 Toilet Rooms
6-403 Employee Accommodations
6-404 Distressed Merchandise
6-405 Refuse, Recyclables, and Returnables

Handwashing Sinks

6-401.10 Conveniently Located.

HANDWASHING SINKS shall be conveniently located as specified under § 5-204.11.

Toilet Rooms

6-402.11 Convenience and Accessibility.

Toilet rooms shall be conveniently located and accessible to EMPLOYEES during all hours of operation.

Employee Accommodations

6-403.11 Designated Areas.

(A) 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.

(B) Lockers 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.

Distressed Merchandise

6-404.11 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.

Refuse, Recyclables, and Returnables

6-405.10 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 § 5-501.19.

6-5 MAINTENANCE AND OPERATION

Subpart

6-501 Premises, Structures, Attachments, and Fixtures - Methods

Premises, Structures, Attachments, and Fixtures - Methods

6-501.11 Repairing.

PHYSICAL FACILITIES shall be maintained in good repair.

6-501.12 Cleaning, Frequency and Restrictions.

(A) PHYSICAL FACILITIES shall be cleaned as often as necessary to keep them clean.

(B) *Except for cleaning that is necessary due to a spill or other accident,* cleaning shall be done during periods when the least amount of FOOD is exposed such as after closing.

6-501.13 Cleaning Floors, Dustless Methods.

(A) Except as specified in ¶ (B) 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.

(B) *Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:*

(1) *Without the use of dust-arresting compounds; and*

(2) *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.

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

(A) 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.

(B) If vented to the outside, ventilation systems may not create a public health HAZARD or nuisance or unLAWful discharge.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.*

FOOD preparation sinks, HANDWASHING SINKS, 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.

6-501.16 Drying Mops.

After use, mops shall be placed in a position that allows them to air-dry without soiling walls, EQUIPMENT, or supplies.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Except as specified in ¶ 6-501.13(B), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

6-501.18 Cleaning of Plumbing Fixtures.

PLUMBING FIXTURES such as HANDWASHING SINKS, toilets, and urinals shall be cleaned as often as necessary to keep them clean and maintained and used as specified under § 5-205.11.

6-501.19 Closing Toilet Room Doors.

Except during cleaning and maintenance operations, toilet room doors as specified under § 6-202.14 shall be kept closed.

6-501.110 Using Dressing Rooms and Lockers.

(A) Dressing rooms shall be used by EMPLOYEES if the EMPLOYEES regularly change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be used for the orderly storage of EMPLOYEE clothing and other possessions.

6-501.111 Controlling Pests.*

The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the PREMISES by:

(A) Routinely inspecting incoming shipments of FOOD and supplies;[N]

(B) Routinely inspecting the PREMISES for evidence of pests;[N]

(C) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under §§ 7-202.12, 7-206.12, and 7-206.13; and

(D) Eliminating harborage conditions.[N]

6-501.112 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.

6-501.113 Storing Maintenance Tools.

Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

(A) Stored so they do not contaminate FOOD, EQUIPMENT,

UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES; and

(B) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The PREMISES shall be free of:

(A) Items that are unnecessary to the operation or maintenance of the establishment such as EQUIPMENT that is nonfunctional or no longer used; and

(B) Litter.

6-501.115 Prohibiting Animals.*

(A) Except as specified in ¶¶ (B) and (C) of this section, live animals may not be allowed on the PREMISES of a FOOD ESTABLISHMENT.

(B) *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:*

(1) *Edible FISH or decorative FISH in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;*

(2) *Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;*

(3) *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;*

(4) *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:*

(a) *Effective partitioning and self-closing doors separate the common dining areas from* FOOD *storage or* FOOD *preparation areas,*

(b) *Condiments,* EQUIPMENT*, and* UTENSILS *are stored in enclosed cabinets or removed from the common dining areas when pets are present, and*

(c) *Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and*

(5) *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.*

(C) *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

7 Poisonous or Toxic Materials

Parts

7-1 LABELING AND IDENTIFICATION
7-2 OPERATIONAL SUPPLIES AND APPLICATIONS
7-3 STOCK AND RETAIL SALE

7-1 LABELING AND IDENTIFICATION

Subparts

7-101 Original Containers
7-102 Working Containers

Original Containers

7-101.11 Identifying Information, Prominence.*

Containers of POISONOUS OR TOXIC MATERIALS and PERSONAL CARE ITEMS shall bear a legible manufacturer's label.

Working Containers

7-102.11 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.

7-2 OPERATIONAL SUPPLIES AND APPLICATIONS

Subparts

7-201 Storage
7-202 Presence and Use
7-203 Container Prohibitions
7-204 Chemicals
7-205 Lubricants
7-206 Pesticides
7-207 Medicines
7-208 First Aid Supplies
7-209 Other Personal Care Items

Storage **7-201.11 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:

(A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning;[S] and

(B) 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.*

Presence and Use **7-202.11 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.[S]

(B) *Paragraph (A) of this section does not apply to PACKAGED POISONOUS OR TOXIC MATERIALS that are for retail sale.*

7-202.12 Conditions of Use.*

POISONOUS OR TOXIC MATERIALS shall be:

(A) Used according to:

(1) LAW and this Code,

(2) 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,

(3) The conditions of certification, if certification is required, for use of the pest control materials, and

(4) Additional conditions that may be established by the REGULATORY AUTHORITY; and

(B) Applied so that:

(1) A HAZARD to EMPLOYEES or other PERSONS is not constituted, and

(2) 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:

(a) Removing the items,

(b) Covering the items with impermeable covers, or

(c) Taking other appropriate preventive actions, and

(d) 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 Definitions, (e) Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act, or a PERSON under the direct supervision of a certified applicator.

Container Prohibitions

7-203.11 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.

Chemicals

7-204.11 Sanitizers, Criteria.*

Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).

7-204.12 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 peeling of fruits and vegetables.

7-204.13 Boiler Water Additives, Criteria.*

Chemicals used as boiler water ADDITIVES shall meet the requirements specified in 21 CFR 173.310 Boiler water additives.

7-204.14 Drying Agents, Criteria.*

Drying agents used in conjunction with SANITIZATION shall:

(A) Contain only components that are listed as one of the following:

(1) 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,

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe,

(3) APPROVED for use as a drying agent under a prior sanction specified in 21 CFR 181 - Prior-Sanctioned Food Ingredients,

(4) Specifically regulated as an indirect FOOD ADDITIVE for use as a drying agent as specified in 21 CFR Parts 175-178, or

(5) 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.

Lubricants

7-205.11 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.

Pesticides

7-206.11 Restricted Use Pesticides, Criteria.*

RESTRICTED USE PESTICIDES specified under ¶ 7-202.12(C) shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.

7-206.12 Rodent Bait Stations.*

Rodent bait shall be contained in a covered, tamper-resistant bait station.

7-206.13 Tracking Powders, Pest Control and Monitoring.*

(A) Except as specified in ¶ (B) of this section, 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.[N]

Medicines

7-207.11 Restriction and Storage.*

(A) *Except for medicines that are stored or displayed for retail sale,* only those medicines that are necessary for the health of EMPLOYEES shall be allowed in a FOOD ESTABLISHMENT.

(B) Medicines that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be labeled as specified under § 7-101.11 and located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7-207.12 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.

First Aid Supplies

7-208.11 Storage.*

First aid supplies that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be:

(A) Labeled as specified under § 7-101.11;[S] and

(B) 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.[S]

Other Personal Care Items

7-209.11 Storage.

Except as specified under §§ 7-207.12 and 7-208.11, EMPLOYEES shall store their PERSONAL CARE ITEMS in facilities as specified under ¶ 6-305.11(B).

7-3 STOCK AND RETAIL SALE

Subpart

7-301 Storage and Display

Storage and Display

7-301.11 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:

(A) Separating the POISONOUS or TOXIC MATERIALS by spacing or partitioning;[S] and

(B) 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

8 Compliance and Enforcement

Parts

8-1 CODE APPLICABILITY
8-2 PLAN SUBMISSION AND APPROVAL
8-3 PERMIT TO OPERATE
8-4 INSPECTION AND CORRECTION OF VIOLATIONS
8-5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

8-1 CODE APPLICABILITY

Subparts

8-101 Use for Intended Purpose
8-102 Additional Requirements
8-103 Variances

Use for Intended Purpose

8-101.10 Public Health Protection.

(A) The REGULATORY AUTHORITY shall apply this Code to promote its underlying purpose, as specified in § 1-102.10, of safeguarding public health and ensuring that FOOD is safe, unADULTERATED, and honestly presented when offered to the CONSUMER.

(B) 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:

(1) Whether the facilities or EQUIPMENT are in good repair and capable of being maintained in a sanitary condition;

(2) Whether FOOD-CONTACT SURFACES comply with Subpart 4-101;

(3) Whether the capacities of cooling, heating, and holding EQUIPMENT are sufficient to comply with § 4-301.11; and

(4) The existence of a documented agreement with the PERMIT HOLDER that the facilities or EQUIPMENT will be replaced as specified under ¶ 8-304.11(G) or upgraded or replaced as specified under ¶ 8-304.11(H).

Additional Requirements

8-102.10 Preventing Health Hazards, Provision for Conditions Not Addressed.

(A) 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.

(B) 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.

Variances

8-103.10 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 § 8-103.11 in its records for the FOOD ESTABLISHMENT.

8-103.11 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 ¶ 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the VARIANCE requested.

8-103.12 Conformance with Approved Procedures.*

If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

(A) Comply with the HACCP PLANS and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver; and

(B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring the CRITICAL CONTROL POINTS,

(2) Monitoring of the CRITICAL CONTROL POINTS,

(3) Verification of the effectiveness of the operation or process, and

(4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT.

8-2 PLAN SUBMISSION AND APPROVAL

Subparts

8-201 Facility and Operating Plans
8-202 Confidentiality
8-203 Construction Inspection and Approval

Facility and Operating Plans

8-201.11 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 ¶ 8-302.14(C) if the REGULATORY AUTHORITY determines that plans and specifications are necessary to ensure compliance with this Code.

8-201.12 Contents of the Plans and Specifications.

The plans and specifications for a FOOD ESTABLISHMENT, including a FOOD ESTABLISHMENT specified under § 8-201.13, 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.

8-201.13 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 § 8-201.14 and the relevant provisions of this Code if:

(1) Submission of a HACCP PLAN is required according to LAW;

(2) A VARIANCE is required as specified under Subparagraph 3-401.11(D)(3), § 3-502.11, or ¶ 4-204.110(B);

(3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.

(B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN as specified under § 3-502.12.

8-201.14 Contents of a HACCP Plan.

For a FOOD ESTABLISHMENT that is required under § 8-201.13 to have a HACCP PLAN, the plan and specifications shall indicate:

(A) A categorization of the types of POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY 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:

(1) Ingredients, materials, and EQUIPMENT used in the preparation of that FOOD, and

(2) 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:

(1) Each CRITICAL CONTROL POINT,

(2) The CRITICAL LIMITS for each CRITICAL CONTROL POINT,

(3) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the FOOD EMPLOYEE designated by the PERSON IN CHARGE,

(4) 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,

(5) Action to be taken by the PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met, and

(6) 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.

Confidentiality

8-202.10 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 §§ 8-201.12 and 8-201.14.

Construction Inspection and Approval

8-203.10 Preoperational Inspections.

The REGULATORY AUTHORITY shall conduct one or more preoperational 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 ¶ 8-201.12(E), and is in compliance with LAW and this Code.

8-3 PERMIT TO OPERATE

Subparts

8-301 Requirement
8-302 Application Procedure
8-303 Issuance
8-304 Conditions of Retention

Requirement

8-301.11 Prerequisite for Operation.

A PERSON may not operate a FOOD ESTABLISHMENT without a valid PERMIT to operate issued by the REGULATORY AUTHORITY.

Application Procedure

8-302.11 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.

8-302.12 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.

8-302.13 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 § 8-402.11, 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.

8-302.14 Contents of the Application.

The application shall include:

(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:

(1) Is mobile or stationary and temporary or permanent, and

(2) Is an operation that includes one or more of the following:

(a) Prepares, offers for sale, or serves POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD):

(i) Only to order upon a CONSUMER'S request,

(ii) In advance in quantities based on projected CONSUMER demand and discards FOOD that is not sold or served at an APPROVED frequency, or

(iii) Using time as the public health control as specified under § 3-501.19,

(b) Prepares POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) in advance using a FOOD preparation method that involves two or more steps which may include combining POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,

(c) 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,

(d) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for service to a HIGHLY SUSCEPTIBLE POPULATION,

(e) Prepares only FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD), or

(f) Does not prepare, but offers for sale only prePACKAGED FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD);

(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 ¶ (D) of this section such as the zone, district, or regional supervisor;

(F) The names, titles, and addresses of:

(1) The PERSONS comprising the legal ownership as specified under ¶ (B) of this section including the owners and officers, and

(2) The local resident agent if one is required based on the type of legal ownership;

(G) A statement signed by the applicant that:

(1) Attests to the accuracy of the information provided in the application, and

(2) Affirms that the applicant will:

(a) Comply with this Code, and

(b) Allow the REGULATORY AUTHORITY access to the establishment as specified under § 8-402.11 and to the records specified under §§ 3-203.12 and 5-205.13 and Subparagraph 8-201.14(D)(6); and

(H) Other information required by the REGULATORY AUTHORITY.

Issuance

8-303.10 New, Converted, or Remodeled Establishments.

For FOOD ESTABLISHMENTS that are required to submit plans as specified under § 8-201.11 the REGULATORY AUTHORITY shall issue a PERMIT to the applicant after:

(A) A properly completed application is submitted;

(B) The required fee is submitted;

(C) The required plans, specifications, and information are reviewed and APPROVED; and

(D) A preoperational inspection as specified in § 8-203.10 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.

8-303.20 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, and APPROVED, the fees are paid, and an inspection shows that the establishment is in compliance with this Code.

8-303.30 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.

Conditions of Retention

8-304.10 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 § 8-304.11, that are applicable to the PERMIT.

(B) *Failure to provide the information specified in ¶ (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.*

8-304.11 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 § 8-103.12, and APPROVED plans as specified under § 8-201.12;

(C) If a FOOD ESTABLISHMENT is required under § 8-201.13 to operate under a HACCP PLAN, comply with the plan as specified under § 8-103.12;

(D) Immediately contact the REGULATORY AUTHORITY to report an illness of a FOOD EMPLOYEE or CONDITIONAL EMPLOYEE as specified under ¶ 2-201.11(B);

(E) Immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist as specified under § 8-404.11;

(F) Allow representatives of the REGULATORY AUTHORITY access to the FOOD ESTABLISHMENT as specified under § 8-402.11;

(G) Except as specified under ¶ (H) of this section, replace existing facilities and EQUIPMENT specified in § 8-101.10 with facilities and EQUIPMENT that comply with this Code if:

(1) 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,

(2) The REGULATORY AUTHORITY directs the replacement of the facilities and EQUIPMENT because of a change of ownership, or

(3) The facilities and EQUIPMENT are replaced in the normal course of operation;

(H) Upgrade or replace refrigeration EQUIPMENT as specified under Subparagraph 3-501.16(A)(2)(b), if the circumstances specified under Subparagraphs (G)(1) - (3) of this section do not occur first, and 5 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.

8-304.20 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 ¶ 8-302.14(C) and the change in operation is not APPROVED.

8-4 INSPECTION AND CORRECTION OF VIOLATIONS

Subparts

8-401 Frequency
8-402 Competency and Access
8-403 Report of Findings
8-404 Imminent Health Hazard
8-405 Critical Violation
8-406 Noncritical Violation

Frequency

8-401.10 Establishing Inspection Interval.

(A) Except as specified in ¶¶ (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:*

(1) *The FOOD ESTABLISHMENT is fully operating under an APPROVED and validated HACCP PLAN as specified under § 8-201.14 and ¶¶ 8-103.12(A) and (B);*

(2) *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*

(3) *The establishment's operation involves only coffee service and other unPACKAGED or prePACKAGED FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) 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 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) and that:

(1) 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

(2) Has inexperienced FOOD EMPLOYEES.

8-401.20 Performance- and Risk-Based.

Within the parameters specified in § 8-401.10, 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.

8-402.10 Competency of Inspectors.

An authorized representative of the REGULATORY AUTHORITY who inspects a FOOD ESTABLISHMENT or conducts plan review for compliance with this Code shall have the knowledge, skills, and ability to adequately perform the required duties.

Access

8-402.11 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.

8-402.20 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:

(1) The PERMIT HOLDER is required to allow access to the REGULATORY AUTHORITY as specified under § 8-402.11 of this Code,

(2) Access is a condition of the acceptance and retention of a FOOD ESTABLISHMENT PERMIT to operate as specified under ¶ 8-304.11(F), and

(3) 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.

8-402.30 Refusal, Reporting.

If after the REGULATORY AUTHORITY presents credentials and provides notice as specified under § 8-402.11, explains the authority upon which access is requested, and makes a final request for access as specified in § 8-402.20, the PERSON IN CHARGE continues to REFUSE access, the REGULATORY AUTHORITY shall provide details of the denial of access on an inspection report form.

8-402.40 Inspection Order to Gain Access.

If denied access to a FOOD ESTABLISHMENT for an authorized purpose and after complying with § 8-402.20, the REGULATORY AUTHORITY may issue, or apply for the issuance of, an inspection order to gain access as provided in LAW.

Report of Findings

8-403.10 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 ¶ 8-302.14(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:

(1) Failure of the PERSON IN CHARGE to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this Code as specified under § 2-102.11,

(2) Failure of FOOD EMPLOYEES, CONDITIONAL EMPLOYEES, and the PERSON IN CHARGE to report a disease or medical condition as specified under ¶¶ 2-201.11(B) and (D),

(3) Nonconformance with CRITICAL ITEMS of this Code,

(4) 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 § 8-103.12,

(5) 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 8-201.14(D)(6), and

(6) Nonconformance with CRITICAL LIMITS of a HACCP PLAN.

8-403.20 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 §§ 8-404.11, 8-405.11, and 8-406.11.

8-403.30 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.

8-403.40 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 § 8-403.30 that:

(1) An acknowledgment of receipt is not an agreement with findings,

(2) 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

(3) 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.

8-403.50 Public Information.

Except as specified in § 8-202.10, 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.

Imminent Health Hazard

8-404.11 Ceasing Operations and Reporting.

(A) Except as specified in ¶ (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 insanitary 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.

8-404.12 Resumption of Operations.

If operations are discontinued as specified under § 8-404.11 or otherwise according to LAW, the PERMIT HOLDER shall obtain approval from the REGULATORY AUTHORITY before resuming operations.

Violation of Critical Item

8-405.11 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall at the time of inspection correct a violation of a CRITICAL ITEM 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 violations of a CRITICAL ITEM or HACCP PLAN deviations.*

8-405.20 Verification and Documentation of Correction.

(A) After observing at the time of inspection a correction of a violation of a CRITICAL ITEM or deviation, the REGULATORY AUTHORITY shall enter the violation and information about the corrective action on the inspection report.

(B) As specified under ¶ 8-405.11(B), after receiving notification that the PERMIT HOLDER has corrected a violation of a CRITICAL ITEM 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.

Noncritical Violation

8-406.11 Time Frame for Correction.

(A) Except as specified in ¶ (B) 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.

(B) *The REGULATORY AUTHORITY may approve a compliance schedule that extends beyond the time limits specified under ¶ (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.*

8-5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

Subpart

8-501 Investigation and Control

Investigation and Control

8-501.10 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 or CONDITIONAL 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 FOOD EMPLOYEE or CONDITIONAL 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 FOOD EMPLOYEE or CONDITIONAL EMPLOYEE.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

Based on the findings of an investigation related to a FOOD EMPLOYEE or CONDITIONAL EMPLOYEE who is suspected of being infected or diseased, the REGULATORY AUTHORITY may issue an order to the suspected FOOD EMPLOYEE, CONDITIONAL EMPLOYEE or PERMIT HOLDER instituting one or more of the following control measures:

(A) RESTRICTING the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE;

(B) EXCLUDING the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE; or

(C) Closing the FOOD ESTABLISHMENT by summarily suspending a PERMIT to operate in accordance with LAW.

8-501.30 Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order.

Based on the findings of the investigation as specified in § 8-501.10 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.

8-501.40 Removal of Exclusions and Restrictions.

The REGULATORY AUTHORITY shall release a FOOD EMPLOYEE, OR CONDITIONAL EMPLOYEE from RESTRICTION or EXCLUSION according to LAW and the conditions specified under § 2-201.13.

Annex

1 *Compliance and Enforcement*

1. PURPOSE
2. EXPLANATION
3. PRINCIPLE
4. RECOMMENDATION
5. PARTS
    - 8-6 CONSTITUTIONAL PROTECTION
    - 8-7 NOTICES
    - 8-8 REMEDIES

1. PURPOSE

The purpose of this Annex is to set forth provisions, in codified form, that provide a full array of enforcement mechanisms while recognizing the diverse statutes and regulations that currently govern the operations of the thousands of State and local regulatory agencies.

2. EXPLANATION

State or local statutes, regulations, and ordinances vary in their design, specificity, and degree of comprehensiveness in that they may:

(A) Contain authorities that provide the basis for certain post-inspection compliance strategies but remain silent with respect to other enforcement mechanisms;

(B) Include specific requirements that are different from those provided in this Annex; and

(C) Be structured so that provisions such as administrative procedures are embodied in sections of the law that transcend and are separate from those governing food establishments.

Consequently, in this document a deliberate attempt is made to extract those provisions that could conceptually be adopted as an extension of Chapter 8 if they were compatible with existing, governing State and local statutes. The extracted provisions are numbered to sequentially follow Chapter 8 but are placed in this Annex so that regulatory agencies can revise them to be consistent with their statutes and their needs as discussed in the Recommendation, below.

It is anticipated that adoption of this Code will be facilitated by the fact that:

(A) The compliance provisions of Chapter 8 that should be an integral part of State or local food regulations are part of the text of the Code; and

(B) The administrative and judicial enforcement provisions that are critical to the framework of a food regulatory program, but that may be repetitive or discrepant when compared to State or local statutes, are separated in this Annex.

3. PRINCIPLE

Although the situations necessitating escalated enforcement actions comprise a small percentage of those encountered by the regulator, a full spectrum of enforcement tools must be available where immediate hazards exist, or where compliance is not obtained voluntarily. Thus, a jurisdiction must have in place both the necessary statutory framework that includes a broad-based, well-defined enforcement component and regulations that specify the requirements within those legal authorities. It is imperative that there be clearly stated and legally sound rules that include the criteria for compliance and enforcement, the responsibilities of all parties, sanctions for noncompliance, and due process guarantees.

4. RECOMMENDATION

FDA recommends that agencies assess their statutory provisions that pertain to food establishments in light of this Annex and consider proposing changes to their statutes and regulations where they determine that provisions contained within this Annex will strengthen their programs. Such an assessment may involve reviewing problems encountered in attempts to prosecute under existing State or local provisions;

considering comments received by the regulatory authority about its enforcement process; consulting with staff and legal counsel to identify gaps or weaknesses in the provisions; comparing provisions with sister agencies for comprehensiveness, equity, and uniformity; and seeking input from outside sources that have experience in taking, or being the subject of, enforcement actions.

Appropriate wording and cross referencing changes to the provisions in this Annex may be necessary, based on whether they are adopted as statutes or regulations. Modifications to the adoption forms (Forms #2-A and #2-B in Annex 7) may also be necessary based on that decision.

Parts

8-6 CONSTITUTIONAL PROTECTION
8-7 NOTICES
8-8 REMEDIES

8-6 CONSTITUTIONAL PROTECTION

Subparts

8-601 Procedural Safeguards
8-602 Judicial Review

Procedural Safeguards

8-601.10 Preservation of Rights.

The REGULATORY AUTHORITY shall justly apply the remedies according to LAW and this Code, to preserve the rights to equal protection and due process of a PERSON to whom the remedies are applied.

Judicial Review

8-602.10 Rights of Recipients of Orders or Decisions.

A recipient of a REGULATORY AUTHORITY order or decision may file a petition for judicial review in a court of competent jurisdiction after available administrative appeal remedies are exhausted.

8-7 NOTICES

Subpart

8-701 Service of Notice

Service of Notice **8-701.10 Proper Methods.**

(Note: Adoption of this section provides the basis for serving notice of inspectional findings as specified in § 8-403.30 and would be cited there.)

A notice issued in accordance with this Code shall be considered to be properly served if it is served by one of the following methods:

(A) The notice is personally served by the REGULATORY AUTHORITY, a LAW enforcement officer, or a PERSON authorized to serve a civil process to the PERMIT HOLDER, the PERSON IN CHARGE, or PERSON operating a FOOD ESTABLISHMENT without a PERMIT;

(B) The notice is sent by the REGULATORY AUTHORITY to the last known address of the PERMIT HOLDER or the PERSON operating a FOOD ESTABLISHMENT without a PERMIT, by registered or certified mail or by other public means so that a written acknowledgment of receipt may be acquired; or

(C) The notice is provided by the REGULATORY AUTHORITY in accordance with another manner of service authorized in LAW.

8-701.20 Restriction or Exclusion Order, Hold Order or Summary Suspension.

An EMPLOYEE RESTRICTION or EXCLUSION order, an order to hold and not distribute FOOD, such as a hold, detention, embargo, or seizure order which is hereinafter referred to as a hold order, or a summary suspension order shall be:

(A) Served as specified in ¶ 8-701.10(A); or

(B) Clearly posted by the REGULATORY AUTHORITY at a public entrance to the FOOD ESTABLISHMENT and a copy of the notice sent by first class mail to the PERMIT HOLDER or to the owner or custodian of the FOOD, as appropriate.

8-701.30 When Notice is Effective.

Service is effective at the time of the notice's receipt or if service is made as specified in ¶ 8-701.20(B), at the time of the notice's posting.

8-701.40 Proof of Proper Service.

Proof of proper service may be made by affidavit of the PERSON making service or by admission of the receipt signed by the PERMIT HOLDER, the PERSON operating a FOOD ESTABLISHMENT without a PERMIT to operate, or an authorized agent.

8-8 REMEDIES

Subparts

8-801 Criteria for Seeking Remedies

Administrative

8-802 Inspection Orders
8-803 Holding, Examination, and Destruction of Food
8-804 Summary Permit Suspension
8-805 Hearings Administration
8-806 Hearing Officer, Purpose, Qualifications, Appointment, and Powers
8-807 Rights of Parties and Evidence
8-808 Settlement

Judicial

8-809 Inspection Orders
8-810 Means of Instituting Judicial Enforcement Proceedings
8-811 Criminal Proceedings
8-812 Injunctive Proceedings
8-813 Civil Proceedings

Criteria for Seeking Remedies

8-801.10 Conditions Warranting Remedy.

The REGULATORY AUTHORITY may seek an administrative or judicial remedy to achieve compliance with the provisions of this Code if a PERSON operating a FOOD ESTABLISHMENT or EMPLOYEE:

(A) Fails to have a valid PERMIT to operate a FOOD ESTABLISHMENT as specified under § 8-301.11;

(B) Violates any term or condition of a PERMIT as specified under § 8-304.11;

(C) Allows serious or repeated code violations to remain uncorrected beyond time frames for correction APPROVED, directed, or ordered by the REGULATORY AUTHORITY under ¶¶ 8-405.11(A) and (B), and ¶¶ 8-406.11(A) and (B);

(D) Fails to comply with a REGULATORY AUTHORITY order issued as specified in § 8-501.20 concerning an EMPLOYEE or CONDITIONAL EMPLOYEE suspected of having a disease transmissible through FOOD by infected PERSONS;

(E) Fails to comply with a hold order as specified in § 8-803.10;

(F) Fails to comply with an order issued as a result of a hearing for an administrative remedy as specified in § 8-806.40; or

(G) Fails to comply with a summary suspension order issued by the REGULATORY AUTHORITY as specified in §§ 8-701.20 and 8-804.10.

Administrative Inspection Orders

8-802.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may order access for one or more of the following purposes, subject to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-802.20 Contents of Inspection Order.

The REGULATORY AUTHORITY'S inspection order shall:

(A) Stipulate that access be allowed on or to the described PREMISES, FOOD, or records under the order's provisions;

(B) Provide a description that specifies the PREMISES, FOOD, or records subject to the order; and

(C) Specify areas to be accessed and activities to be performed.

Holding, Examination, and Destruction of Food

8-803.10 Hold Order, Justifying Conditions and Removal of Food.

(Note: Adoption of this section provides the basis for ¶ 3-202.18(B) and would be cited there.)

(A) According to time limits imposed by LAW, the REGULATORY AUTHORITY may place a hold order on a FOOD that:

(1) Originated from an unAPPROVED source;

(2) May be unsafe, ADULTERATED, or not honestly presented;

(3) Is not labeled according to LAW, or, if raw MOLLUSCAN SHELLFISH, is not tagged or labeled according to LAW; or

(4) Is otherwise not in compliance with this Code.

(B) If the REGULATORY AUTHORITY has reasonable cause to believe that the hold order will be violated, or finds that the order is violated, the REGULATORY AUTHORITY may remove the FOOD that is subject to the order to a place of safekeeping.

8-803.20 Hold Order, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the FOOD, as specified in § 8-803.10, without prior warning, notice of a hearing, or a hearing on the hold order.

8-803.30 Hold Order, Contents.

The hold order notice shall:

(A) State that FOOD subject to the order may not be used, sold, moved from the FOOD ESTABLISHMENT, or destroyed without a written release of the order from the REGULATORY AUTHORITY;

(B) State the specific reasons for placing the FOOD under the hold order with reference to the applicable provisions of this Code and the HAZARD or adverse effect created by the observed condition;

(C) Completely identify the FOOD subject to the hold order by the common name, the label information, a container description, the quantity, REGULATORY AUTHORITY'S tag or identification information, and location;

(D) State that the PERMIT HOLDER has the right to an appeal hearing and may request a hearing by submitting a timely request as specified in §§ 8-805.10 and 8-805.20;

(E) State that the REGULATORY AUTHORITY may order the destruction of the FOOD if a timely request for an appeal hearing is not received; and

(F) Provide the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-803.40 Hold Order, Official Tagging of Food.

(A) The REGULATORY AUTHORITY shall securely place an official tag or label on the FOOD or containers or otherwise conspicuously identify FOOD subject to the hold order.

(B) The tag or other method used to identify a FOOD that is the subject of a hold order shall include a summary of the provisions specified in § 8-803.30 and shall be signed and dated by the REGULATORY AUTHORITY.

8-803.51 Hold Order, Food May Not Be Used or Moved.

(A) Except as specified in ¶ (B) of this section, a FOOD placed under a hold order may not be used, sold, served, or moved from the establishment by any PERSON.

(B) *The* REGULATORY AUTHORITY *may allow the* PERMIT HOLDER *the opportunity to store the* FOOD *in an area of the* FOOD ESTABLISHMENT *if the* FOOD *is protected from subsequent deterioration and the storage does not restrict operations of the establishment.*

8-803.60 Examining, Sampling, and Testing Food.

The REGULATORY AUTHORITY may examine, sample, and test FOOD in order to determine its compliance with this Code.

8-803.70 Hold Order, Removing the Official Tag.

Only the REGULATORY AUTHORITY may remove hold order tags, labels, or other identification from FOOD subject to a hold order.

8-803.80 Destroying or Denaturing Food.

If a hold order is sustained upon appeal or if a timely request for an appeal hearing is not filed, the REGULATORY AUTHORITY may order the PERMIT HOLDER or other PERSON who owns or has custody of the FOOD to bring the FOOD into compliance with this Code or to destroy or denature the FOOD under the REGULATORY AUTHORITY'S supervision.

8-803.90 Releasing Food from Hold Order.

The REGULATORY AUTHORITY shall issue a notice of release from a hold order and shall remove hold tags, labels, or other identification from the FOOD if the hold order is vacated.

Summary Permit Suspension

8-804.10 Conditions Warranting Action.

The REGULATORY AUTHORITY may summarily suspend a PERMIT to operate a FOOD ESTABLISHMENT if it determines through inspection, or examination of EMPLOYEES, FOOD, records, or other means as specified in this Code, that an IMMINENT HEALTH HAZARD exists.

8-804.20 Summary Suspension, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may summarily suspend a PERSON'S PERMIT as specified in § 8-804.10 by providing written notice as specified in § 8-701.20 of the summary suspension to the PERMIT HOLDER or PERSON IN CHARGE, without prior warning, notice of a hearing, or a hearing.

8-804.30 Contents of the Notice.

A summary suspension notice shall state:

(A) That the FOOD ESTABLISHMENT PERMIT is immediately suspended and that all FOOD operations shall immediately cease;

(B) The reasons for summary suspension with reference to the provisions of this Code that are in violation;

(C) The name and address of the REGULATORY AUTHORITY representative to whom a written request for reinspection may be made and who may certify that reasons for the suspension are eliminated; and

(D) That the PERMIT HOLDER may request an appeal hearing by submitting a timely request as specified in §§ 8-805.10 and 8-805.20.

8-804.40 Time Frame for Reinspection.

After receiving a written request from the PERMIT HOLDER stating that the conditions cited in the summary suspension order no longer exist, the REGULATORY AUTHORITY shall conduct a reinspection of the FOOD ESTABLISHMENT for which the PERMIT was summarily suspended within 2 business days, which means 2 days during which the REGULATORY AUTHORITY'S office is open to the public.

8-804.50 Term of Suspension, Reinstatement of Permit.

(A) A summary suspension shall remain in effect until the conditions cited in the notice of suspension no longer exist and their elimination has been confirmed by the REGULATORY AUTHORITY through reinspection and other means as appropriate.

(B) The suspended PERMIT shall be reinstated immediately if the REGULATORY AUTHORITY determines that the public health HAZARD or nuisance no longer exists. A notice of reinstatement shall be provided to the PERMIT HOLDER or PERSON IN CHARGE.

Hearings Administration

8-805.10 Response to Notice of Hearing or Request for Hearing, Basis and Time Frame.

(Note: Adoption of this section provides the basis for ¶¶ 8-303.30(C) and 8-501.30(C). ¶¶ 8-805.10(C) and (D) would be cited there.)

(A) A PERSON who receives a notice of hearing for an administrative remedy as specified in Part 8-7, § 8-801.10, or ¶ 8-805.30(A) and elects to respond to the notice shall file a response to notice as specified in § 8-805.20 within 7 calendar days after service.

(B) A PERMIT applicant may request a hearing regarding the disposition of an application for a new or revised PERMIT if the REGULATORY AUTHORITY does not issue or deny the PERMIT within the time frame specified in LAW.

(C) A PERMIT HOLDER may request a hearing to address concerns about the REGULATORY AUTHORITY'S denial of application for a PERMIT or request for a VARIANCE, or compliance actions, except that a hearing request does not stay the REGULATORY AUTHORITY'S restriction or exclusion of EMPLOYEES specified in §§ 8-501.10 - 8-501.40, a hold order specified in § 8-803.10, or the imposition of a summary suspension specified in § 8-804.10.

(D) A PERSON desiring a hearing in response to a denial of an application for PERMIT or an adverse administrative determination shall submit a hearing request to the REGULATORY AUTHORITY within 10 calendar days of the date of the denial, inspection, or compliance action, unless the REGULATORY AUTHORITY specifies in

certain situations that the request shall be submitted within a shorter period of time.

8-805.20 Response to a Notice of Hearing or Request for Hearing, Required Form and Contents.

A response to a hearing notice or a request for hearing as specified in § 8-805.10 shall be in written form and contain the following:

(A) If a response to notice of hearing,

(1) An admission or denial of each allegation of fact;

(2) A statement as to whether the respondent waives the right to a hearing; and may also contain

(3) A statement of defense, mitigation, or explanation concerning any allegation of fact; and

(4) A request to the REGULATORY AUTHORITY for a settlement of the proceeding by consent agreement, if the REGULATORY AUTHORITY will provide this opportunity.

(B) If a request for hearing,

(1) A statement of the issue of fact specified in ¶ 8-805.30(B) for which the hearing is requested; and

(2) A statement of defense, mitigation, denial, or explanation concerning each allegation of fact.

(C) If either a response to notice of hearing or a request for a hearing,

(1) A statement indicating whether the presence of witnesses for the REGULATORY AUTHORITY is required; and

(2) The name and address of the respondent's or requester's legal counsel, if any.

8-805.30 Provided Upon Request.

The REGULATORY AUTHORITY shall hold hearings according to LAW and the provisions of this Code:

(A) As determined necessary by LAW or the REGULATORY AUTHORITY to accomplish the purpose and intent of this Code specified in § 8-101.10; and

(B) As requested by a PERMIT applicant or a PERMIT HOLDER if:

(1) Requested as specified in § 8-805.10, and

(2) The request demonstrates that there is a genuine and material issue of fact that justifies that a hearing be held.

8-805.40 Provided in Accordance with Law.

Hearings shall be conducted according to LAW, administrative procedures, and this Code.

8-805.50 Timeliness, Appeal Proceeding Within 5 Business Days, Other Proceeding Within 30 Calendar Days.

(A) The REGULATORY AUTHORITY shall afford a hearing:

(1) Except as provided in ¶ (B) of this section, within 5 business days after receiving a written request for an appeal hearing from:

(a) A PERSON who is EXCLUDED by the REGULATORY AUTHORITY from working in a FOOD ESTABLISHMENT as specified in §§ 8-501.10 - 8-501.40,

(b) A PERMIT HOLDER or PERSON whose FOOD is subject to a hold order as specified in Subpart 8-803, or

(c) A PERMIT HOLDER whose PERMIT is summarily suspended as specified in Subpart 8-804; and

(2) Within 30 calendar days but no earlier than 7 calendar days after the service of a hearing notice to consider administrative remedies for other matters as specified in ¶ 8-805.10(C) or for matters as determined necessary by the REGULATORY AUTHORITY.

(B) A PERMIT HOLDER or PERSON who submits a request for a hearing as specified in Subparagraphs (A)(1)(a)-(c) of this section may waive the prompt hearing in the written request to the REGULATORY AUTHORITY.

8-805.60 Notice, Contents.

A notice of hearing shall contain the following information:

(A) Time, date, and place of the hearing;

(B) Purpose of the hearing;

(C) Facts that constitute the basis or reason for the hearing including specific details of violations or allegations;

(D) The rights of the respondent, including the right to be represented by counsel and to present witnesses and evidence on the respondent's behalf as specified in § 8-807.10;

(E) At the REGULATORY AUTHORITY'S discretion, the procedure for the respondent to request an offer from the REGULATORY AUTHORITY to settle the matter;

(F) The consequences of failing to appear at the hearing;

(G) The maximum sanctions or penalties as specified in ¶¶ 8-806.40(B) - (D) that may result from the hearing if the hearing concerns a proposed administrative remedy and if the facts are found to be as alleged;

(H) If the hearing concerns a proposed administrative remedy, a statement specifying the form and time frame for response as specified in § 8-805.10;

(I) Notification that the written response shall include the information specified in § 8-805.20; and

(J) The name and address of the PERSON to whom such written response shall be addressed.

8-805.70 Proceeding Commences Upon Notification.

A hearing proceeding commences at the time the REGULATORY AUTHORITY notifies the respondent of the hearing proceeding.

8-805.80 Procedure, Expeditious and Impartial.

Hearings shall be conducted in an expeditious and impartial manner.

8-805.90 Confidential.

(A) Hearings or portions of hearings may be closed to the public:

(1) If compelling circumstances, such as the need to discuss in the hearing a PERSON'S medical condition or a FOOD ESTABLISHMENT'S trade secrets, indicate that it would be prudent; and

(2) According to LAW, such as an open meetings LAW.

(B) A party to a hearing shall maintain confidentiality of discussions that warrant closing the hearing to the public.

8-805.100 Record of Proceeding.

A complete record of a hearing shall be prepared under the direction of the PERSON conducting the hearing and maintained as part of the REGULATORY AUTHORITY'S records for the FOOD ESTABLISHMENT. *Except as required by LAW, a verbatim transcript of the hearing need not be prepared*.

Hearing Officer, Purpose Qualifications, Appointment, and Powers

8-806.10 Appointment by Regulatory Authority and Purpose.

The REGULATORY AUTHORITY may appoint a PERSON such as an adjudicator, administrative LAW judge, or examiner, hereinafter referred to as a hearing officer, who presides over a proceeding initiated by the REGULATORY AUTHORITY or by a PERSON contesting an action of the REGULATORY AUTHORITY, to perform one or more of the following:

(A) Hear the facts presented by an applicant or a PERMIT HOLDER;

(B) Make a decision or recommendation concerning administrative remedies to achieve compliance with this Code; or

(C) Address other concerns or allegations appropriately raised according to LAW, in the matter before the hearing officer.

8-806.20 Qualifications.

A hearing officer shall be knowledgeable of the provisions of this chapter and the LAW as they relate to hearings, and be:

(A) A REGULATORY AUTHORITY representative other than the PERSON who inspects the FOOD ESTABLISHMENT or who has any other role in making the decision that is being contested; or

(B) An individual who is not employed by the REGULATORY AUTHORITY.

8-806.30 Powers, Administration of Hearings.

(A) A hearing officer shall have the following powers in a hearing in which the hearing officer presides:

(1) Setting and conducting the course of a hearing requested in accordance with or authorized by this Code,

(2) Issuing subpoenas in the name of the REGULATORY AUTHORITY at the request of a party to a hearing, administering oaths and affirmations, examining witnesses, receiving evidence,

(3) Approving a consent agreement on the issues involved in the hearing entered into by the REGULATORY AUTHORITY and the respondent after the respondent receives a hearing notice,

(4) Sustaining, modifying, rescinding, or vacating an order or directive of the REGULATORY AUTHORITY in an appeal hearing proceeding, and if the order or directive is sustained, ordering appropriate measures to execute the REGULATORY AUTHORITY'S order or directive; and

(B) *Unless a party appeals to the head of the REGULATORY AUTHORITY within 15 days of the hearing or a lesser number of days specified by the hearing officer:*

(1) Rendering a binding decision and final order in a proceeding after conducting a hearing, if the respondent has not waived the right to a hearing, and

(2) Then notifying the respondent of the decision and the order which contains the findings and conclusions of LAW.

8-806.40 Powers, Administrative Remedies.

The hearing officer shall have the following powers in a hearing proceeding concerning an administrative remedy specified in §§ 8-801.10 and 8-805.30:

(A) Issuing orders to abate or correct violations of this Code and establishing a schedule for the abatement or correction of violations;

(B) Making a finding of fact regarding the occurrence of each violation and assessing, levying, and ordering a reasonable civil penalty, according to LAW and not to exceed the amount specified in ¶ 8-813.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-813.10(C);

(C) Suspending, revoking, modifying, or imposing reasonable restrictions or conditions on a PERMIT to operate a FOOD ESTABLISHMENT, or ordering the closure of a FOOD ESTABLISHMENT that is operated without a valid PERMIT as required under § 8-301.11;

(D) Making a finding of fact regarding the occurrence of each violation of the REGULATORY AUTHORITY'S or hearing officer's LAWful order issued in accordance with this Code and assessing, levying, and ordering a reasonable civil penalty, in accordance with LAW and not to exceed the amount specified in ¶ 8-813.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-813.10(C);

(E) Deferring or suspending the imposition of a decision or execution of an order, and imposing a probationary period, upon the condition that the respondent comply with the hearing officer's reasonable terms and conditions;

(F) Dismissing the appeal if the matter is settled between the REGULATORY AUTHORITY and the respondent after a hearing notice is served;

(G) Ordering reinspection of a FOOD ESTABLISHMENT to determine compliance with a hearing officer's order;

(H) Suspending or ordering the payment of a fee established by the REGULATORY AUTHORITY for a reinspection that is required to determine compliance and for the reinstatement of a PERMIT after suspension;

(I) Retaining and exercising jurisdiction for a specific period of time not to exceed 90 calendar days after the hearing officer's decision and final order is issued, over a respondent who receives a hearing notice; and

(J) Modifying or setting aside an order by rehearing upon the hearing officer's own motion, the motion of the REGULATORY AUTHORITY, or the motion of the respondent.

Rights of Parties and Evidence

8-807.10 Rights of Parties.

Parties to a hearing may be represented by counsel, examine and cross examine witnesses, and present evidence in support of their position.

8-807.20 Evidence to be Presented by the Regulatory Authority.

The REGULATORY AUTHORITY shall present at the hearing its evidence, orders, directives, and reports related to the proposed or appealed administrative remedy.

8-807.30 Evidence to be Excluded.

Evidence shall be EXCLUDED:

(A) If it is irrelevant, immaterial, unduly repetitious, or excludable on constitutional or statutory grounds or on the basis of evidentiary privilege recognized by the state's courts; or

(B) Otherwise according to LAW.

8-807.40 Testimony under Oath.

Testimony of parties and witnesses shall be made under oath or affirmation administered by a duly authorized official.

8-807.50 Written Evidence.

Written evidence may be received if it will expedite the hearing without substantial prejudice to a party's interests.

8-807.60 Documentary Evidence.

Documentary evidence may be received in the form of a copy or excerpt.

Settlement

8-808.10 Authorization.

The REGULATORY AUTHORITY may settle a case after a notice of hearing is served by providing a respondent with an opportunity to request a settlement before a hearing commences on the matter and by entering into a consent agreement with the respondent.

8-808.20 Respondent Acceptance of Consent Agreement Is Waiver of Right to Appeal.

Respondents accepting a consent agreement waive their right to a hearing on the matter.

Judicial

Inspection Orders

8-809.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may seek access for one or more of the following purposes, according to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-809.20 Contents of Court Petition.

In the absence of a specific set of requirements established by LAW, in its petition to the court to compel access the REGULATORY AUTHORITY shall:

(A) Describe in detail the PREMISES, FOOD, or records on or to which access was denied;

(B) Detail the legal authority to regulate and to have access for a specific purpose on or to the PREMISES, FOOD, or records where access was denied; and

(C) Provide information that the FOOD ESTABLISHMENT possesses a valid PERMIT from the REGULATORY AUTHORITY and that it applies to the PREMISES where access was denied; or

(D) Provide information that a PERSON is known to be or suspected of operating a FOOD ESTABLISHMENT without possessing a valid PERMIT as specified in LAW and under this Code.

8-809.30 Sworn Statement of Denied Access.

The REGULATORY AUTHORITY shall demonstrate to the court by affidavit, sworn testimony, or both that:

(A) Access on or to the PREMISES, FOOD, or records was denied after the REGULATORY AUTHORITY acted as specified in §§ 8-402.20 and 8-402.30; or

(B) There is reason to believe that a FOOD ESTABLISHMENT is being operated on the PREMISES and that access was denied or is sought under a REGULATORY AUTHORITY'S reasonable administrative plan to enforce the provisions of this Code.

8-809.40 Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may issue an inspection order that:

(A) Includes the information specified in ¶¶ 8-802.20(A) - (C); and

(B) Orders or authorizes any other identified agencies and persons including LAW enforcement agencies to execute, or assist with the execution of, the order.

8-809.50 Optional Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may further issue an inspection order that:

(A) Provides a maximum time limit for the order's execution;

(B) Authorizes LAW enforcement officers who assist in the order's execution to use necessary force against PERSONS or property to execute the order; and

(C) Requires that the agencies or PERSONS ordered or authorized to execute the order shall report to the court the date and time of the order's execution and the findings reached by the inspection, examination, or sampling conducted under the order.

Means of Instituting Judicial Enforcement Proceedings

8-810.10 Institution of Proceedings.

(A) Proceedings to enforce this Code may be instituted by the REGULATORY AUTHORITY according to LAW by issuing a citation or summons, by filing a misdemeanor complaint affidavit and request for a warrant of arrest with the court of competent jurisdiction, or by referring the complaint to a grand jury for indictment, as appropriate.

(B) The REGULATORY AUTHORITY may designate a representative to issue summons or citations or sign warrants on behalf of the agency.

Criminal Proceedings

8-811.10 Authorities, Methods, Fines, and Sentences.

(A) The REGULATORY AUTHORITY may seek to enforce the provisions of this Code and its orders by instituting criminal proceedings as provided in LAW against the PERMIT HOLDER or other PERSONS who violate its provisions.

(B) A PERSON who violates a provision of this Code shall be guilty of a misdemeanor, punishable by:

(1) A fine of not more than (designate amount) dollars, or by imprisonment not exceeding 1 year, or both the fine and imprisonment; or

(2) If the PERSON has been convicted once of violating this Code or if there is an intent to defraud or mislead, a fine not exceeding (designate amount) or imprisonment not exceeding (designate time) year(s) or both.

(C) Each day on which a violation occurs is a separate violation under this section.

Injunctive Proceeding

8-812.10 Petitions for Injunction.

The REGULATORY AUTHORITY may, according to LAW, petition a court of competent jurisdiction for temporary or permanent injunctive relief to achieve compliance with the provisions of this Code or its orders.

Civil Proceedings

8-813.10 Petitions, Penalties, and Continuing Violations.

(A) The REGULATORY AUTHORITY may petition a court of competent jurisdiction to enforce the provisions of this Code or its administrative orders and according to LAW collect penalties and fees for violations.

(B) In addition to any criminal fines and sentences imposed as specified in § 8-811.10, or to being enjoined as specified in § 8-812.10, a PERSON who violates a provision of this Code, any rule or regulation adopted in accordance with LAW related to FOOD ESTABLISHMENTS within the scope of this Code, or to any term, condition, or limitation of a PERMIT issued as specified in §§ 8-303.10 and 8-303.20 is subject to a civil penalty not exceeding (designate amount).

(C) Each day on which a violation occurs is a separate violation under this section.

Annex

2 References

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS
2. BIBLIOGRAPHY
3. SUPPORTING DOCUMENTS
4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS

The *Food Code* makes frequent reference to federal statutes contained in the United States Code (USC) and the *Code of Federal Regulations* (CFR). Copies of the USC and CFR can be viewed and copied at government depository libraries or may be purchased as follows.

(A) Viewing and Copying the USC or CFR

(1) Federal Depository Library

The USC and CFR are widely available for reference and viewing in some 1300 "depository libraries" located throughout the United States. *A Directory of U.S. Government Depository Libraries* is published by the Joint Committee on Printing of the United States Congress and is available through the Superintendent of Documents, U.S. Government Printing Office. This publication lists all depository libraries by state, city, and congressional district.

Persons may also obtain information about the location of the depository library nearest to them by contacting:

GPO Customer Contact Center, IDCC
U.S. Government Printing Office
732 North Capitol Street, NW
Washington, DC 20401-0001
(866) 512-1800, Fax (202) 512-2104

(2) Internet World Wide Web Information System

The CFR are available on-line in downloadable form through the Internet World Wide Web information system. The source is:

The National Archives and Records Administration
Copies of Federal Regulations - Retrieve CFR by Citation
Provided through the Government Printing Office Web Site - GPO Inet Services

http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1

(B) Purchasing Portions of the USC or CFR

Persons wishing to purchase relevant portions of the USC or CFR may do so by

writing:	or by calling:
Superintendent of Documents (New Orders) U.S. Government Printing Office P.O. Box 371954 Pittsburgh, PA 15250-7954;	(202) 512-1800 from 7:30 a.m. to 9:00 p.m. eastern time, Monday-Friday (except holidays. Orders may be charged to American Express, Discover, MasterCard, or Visa.

(C) USC as it Relates to the Code Definition of "Adulterated"

This language has been retyped as accurately as possible and inserted in the Food Code Annex for informational purposes. For legal purposes, use only language taken directly from the United States Code (USC).

21 USC Sec. 342
Title 21 - Food and Drugs
Chapter 9 - Federal Food, Drug and Cosmetic Act
Subchapter IV - Food

ADULTERATED FOOD

Sec. 402 [342]

A food shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients

A food shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.[1]

(2)

(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a (a) of this title; or

(C) if it is or if it bears or contains

(i) any food additive that is unsafe within the meaning of section 348 of this title; or

(ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e (a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury under—

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is

adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph [2] (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(h) Reoffer of food previously denied admission

If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381 (a) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this chapter, as determined by the Secretary.

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[1] So in or". original. The period probably should be ";

[2] So in original. Probably should be "subparagraph".

(As amended by Congress, 2002 – Subsec. (h). Pub. L. 107-188 added subsec. (h).)

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2-304.11 Clean Condition. (Outer Clothing)
2-401.11 Eating, Drinking, or Using Tobacco.*
2-402.11 Effectiveness. (Hair Restraints)

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Chapter 3 Food

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Chapter 4 Equipment, Utensils, and Linens

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2. Peterson, C.S., 1979. Microbiology of Food Fermentation, 2nd Ed. AVI Publishing Co., Inc., Westport, Connecticut, pp. 288-293.

4-101.16 Sponges, Use Limitation.

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4-101.17 Wood, Use Limitation.

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2. Agricultural Research Service, U.S. Department of Agriculture. ARS Affirms Plastic Cutting Board Policies. Food Chemical News, December 6, 1993, pp. 56-57.

3. Code of Federal Regulations, Title 21, Part 178.3800 Preservatives for wood.

4-501.13 Microwave Ovens.

1. Code of Federal Regulations, Title 21, Part 1030.10 Microwave ovens.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.*

1. Code of Federal Regulations, Title 21, Part 1030.10 Microwave ovens.

2. Code of Federal Regulations, Title 40, Part 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions), found at http://www.access.gpo.gov/nara/cfr/waisiox_04/40cfr180_04.html.

3. Miller, M.P., Principal Investigator, 1984. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.

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4-602.11 Equipment Food-Contact Surfaces and Utensils.*

1. Tauxe, R.V., M.D., Chief, Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Disease and M.L. Cohen, M.D., Director, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, memo dated January 10, 1996 re: "Bacterial Contamination of Iced Tea," to State and Territorial Epidemiologists and State and Territorial Public Health Laboratory Directors. Memo includes two fact sheets by the Tea Association of the U.S.A., Inc.

4-603.17 Returnables, Cleaning for Refilling.*

1. Food and Drug Administration, 1985. Food Protection - Refilling of take-home beverage containers (8/29/85). Retail Food Protection Program Information Manual.

4-703.11 Hot Water and Chemical.*

1. Miller, M.P., Principal Investigator, 1984. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.

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3. National Sanitation Foundation, Ann Arbor, MI. November, 1990. Report on the Bacterial Effectiveness of a Chlorine Sanitizing Solution at Contact Times of Less than Ten Seconds. Purchase Order #FDA 665531-00-90-RB.

4-901.11 Equipment and Utensils, Air-Drying Required.

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (food-contact surface sanitizing solutions), before contact with food.

Chapter 5 Water, Plumbing, and Waste

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (food-contact surface sanitizing solutions), before contact with food.

2. Code of Federal Regulations, Title 21, Part 129 – Processing and Bottling of Bottled Drinking Water.

3. International Association of Plumbing and Mechanical Officials, 2003 Uniform Plumbing Code, Walnut, CA. Available for sale at http://publications.iapmo.org/categories.asp?id=1.

4. International Code Council. 2003 International Plumbing Code, Falls Church, VA. Available for sale at http://www.iccsafe.org/e/prodcat.html?catid=C-P&pcats=ICCSafe.MP&stateInfo=nTMTVilbdXdaLjAa6624l4.

5-202.12 Handwashing Facility, Installation.

1. American Society for Testing and Materials, Designation: E 1838-02, Standard Test Method for Determining the Virus-Eliminating Effectiveness of Liquid Hygienic Handwash and Handrub Agents Using the Fingerpads of Adult Volunteers. ASTM, Philadelphia, PA.

2. American Society for Testing and Materials, Designation: E 2011-99, Standard Test Method for Evaluation of Handwashing Formulations for Virus-Eliminating Activity Using the Entire Hand. ASTM, Philadelphia, PA.

3. American Society for Testing and Materials, Designation: E 1327-90 (reapproved 2000), Standard Test Method for Evaluation of Health Care Personnel Handwash Formulations by Utilizing Fingernail Regions. ASTM, Philadelphia, PA.

4. American Society for Testing and Materials, Designation: E 1174-00, Standard Test Method for Evaluation of Health Care Personnel or Consumer Handwash Formulations. ASTM, Philadelphia, PA.

5. Code of Federal Regulations, Title 21, Part 129 Processing and Bottling of Drinking Water.

Chapter 6 Physical Facilities

6-202.15 Outer Openings, Protected.

1. National Fire Protection Association, NFPA 101 Life Safety Code, 2003 Edition, Quincy, MA. Available for sale at http://www.nfpa.org/Catalog/category.asp?%5Fname=codes+and+standards&page=2&src=catalog.

2. National Fire Protection Association, NFPA 101 Life Safety Code Handbook, 2003 Edition, Quincy, MA.

6-303.11 Intensity.

1. Illuminating Engineering Society of North America, 2000. Lighting Handbook, 9th Ed., IESNA Publications Dept., New York, NY. 900+ pp.

Chapter 7 Poisonous or Toxic Materials

7-202.12 Conditions of Use.*

1. Federal Insecticide, Fungicide, and Rodenticide Act, 7 USC 136 Definitions, (e) Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act found at http://www.epa.gov/opp00001/regulating/fifra.pdf.

7-204.11 Sanitizers, Criteria.*

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).

7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.*

1. Code of Federal Regulations, Title 21, Part 173.315, Chemicals used in washing or to assist in the peeling of fruits and vegetables.

7-204.13 Boiler Water Additives, Criteria.*

2. Code of Federal Regulations, Title 21, Part 173.310, Boiler water additives.

7-204.14 Drying Agents, Criteria.*

1. Code of Federal Regulations, Title 21, Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe.

2. Code of Federal Regulations, Title 21, Parts 175, Indirect Food Additives: Adhesives and Components of Coatings.

3. Code of Federal Regulations, Title 21, Parts 178, Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers.

4. Code of Federal Regulations, Title 21, Parts 176, Indirect Food Additives: Paper and Paperboard Components.

5. Code of Federal Regulations, Title 21, Parts 177, Indirect Food Additives: Polymers.

6. Code of Federal Regulations, Title 21, Part 186, Indirect Food Substances Affirmed as Generally Recognized as Safe.

7. Code of Federal Regulations, Title 21, Part 181, Prior-Sanctioned Food Ingredients.

8. Code of Federal Regulations, Title 21, Part 182, Substances Generally Recognized as Safe.

9. Code of Federal Regulations, Title 21, Part 170.39, Threshold of regulation for substances used in food-contact articles.

7-205.11 Incidental Food Contact, Criteria.*

1. Code of Federal Regulations, Title 21, Part 178.3570, Lubricants with incidental food contact.

7-206.11 Restricted use Pesticides, Criteria.*

1. Code of Federal Regulations, Title 40, Part 152 Subpart I, Classification of Pesticides.

3. SUPPORTING DOCUMENTS

FDA is providing the following guidance documents for reference. A brief summary for each document is provided.

A. (Draft) Recommended National Retail Food Regulatory Program Standards
B. FDA Procedures for Standardization and Certification of Retail food Inspection/Training Officers
C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments
D. Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems
E. Food Establishment Plan Review Guide
F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)
G. Growing Sprouts in a Retail Food Establishment
H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety
I. Evaluation and Definition of Potentially Hazardous Foods
J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers"
K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information
L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003
M. Comprehensive Guidelines for Food Recovery Programs

A. (Draft) Recommended National Retail Food Regulatory Program Standards

This document can be found at the web site http://www.cfsan.fda.gov/~dms/ret-toc.html and was formulated from ideas and input by Federal, State, and local regulatory officials, industry, trade and professional associations, academia, and consumers. The purposes of these standards are:

- To serve as a bench mark to retail food regulatory program managers in the design and management of a retail food program;

- To provide a means of recognition of programs meeting these standards;
- To promote uniformity in retail food programs to reduce the risk factors known to cause foodborne illness;
- To provide a foundation for the food regulatory program that is focused on the risk factors and other factors that may contribute to foodborne illness; and
- To promote, through the management of a retail food regulatory program, the active managerial control in the retail establishment of all the factors that may cause foodborne illness.

Further purposes of these standards are to serve as a guide to regulatory retail food program managers in the design and management of a retail food program and to provide a means of recognition for those programs that meet these standards.

The intent in the development of these standards is to establish a basic foundation in design and management of a retail food program. Program management may add additional requirements to meet individual program needs.

The standards apply to the operation and management of a regulatory retail food program focused on the reduction of risk factors known to cause foodborne illness as well as other factors that may contribute to foodborne illness and on the promotion of active managerial control of all factors that may cause foodborne illness.

B. FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers

This document can be found at the web site http://www.cfsan.fda.gov/~ear/rfi-toc.html. This is a procedure that integrates the assessment of an individual's knowledge, skills, and abilities in a manageable number of inspections while preserving the quality and integrity of the process. At the same time, we continue to learn from our experiences in applying it and remain open to improving these Procedures based on your experiences and feedback.

As they are written, the Procedures address the situation wherein an FDA Standard is assessing a CANDIDATE who is not employed by FDA. For example, Paragraph 3-301(C) mentions but does not require recording citations (i.e., identifying the codified provision that relates to each observed violation). Since jurisdiction's codification systems (numeric or alphanumeric) are usually different from the system in the FDA Food Code, the utility of that practice would be minimal in an FDA-to-jurisdiction field exercise. However, within a jurisdiction where the same Code is in use, the practice could be useful in reinforcing diligence in ensuring that violations listed during inspections are, in fact, soundly based in regulation.

FDA invites and encourages jurisdictions to use these Procedures in their internal Standardization and Certifications and to add dimensions that promote uniformity such as citing codified provisions, as discussed above. With a few language changes, the document can be custom-tailored to fit individual jurisdictions and serve as their procedures. As with other documents provided as guidance for applying regulatory requirements in the retail sector, these Procedures are in the "public domain" and we encourage their duplication and use.

C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

The Operator's Manual can be found by accessing the following web site: http://www.cfsan.fda.gov/~dms/hret2toc.html. FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. It recognizes that there are differences between using HACCP at retail and in food manufacturing. 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. This document is intended to serve as a guide in the writing of a simple plan based on HACCP principles that can be used to manage food safety. It is very important to understand that this Guide is intended to assist industry's voluntary implementation of HACCP principles. It is not meant to stand alone, but instead should be used together with advice from and in consultation with your Federal, State, local, or tribal food safety regulatory authority. The regulatory authority is an important resource for reviewing your food safety management system. Regulatory food safety professionals can provide important information for the public health rationale for controlling a particular hazard. Users of this document also need to consult and use the latest edition of the FDA Food Code since many of its requirements are not reproduced here but constitute a fundamental program that is prerequisite to implementing a HACCP program.

Hazard Analysis Critical Control Point (HACCP) is a common sense technique to control food safety hazards. It is a preventive system of hazard control rather than a reactive one. Food establishments can use it to ensure safer food products for consumers. It is not a zero risk system, but is designed to minimize the risk of food safety hazards. HACCP is not a stand alone program but is one part of a larger system of control procedures that must be in place in order for HACCP to function effectively. These control procedures are prerequisite programs and are discussed more in Annex 4.

The success of a HACCP program is dependent upon both people and facilities. Management and employees must be properly motivated and trained if a HACCP program is to successfully reduce the risk of foodborne illness. Education and training in the principles of food safety and management commitment to the implementation of a HACCP system are critical and must be continuously reinforced. Instilling food worker commitment and dealing with problems such as high employee

turnover and communication barriers must be considered when designing a HACCP plan.

Successful implementation of a HACCP plan is also dependent upon the design and performance of facilities and equipment. The likelihood of the occurrence of a hazard in a finished product is definitely influenced by facility and equipment design, construction, and installation that play a key role in any preventive strategy.

The Agency recognizes that this document has areas that need to be further clarified and developed with broader input and based on industry's experiences with the practicalities of integrating the HACCP approach in their operations. This Guide will continue to evolve and improve.

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

The Regulator's Manual can be found by accessing the following website: http://www.cfsan.fda.gov/~dms/hret3toc.html. This document provides State, local, and tribal regulatory authorities with a step-by-step scheme for conducting risk-based inspections based on HACCP principles to assist them with identifying and assessing control of foodborne illness risk factors. In addition, the manual details intervention strategies that can be developed with retail and food service operators to reduce the occurrence of foodborne illness risk factors. It also provides recommendations for evaluating voluntarily-implemented food safety management systems if invited to do so by industry.

The utilization of voluntary food safety management systems by industry and the incorporation of risk-based methodology into regulatory inspection programs are important elements in reaching the goals established by the Healthy People 2010 health improvement strategy and FDA retail program goals.

In 2004, the Conference for Food Protection (CFP) endorsed both documents with a recommendation that both industry and regulatory entities consider implementing the principles of the documents into their respective food safety programs. The CFP is composed of regulators, industry, academia, professional organizations, and consumers whose purpose is to identify problems, formulate recommendations, and develop and implement practices that relate to food safety.

A Federal Register notice announcing the availability of these documents was published July 21, 2005 (Docket No. 2005D-0274).

E. Food Establishment Plan Review Guide

This document can be found at the web site http://www.cfsan.fda.gov/~dms/previntr.html. This Food Establishment Plan Review document has been developed for the purpose of assisting both regulatory and industry personnel in achieving greater uniformity in the plan review process. It is the result of a joint effort by FDA and the Conference for Food Protection.

Plan review of food service establishments, retail food stores, and all other food operations, must be maintained as a high priority by all regulatory food agencies for both new and existing facilities.

This document has been developed to serve as a guide in facilitating greater uniformity and ease in conducting plan review whether your position is a regulator or an industry person wishing to build or to expand. You need not be an expert to effectively complete this process.

A good review of plans helps to avoid future problems. By listing and locating equipment on floor plans and diagramming specifications for electrical, mechanical and plumbing systems, potential problems can be spotted while still on paper and modifications made BEFORE costly purchases, installation and construction.

Food establishment plan review is recognized as an important food program component that allows:

-- Regulatory agencies to ensure that food establishments are built or renovated according to current regulations or rules.
-- Industry to establish an organized and efficient flow of food.
-- Regulatory agencies to eliminate code violations prior to construction.

F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)

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

second report is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/retrsk2.html . An additional data collection project is planned for 2008.

G. Growing Sprouts in a Retail Food Establishment

This document, Growing Sprouts in a Retail Food Establishment, can be found at the web site http://www.cfsan.fda.gov/~dms/sprouret.html. There were 25 reported outbreaks associated with raw and lightly cooked seed sprouts in the United States between January 1996 and December 2003. No single treatment so far has been shown to completely eliminate pathogens on seeds or sprouts without affecting germination or yield; therefore a combination of factors is used to eliminate and control potential pathogens and assure a safe, ready-to-eat food product. Seeds or beans grown using Good Agricultural Practices (GAPs) and conditioned, transported, and stored according to GMPs reduce the potential for seed to serve as a source of contamination. Retail Sprouting Industry Best Practices help ensure that no further contamination occurs and precautionary measures are taken to prevent high levels of bacteria from growing on the seeds or sprouts. Seeds for sprouting or sprouts should receive a chemical disinfection treatment that has been approved by EPA for reduction of pathogens. Other treatments such as irradiation of seeds [21 CFR 179.26(b)(10)] have been approved. Because no treatments are known to completely eliminate pathogens without adversely affecting germination or yield, microbial testing of spent irrigation water from the sprouting process is also necessary to verify that no pathogens are present. Raw sprouts are considered potentially hazardous food (PHF)/time/temperature control for safety food (TCS) and therefore, require refrigeration.

H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety

These documents are available for purchase at minimum cost from the Association of Food and Drug Officials (AFDO) at the website http://www.afdo.org/afdo/publication/index.cfm. These guides were funded by USDA through the University of Florida in cooperation with Florida A&M University and the Association of Food and Drug Officials and developed by experts from academic, regulatory, and industry areas. Nine guides help retailers and regulatory personnel understand the food safety controls to implement in retail food and food service operations in order to process and sell safe food products. They can also be used as a reference in applying for or reviewing a variance and HACCP Plan, where required, for retail processing of beef jerky, cured and hot smoked sausage, cured and smoked ham, fermented and dried sausage, fresh-cut produce, fresh juice, reduced oxygen packaging (ROP), smoked seafood, and sushi.

Each guide provides a definition of terms, a flow diagram, and a detailed check list for operations including receiving, food storage, preparation, and display. Information in the Appendices helps identify specific food safety hazards associated with that product, necessary equipment calibrations, product labeling, recommended record keeping with sample log sheets, and a daily SOP check list. Authoritative sources are also referenced such as FDA's "Fish and Fisheries Products Hazards & Controls Guidance" and 21 CFR 101 for labeling requirements.

These guides are not intended to replace or duplicate existing regulations within the jurisdictions of the regulatory authority or food establishment but they offer information and references for more uniform practices.

I. Evaluation and Definition of Potentially Hazardous Foods

This document can be found at the web site http://www.cfsan.fda.gov/~comm/ift4-toc.html. The Institute of Food Technologists (IFT) prepared and submitted this report as part of a contract with FDA. It contains responses to various questions posed by FDA about potentially hazardous food (PHF)/time/temperature control for safety food (TCS food). The IFT reviewed the evolution of the term PHF and recommended a change to time/temperature control for safety (TCS) food as well as a science-based framework for determining the effectiveness of processing technologies that formulate a food so that it is nonpotentially hazardous/non-TCS.

The IFT Science and Technology Expert Panel reviewed the two protocols used by NSF International and the American Baking Association for determining if a food is a PHF and proposed an alternate approach. The report examines intrinsic factors such as a_w, pH, redox potential, natural and added antimicrobials and competitive microorganisms, and extrinsic factors such as packaging, atmospheres, storage conditions, processing steps, and new preservation technologies that influence microbial growth. The report also analyzes microbial hazards related to time/temperature control of foods for safety.

The IFT developed a framework that could be used to determine whether a food is a PHF (TCS food) or not. Part of the framework includes two tables that consider the interaction of pH and a_w in a food, whether the food is raw or heat-treated, and whether it is packaged. When further product assessment is required, the application of microbiological challenge testing (inoculation studies) is discussed along with pathogen modeling programs and reformulation of the food. An extensive reference list is included in the report.

J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers" October 28, 2004

The guide is designed to assist restaurants and other food service employers in complying with the employment provisions of the Americans with Disabilities Act (ADA). The EEOC worked extensively with the Food and Drug Administration in developing this new publication.

Available online at http://www.eeoc.gov/facts/restaurant_guide.html, http://www.eeoc.gov/facts/restaurant_guide_summary.html, and www.fda.gov, the guide covers such topics as how the FDA Food Code provisions about restricting and excluding sick employees interact with the ADA's requirements; types of reasonable accommodations, including the use of service animals; and what an employer should do if a charge of discrimination is filed against the employer's business.

Title I of the ADA, which prohibits employment discrimination against people with disabilities in the private sector and State and local governments, and the Rehabilitation Act's prohibitions against disability discrimination in the federal government. The EEOC enforces Title VII of the Civil Rights Act of 1964, which prohibits employment discrimination based on race, color, religion, sex, and national origin; the Age Discrimination in Employment Act, which prohibits discrimination against individuals 40 years of age or older; the Equal Pay Act; and sections of the Civil Rights Act of 1991.

K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

This document may be found at the web site for "Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7" at http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/10.010.1.pdf. On October 7, 2002, USDA/FSIS published a Federal Register Notice (67 FR 62332) entitled, *E. coli* O157:H7 Contamination of Beef Products, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf, in which the Agency discussed its views on the application of the Hazard Analysis and Critical Control Point (HACCP) system regulations with respect to *Escherichia coli (E. coli)* O157:H7 contamination.

USDA/FSIS announced that there is sufficient new scientific data on the increased prevalence of *E. coli* O157:H7 in live cattle coming to slaughter and on its impact on public health to require that all establishments producing raw beef products reassess their HACCP plans, in light of these data.

Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback *E. coli* O157:H7 contaminated product that is in commerce to its source and to remove it from commerce. In March 2004, the agency issued "FSIS Directive 10,010.1; revision 1, Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components" available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf. In this Directive, the Agency stated that, effective May 17, 2004, it would conduct sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities, as well as at import facilities. Some of the products most likely to be sampled and tested at retail facilities are:

- Ground beef products produced from retail steaks and roasts.
- Manufacturing trimmings derived at retail.
- Ground beef that is formulated at retail by co-mingling in-store trim and trim from federally inspected establishments.
- Irradiated ground beef co-mingled with non-irradiated meat or poultry.

To facilitate product traceback and to meet regulatory requirements, USDA/FSIS expects retail facilities as well as federally inspected establishments to maintain and provide FSIS with access to all applicable records associated with the source material used for ground beef products. In cases where USDA/FSIS identifies *E. coli* O157:H7 ground beef in a product, and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

The following information would be adequate for meeting federal transaction requirements:

- The name or description of the purchased or received article(s).
- The name, address, and establishment number of the seller of the articles purchased or received.
- The supplier lot numbers and production dates of the articles purchased or received.
- Any other information that would be useful in the quick removal of adulterated product from the market or commerce.

In addition to the references cited above, the following references also provide information:

1. Federal Meat Inspection Act (21 USC Sec. 642).

2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.

3. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program and Other Verification Activities For *Escherchia coli* O157:H7 http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010 1/ecolio157h7dirguid4-13-04.pdf.

L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003

This document can be found at http://www.foodprotect.org/documents.html. Permanent Outdoor Cooking Establishments (POCE) include a wide range of facilities from barbecue pits at beach resorts to campfire meals at dude ranches, pig roasts and clam bakes, and multi-menu food service sites in amusement and theme parks. It is essential that the equipment and physical facility requirements be based upon a menu review of the items to be prepared, cooked, held, and served. Many of these POCEs are high risk operations engaging in extensive preparation of raw ingredients: processes that include the cooking, hot and cold holding, and reheating of potentially hazardous foods (time/temperature control for safety foods). These guidelines provide the basis on which regulatory authorities can evaluate and permit permanent outdoor cooking establishments.

M. Comprehensive Guidelines for Food Recovery Programs

Food recovery programs collect foods from commercial production and distribution channels and redistribute them to people in need. There are food recovery efforts carried out by public, private, and nonprofit organizations across the country. The primary goal of food recovery programs is to collect safe and wholesome food donated from commercial sources to meet the nutritional needs of the hungry.

With bipartisan support, Congress passed the Bill Emerson Good Samaritan Food Donation Act in 1996. The Act is designed to encourage the donation of food and grocery products to nonprofit organizations such as homeless shelters, soup kitchens, and churches for distribution to hungry individuals. The Bill Emerson Good Samaritan Food Donation Act promotes food recovery by limiting the liability of donors to instances of gross negligence or intentional misconduct.

The *Guidelines* are intended to provide guidance to those who want to participate in food recovery programs as donors and receiving operations as well as to those who oversee standards compliance as regulators or peer inspectors.

The *Guidelines* also give advice on implementing a food recovery program, various ways to contribute to food recovery programs, choosing suitable partners, and laying the foundation for a successful program. This includes food safety provisions in alignment with the FDA Food Code, guidelines for monitoring food recovery programs, and handling of donations of game animals. For simple recordkeeping, the *Guidelines*

contain sample forms designed to facilitate the management of a variety of aspects of food recovery programs.

For in-depth information, see the *Comprehensive Guidelines for Food Recovery Programs* available via the Conference for Food Protection web page at http://www.foodprotect.org/documents.html.

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all-inclusive. It contains links to publications from federal regulatory agencies (primarily FDA, CDC, and USDA) and industry groups with information of interest to regulators, industry, and consumers. Responsibility for updating the web pages lies with the listed organization and those listed are up-to-date as of the printing of the 2005 Food Code.

FDA Publications:

These guidance documents identify the kinds of preventive measures that food establishment and food processing operators may take to minimize risks to food under their control, from tampering or other malicious, criminal, or terrorist actions:

- **Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance** at http://www.cfsan.fda.gov/~dms/secgui11.html.

- **Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance** at http://www.cfsan.fda.gov/~dms/secguid6.html.

- **Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance** at http://www.cfsan.fda.gov/~dms/secguid8.html.

- **Importers and Filers: Food Security Preventive Measures Guidance** at http://www.cfsan.fda.gov/~dms/secguid7.html.

- The **Bioterrorism Act of 2002** at http://www.fda.gov/oc/bioterrorism/bioact.html

  Additional information on FDA food security guidance publications is available over the Internet at http://www.cfsan.fda.gov; individual copies are available by mail from CFSAN (1-888-SAFE-FOOD).

  Further information on Countering Bioterrorism and Other Threats to the Food Supply can be found at http://www.foodsafety.gov/~fsg/bioterr.html.

USDA Publications:

- **Food Safety and Inspection Service (FSIS) Security Guidelines for Food Processors** at http://www.fsis.usda.gov/oa/topics/securityguide.htm.

- **FSIS Guidelines "Keep America's Food Safe"** at http://www.fsis.usda.gov/Food_Security_&_Emergency_Preparedness/Keep_Americas_Food_Safe/index.asp. This guidance is designed to assist transporters, warehouses, distributors, retailers, and restaurants with enhancing their security programs to further protect the food supply from contamination due to criminal or terrorist acts.

- **FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products** at http://www.fsis.usda.gov/oa/topics/transportguide.htm. This guidance contains recommendations to ensure the security of food products through all phases of the distribution process.

  Additional information on FSIS food security guidance publications is available over the Internet at http://www.fsis.usda.gov.

Industry Publications:

- **National Restaurant Association**. Information for restaurants can be found on the National Restaurant Association's web page at http://www.restaurant.org.

- **Food Marketing Institute** (FMI) Security Information and Resources web page at http://www.fmi.org/foodsafety/bio_security.htm, provides access to security information and guidelines targeted specifically to food retailers.

- **Food and Agriculture ISAC** – Information Sharing and Analysis Center web page at http://www.fmi.org/isac/.

  The Food and Agriculture ISAC is a partnership of food industry associations coordinated by the Food Marketing Institute (FMI). The primary purpose of the partnership is the rapid and confidential dissemination of information gathered by

the government's intelligence community to the food industry regarding any actual or potential threats arising from deliberately malicious or terrorist activity.

Guidance on Responding to Food Emergencies:

- Centers for Disease Control and Prevention (CDC) Emergency Preparedness and Response information can be found at http://www.bt.cdc.gov/.

- USDA – Food and Nutrition Service food emergency publication, **Responding to a Food Recall** at http://www.nfsmi.org/Information/recallmanual.pdf.

  FDA's Office of Emergency Operations at 301-443-1240 for FDA regulated products and FSIS Technical Service Center at 1-800-233-3935 for USDA regulated products.

Food Defense and Emergency Guidance of Interest to Schools:

- **A Biosecurity Checklist for School Foodservice: Developing a Biosecurity Management Plan**

  The document is from the USDA – Food and Nutrition Service and provides information for school food service managers. It can be found on the Healthy School Meals Resource System website at http://schoolmeals.nal.usda.gov/Safety/FNSFoodSafety.htm. The exact link to the checklist is http://schoolmeals.nal.usda.gov/Safety/biosecurity.pdf. Currently the checklist is only available in an electronic format.

- USDA – Food and Nutrition Service food emergency publication, **Emergency Readiness Plan: A Guide for the School Foodservice Operation** at http://www.nfsmi.org/Information/e-readinessguide.pdf.

Defense Guidance of Interest to Consumers:

- **Food Safety and Security: What Consumers Need to Know**, at http://www.fsis.usda.gov/OA/topics/foodsec_cons.htm.

- **Frequently Asked Consumer Questions About Food Safety and Terrorism**. An FDA /CFSAN publication to assist consumers in understanding the FDA role in protecting the food supply and the consumer role protecting their own food at http://www.cfsan.fda.gov/~dms/fsterrqa.html.

- **Food Tampering: An Extra Ounce of Caution**, at http://www.cfsan.fda.gov/~dms/fstamper.html.

Annex

3 Public Health Reasons/ Administrative Guidelines

CHAPTER 1	PURPOSE AND DEFINITIONS
CHAPTER 2	MANAGEMENT AND PERSONNEL
CHAPTER 3	FOOD
CHAPTER 4	EQUIPMENT, UTENSILS, AND LINENS
CHAPTER 5	WATER, PLUMBING, AND WASTE
CHAPTER 6	PHYSICAL FACILITIES
CHAPTER 7	POISONOUS OR TOXIC MATERIALS
CHAPTER 8	COMPLIANCE AND ENFORCEMENT

Chapter 1 Purpose and Definitions

Applicability and Terms Defined **1-201.10** **Statement of Application and Listing of Terms.**

(B) ***Terms Defined***

The individual definitions in Chapter 1 are not numbered, consistent with current conventions regarding the use of plain language in drafting rules, and with use in national and international standards and some Federal regulations. This facilitates making changes to the definitions as they become necessary in subsequent editions of the Food Code. The intent of the definitions to be binding in terms of the application and interpretation of the Code is clearly stated in Chapter 1.

Accredited Program.

Food protection manager *certification* occurs when *individuals* demonstrate through a certification program that they have met specified food safety knowledge standards.

Food protection certification program *accreditation* occurs when *certification organizations* demonstrate through an accreditation program that they have met specified program standards.

Accreditation is a conformity assessment process through which organizations that certify individuals may voluntarily seek independent evaluation and listing by an

accrediting agency based upon the certifying organization's meeting program accreditation standards. Such accreditation standards typically relate to such factors as the certifying organization's structure, mission, policies, procedures, and the defensibility of its examination processes. These standards are intended to affirm or enhance the quality and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness to candidates for certification and others, and thereby increase public health protection.

Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the *Standards for Accreditation of Food Protection Manager Certification Programs* available from the Conference for Food Protection, 1085 Denio Avenue, Gilroy, CA 95020-9206 and found at http://www.foodprotect.org/pdf/standards.pdf.

Allowing food protection managers to demonstrate their required food safety knowledge "through passing a test that is part of an accredited program" is predicated on the fact that their credentials have been issued by certifying organizations that have demonstrated conformance with rigorous and nationally recognized program standards.

Egg.

The definition of egg includes avian species' shell eggs known to be commercially marketed in the United States. Also included are the eggs of quail and ratites such as ostrich.

Not included are baluts. Baluts are considered a delicacy among Philippine and Vietnamese populations. They are derived from fertile eggs, typically duck eggs, subjected to incubation temperatures for a period of time less than necessary for the embryo to hatch resulting in a partially formed embryo within the shell. Under the Egg Products Inspection Act (EPIA), an egg is typically considered adulterated if it has been subjected to incubation. However, in 9 CFR 590.5, baluts are specifically exempted from inspection as eggs under the EPIA.

In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 42.5°C (108.5°F) in incubators with a relatively high humidity. (Complete development and hatching would take place in 28 days.) Under these conditions, the potential for growth of transovarian *Salmonella* organisms such as *S.* Enteritidis within the shell, and the potential for an increase in pathogenic microflora on the shell itself, are increased. Where chicken eggs are used in preparing baluts, the incubation period may only be 14 days at an incubation temperature of 37°C (99°F). A balut is a potentially hazardous food (time/temperature control for safety food) subject to time/temperature management including proper cooking and hot and cold holding. Baluts are typically boiled and packed in salt before sale or service.

Also, not included in this definition are the eggs of reptile species such as alligators and turtles. Alligator eggs are available for sale in some parts of the southern United States. In restaurants, the menu item “Alligator Eggs” is sometimes made of alligator egg, but other times is simply a fanciful name for a menu item that may include seafood items such as shrimp, but contains no alligator egg.

Sea turtle eggs have been consumed in Asian and Latin American Countries. However, turtle eggs are not mentioned in the definitions section because sea turtles (Loggerhead, East Pacific Green, Leatherback, Hawksbill, Kemp’s Ridley, and Olive Ridley) are protected by The Endangered Species Act of 1973 and therefore may not be sold or consumed. This Act, with respect to turtle eggs, is enforced by the United States Department of Interior, U.S. Fish and Wildlife Service, Washington, DC.

Potentially Hazardous Food (Time/Temperature Control for Safety Food)

Potentially hazardous food (PHF/TCS food) is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is considered whether slow or rapid.

The definition of PHF/TCS food takes into consideration pH, a_w, pH and a_w interaction, heat treatment, and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. If the food is heat-treated to eliminate vegetative cells, it needs to be addressed differently than a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to destroy negative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because remaining spore-forming bacteria are the only microbial hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the package, they must be protected from contamination in an area with limited access and packaged before temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the a_w value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and a_w may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone.

In determining if time/temperature control is required, combination products present their own challenge. A combination product is one in which there are two or more distinct food components and an interface between the two components may have a different property than either of the individual components. A determination must be made about whether the food has distinct components such as pie with meringue topping, focaccia bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform consistency such as gravies, puddings, or sauces. In these products, the pH at the interface is important in determining if the item is a PHF/TCS food.

A well designed inoculation study or other published scientific research should be used to determine whether a food can be held without time/temperature control when:

- process technologies other than heat are applied to destroy foodborne pathogens (e.g., irradiation, high pressure processing, pulsed light, ozonation);
- combination products are prepared; or
- other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential, salt content, antimicrobials) are used to control or eliminate pathogen growth.

Before using Tables A and B in paragraph 1-201.10(B) of the definition for "potentially hazardous food (time/temperature control for safety food)" in determining whether a food requires time/temperature control for safety (TCS), answers to the following questions should be considered:

- Is the intent to hold the food without using time or temperature control?
    - If the answer is No, no further action is required. The decision tree later in this Annex is not needed to determine if the item is a PHF/TCS food.
- Is the food raw, or is the food heat-treated?
- Does the food already require time/temperature control for safety by definition in paragraph 1-201.10(B)?
- Does a product history with sound scientific rationale exist indicating a safe history of use?
- Is the food processed and packaged so that it no longer requires TCS such as ultra high temperature (UHT) creamers or shelf-stable canned goods?
- What is the pH and a_w of the food in question using an independent laboratory and Association of Official Analytical Chemists (AOAC) methods of analysis?

A food designated as meeting product assessment (PA), in either table should be considered PHF until further study proves otherwise. The PA means that based on the food's pH and a_w and whether it was raw or heat-treated or packaged, it has to be considered PHF until inoculation studies or some other acceptable evidence shows that the food is a PHF/TCS food or not. The Food Code requires a variance request to the regulatory authority with the evidence that the food does not require time/temperature control for safety.

If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than flavor enhancement, a variance is required under ¶ 3-502.11(C). A HACCP plan is required whether the food is a PHF/TCS food as in (C)(1) or not a PHF/TCS food, as in (C)(2). A standardized recipe validated by lab testing for pH and a_w would be an appropriate part of the variance request with annual (or other frequency as specified by the regulatory authority) samples tested to verify compliance with the conditions of the variance.

More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at http://www.cfsan.fda.gov/~comm/ift4-toc.html.

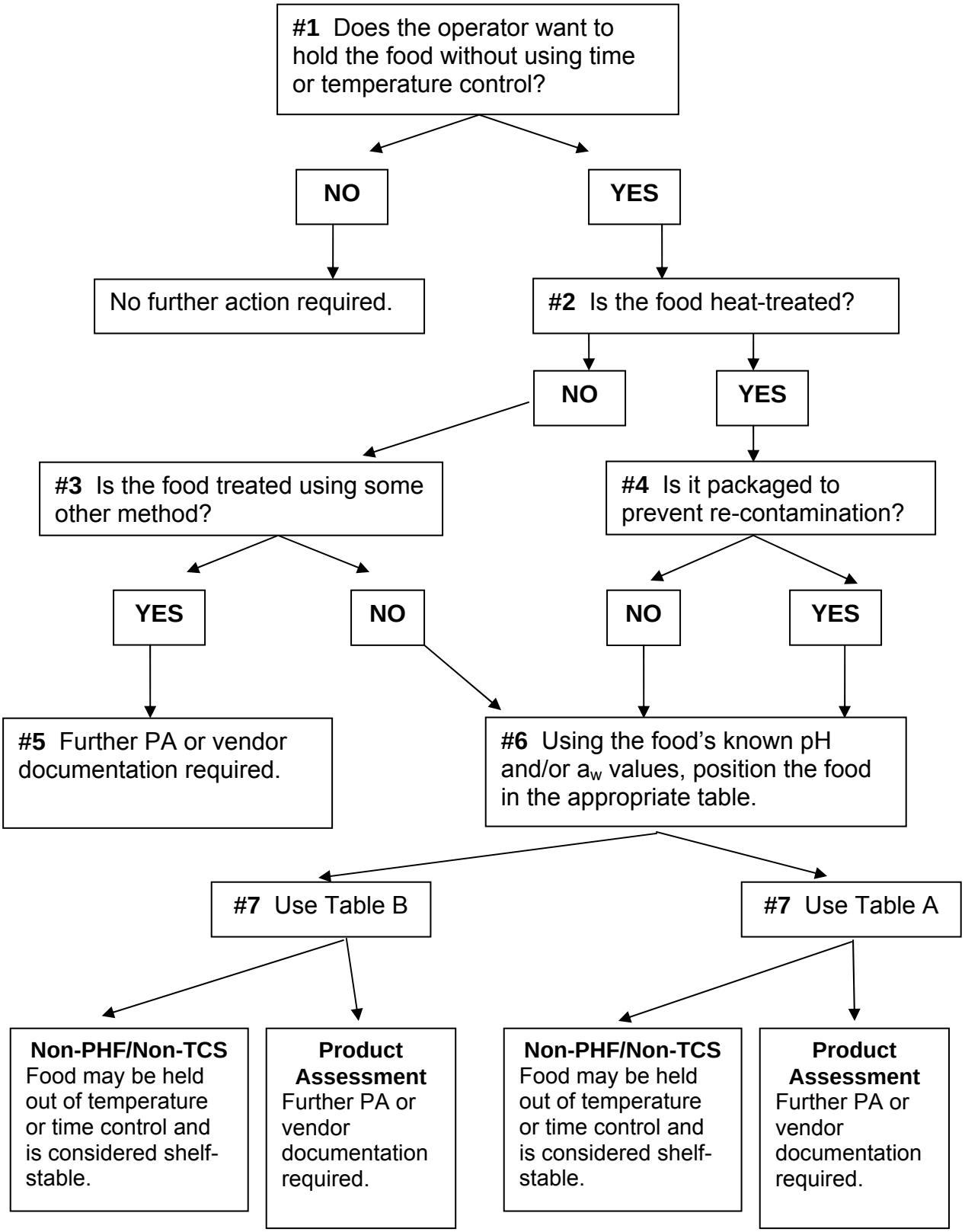
Instructions for using the following Decision Tree and Table A and Table B:

1. Does the operator want to hold the food without using time or temperature control?
    a. No – Continue holding the food at ≤5°C(41°F) or ≥57°C(135°F) for safety and/or quality.
    b. Yes – Continue using the decision tree to identify which table to use to determine whether time/temperature control for safety (TCS) is required.
2. Is the food heat-treated?
    a. No – The food is either raw, partially cooked (not cooked to the temperature specified in section 3-401.11 of the Food Code) or treated with some other method other than heat. Proceed to step #3.
    b. Yes – If the food is heat-treated to the required temperature for that food as specified under section 3-401.11 of the Food Code, vegetative cells will be destroyed although spores will survive. Proceed to step #4.
3. Is the food treated using some other method?
    a. No –The food is raw or has only received a partial cook allowing vegetative cells and spores to survive. Proceed to step #6.
    b. Yes – If a method other than heat is used to destroy pathogens such as irradiation, high pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the effectiveness of the process needs to be validated by inoculation studies or other means. Proceed to step #5.
4. Is it packaged to prevent re-contamination?
    a. No – Re-contamination of the product can occur after heat treatment because it is not packaged. Proceed to step #6.
    b. Yes – If the food is packaged immediately after heat treatment to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because spore-forming bacteria are the only microbial hazard. Proceed to step #7.
5. Further product assessment or vendor documentation required.
    a. The vendor of this product may be able to supply documentation that inoculation studies indicate the food can be safely held without time/temperature control for safety.
    b. Food prepared or processed using new technologies may be held without time/temperature control provided the effectiveness of the use of such technologies is based on a validated inoculation study.
6. Using the food's known pH and/or a_w values, position the food in the appropriate table.
    a. Choose the column under "pH values" that contains the pH value of the food in question.
    b. Choose the row under "a_w values" that contains the a_w value of the food in question.

c. Note where the row and column intersect to identify whether the food is “non-PHF/non-TCS food” and therefore does not require time/temperature control, or whether further product assessment (PA) is required. Other factors such as redox potential, competitive microorganisms, salt content, or processing methods may allow the product to be held without time/temperature control but an inoculation study is required.

7. Use **Table A** for foods that are heat-treated and packaged **OR** use **Table B** for foods that are not heat-treated or heat-treated but not packaged.
8. Determine if the item is non-PHF/non-TCS or needs further product assessment (PA).

1-201.10(B) Decision Tree #1 – Using pH, a_w, or the Interaction of pH and a_w to Determine if a Food Requires Time/Temperature Control for Safety



1-201.10(B) – Table A and Table B

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged

a_w values	pH values		
	4.6 or less	> 4.6 - 5.6	> 5.6
≤0.92	non-PHF*/non-TCS FOOD**	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD
> 0.92 - .95	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD	PA***
> 0.95	non-PHF/non-TCS FOOD	PA	PA

* PHF means Potentially Hazardous Food
** TCS food means Time/Temperature Control for Safety food
*** PA means Product Assessment required

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged

a_w values	pH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	non-PHF*/ non-TCS food**	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food
0.88 – 0.90	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA***
> 0.90 – 0.92	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA	PA
> 0.92	non-PHF/ non-TCS food	PA	PA	PA

* PHF means Potentially Hazardous Food
** TCS food means Time/Temperature Control for Safety food
*** PA means Product Assessment required

Chapter 2 Management and Personnel

Responsibility **2-101.11 Assignment.***

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

Knowledge **2-102.11 Demonstration.***

The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

The Food Code does not require reporting of uninfected cuts or reporting of covered, protected infected cuts/lesions/boils since no bare hand contact with ready-to-eat (RTE) food is a Code requirement.

2-102.20 Food Protection Manager Certification.

Many food protection manager certification programs have shared a desire to have the food manager certificates they issue universally recognized and accepted by others – especially by the increasing number of regulatory authorities that require food manager certification.

Needed has been a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and administration.

After a multi-year effort involving a diversity of stakeholder groups, the Conference for Food Protection (CFP) completed work on its ***Standards for Accreditation of Food Protection Manager Certification Programs*** found at http://www.foodprotect.org/pdf/standards.pdf. In 2002 the Conference entered into a cooperative agreement with the American National Standards Institute (ANSI) to provide independent third-party evaluation and accreditation of certification bodies determined to be in conformance with these Conference standards. ANSI published its first listing of accredited certifiers in 2003.

The Acting Commissioner of the Food and Drug Administration, in his address before the 2004 biennial meeting of the Conference for Food Protection, commended this Conference achievement and encouraged universal acceptance based on the CFP/ANSI accreditation program.

Distributed at this meeting was the following letter addressed to the Conference Chair and signed by the Director of FDA's Center for Food Safety and Applied Nutrition. The letter puts forth the Agency's basis for its support of universal acceptance of food protection manager certifications.

> "The 2004 biennial meeting of the **Conference for Food Protection** is a fitting occasion for FDA's Center for Food Safety and Applied Nutrition to commend the Conference for its significant achievements in support of State and local food safety programs.
>
> The FDA in a Memorandum of Understanding recognizes the Conference for Food Protection as a voluntary national organization qualified to develop standards to promote food protection. Conference recommendations contribute to improvements in the model FDA Food Code and help jurisdictions justify, adopt and implement its provisions.
>
> Conference mechanisms involving active participation by representatives of diverse stakeholder groups produce consensus standards of the highest quality. An excellent example is the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***, and its announcement of the new on-line listing of accredited certifiers of industry food protection managers. Many years in their development, these Conference standards identify the essential components necessary for a credible certification program. Components cover a wide range of requirements such as detailed criteria for exam development and administration, and responsibilities of the certification organization to candidates and the public.
>
> FDA applauds the Conference for this significant achievement, and encourages agencies at all levels of government to accept certificates issued by listed certifiers as meeting their jurisdictions' food safety knowledge and certification requirements. The American National

Standards Institute (ANSI) has independently evaluated these certification programs under an agreement with the Conference for Food Protection. Governments and industry widely recognize and respect ANSI as an accrediting organization. ANSI has found certifiers it lists as accredited (http://www.ansi.org/) under "conformity assessment" – "personnel certification accreditation" to conform to the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***.*

The Food Code states the person in charge of a food establishment is accountable for developing, carrying out, and enforcing procedures aimed at preventing food-borne illness. Section 2-102.11 states that one means by which a person in charge may demonstrate required knowledge of food safety is through certification as a food protection manager by passing an examination that is part of an accredited program.

FDA encourages food regulatory authorities and others evaluating credentials for food protection managers to recognize the Conference for Food Protection/ANSI means of accrediting certification programs. This procedure provides a means for universal acceptance of individuals who successfully demonstrate knowledge of food safety. The procedure provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria. In addition, universal acceptance eliminates the inconvenience and unnecessary expense of repeating training and testing when managers work across jurisdictional boundaries.

FDA, along with State, local, tribal, and other Federal agencies and the food industry, share the responsibility for ensuring that our food supply is safe. It is anticipated that this new Conference for Food Protection/ANSI program will lead to enhanced consumer protection, improve the overall level of food safety, and be an important component of a seamless national food safety system."

Duties **2-103.11 Person in Charge.**

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

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*ANSI's "***Directory of Accredited Personnel Certification Programs utilizing Conference for Food Protection (CFP) Standards***" may be viewed on-line by going to http://www.ansi.org. Select "Accreditation Services" in the menu on the left. Then select "ANSI Accredited Personnel Certification Bodies and Applicants" in the new left-hand menu under the heading "Personnel Certification Accreditation."

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced. Paragraph (L) "EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties" allows industry to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

2-2 Employee Health

Overall goals

The purpose of this section of the Food Code is to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food workers into food. The agents of concern are known to be readily transmissible via food that has been contaminated by ill food workers, and so for that reason, are the primary focus of the Employee Health section of the Food Code. However, there are different levels of risk associated with different levels of clinical illness. The structure of the restrictions and exclusions has, therefore, been designed in a tiered fashion depending on the clinical situation to offer the maximum protection to public health with the minimal disruption to employees and employers.

Four levels of illness or potential illness have been identified with the first level being the highest potential risk to public health and the fourth level being the lowest. The first level relates to employees who have specific symptoms (e.g., vomiting, diarrhea, jaundice) while in the workplace. These symptoms are known to be associated commonly with the agents most likely to be transmitted from infected food workers through contamination of food. The first level also relates to employees who have been diagnosed with typhoid fever or an infection with hepatitis A virus (within 14 days of symptoms). The second level relates to employees who have been diagnosed with the specific agents that are of concern, but who are not exhibiting symptoms of disease because their symptoms have resolved. The third level relates to employees who are diagnosed with the specific agents, but never develop any gastrointestinal symptoms. The fourth level relates to those individuals who are clinically well but who may have been exposed to a listed pathogen and are within the normal incubation period of disease.

The most significant degree of restriction and exclusion applies to the first level of food employee illness. Infected food employees in the first level are likely to be excreting high levels of their infectious pathogen, increasing the chance of transmission to food products, and thus on to those consuming the food. The first level includes food employees who are:

- Experiencing active symptoms of diarrhea or vomiting – with no diagnosis,
- Experiencing jaundice within the last 7 days-- with no diagnosis,
- Diagnosed with typhoid fever,
- Diagnosed with hepatitis A within 7 days of jaundice or 14 days of any symptoms, or
- Experiencing active symptoms of diarrhea or vomiting, and diagnosed with Norovirus, ***E. coli*** O157:H7 or other Enterohemorrhagic ***Escherichia coli*** (EHEC) or Shiga toxin-producing ***Escherichia coli*** (STEC), or ***Shigella*** spp. infection.

Diagnosis with typhoid fever or hepatitis A virus is included in level 1 because employees diagnosed with these pathogens are likely to be shedding high levels of the pathogen in their stool without exhibiting gastrointestinal symptoms. Peak levels of hepatitis A viral shedding in the feces typically occurs before symptoms appear. Diarrhea and vomiting are reliable indicators of infection with Norovirus, ***E. coli*** O157:H7 or other EHEC, and ***Shigella*** spp., but are not typical symptoms of typhoid fever or hepatitis A. For example, employees diagnosed with typhoid fever are more likely to experience constipation, rather than diarrhea. Jaundice is also not always reliable as an indicator of a hepatitis A infection because employees can be infected with hepatitis A virus without experiencing jaundice (anicteric employees).

Maximum protection to public health requires excluding food employees suffering from typhoid fever, hepatitis A virus, or specific gastrointestinal symptoms associated with diseases identified as likely to be transmitted through contamination of food (See section 2-201.12, Tables 2-201.12 #1a and #1b in this Annex). This situation describes the highest level of risk in transmitting pathogens to food, or what we would find in the first level.

Food employees who have been diagnosed with one of the agents of concern, but are not symptomatic because their symptoms have resolved, are still likely to be carrying the infected agent in their intestinal tract. This makes such employees less likely to spread the agent into food than others who are actually symptomatic, but employees diagnosed with one of the agents of concern still pose an elevated threat to public health. For this reason, there are a series of exclusions (if the employees work in facilities serving highly susceptible populations (HSP)) and restrictions (for non-HSP facilities) depending on the agent involved (See section 2-201.12, Table #2). This situation describes the second level of risk in transmitting pathogens to food.

Diagnosed, asymptomatic food employees who never develop symptoms are typically identified during a foodborne illness outbreak investigation through microbiological testing. If infected and asymptomatic employees are not microbiologically tested, they will remain undetected and could therefore extend the duration of a foodborne illness outbreak through continued contamination of food. The Food Code provides restriction or exclusion guidelines for employees that are identified through microbiological testing with an infection from a listed foodborne pathogen, but are otherwise asymptomatic and clinically well (See section 2-201.12, Table #3). The exclusion or restriction guidelines

are applied until the identified food employees no longer present a risk for foodborne pathogen transmission. This situation describes the third level of risk in transmitting pathogens to food.

Some food employees or conditional employees may report a possible exposure to an agent. For example, a food employee may have attended a function at which the food employee ate food that was associated with an outbreak of shigellosis, but the employee remains well. Such individuals fall into the category of having had a potential exposure and present a lower risk to public health than someone who is either symptomatic or who has a definitive diagnosis. They present a level of risk to public health that is greater than if they had not had the exposure. The approach taken in the Food Code to food employees who have had a potential exposure is based on the incubation times (time between exposure and the onset of symptoms) of the various agents. The times chosen for restriction are the upper end of the average incubation periods for the specific agents. The reasoning is that this will restrict food employees only up to the time when it is unlikely they will develop symptoms. As a further protection to public health, it is recommended that such exposed food employees pay particular attention to personal hygiene and report the onset of any symptoms (See section 2-201.12, Table #4). This situation describes the fourth level of risk in transmitting pathogens to food.

This structured approach has linked the degree of exclusion and restriction to the degree of risk that an infected food worker will transmit an agent of concern into food. The approach strikes a balance between protecting public health and the needs of the food employee and employer.

The Food Code provisions related to employee health are aimed at removing highly infectious food employees from the work place. They were developed with recognition of the characteristics of the five important pathogens, and of the risk of disease transmission associated with symptomatic and asymptomatic shedders. The provisions also account for the increased risk associated with serving food to HSP's and the need to provide extra protection to those populations.

The Employee Health section was developed and revised with assistance and input from the Centers for Disease Control and Prevention (CDC) and the U.S. Equal Employment Opportunity Commission (EEOC). The exclusion and restriction criteria are based on communicable disease information, as required by the Americans with Disabilities Act of 1990, in the "The List of Infectious and Communicable Diseases Which are Transmitted through the Food Supply" published in the Federal Register on October 4, 2004, (Volume 69, Number 191) by the CDC, and from the Control of Communicable Diseases Manual, 18th Ed., David L. Heymann, MD, Editor, by the American Public Health Association, Washington D.C., 2004.

2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201

The information provided in Subpart 2-201 is designed to assist food establishment managers and regulatory officials in removing infected food employees when they are at greatest risk of transmitting foodborne pathogens to food. Practical applications of the information in Subpart 2-201 by a food establishment manager may involve using Subpart 2-201 as a basis for obtaining information on the health status of food employees and can also be used as a basis in developing and implementing an effective Employee Health Policy. Regulatory officials can benefit by using the information provided below as a basis for determining compliance with Subpart 2-201 during a facility food safety inspection.

The development and effective implementation of an employee health policy based on the provisions in Subpart 2-201 may help to prevent foodborne illness associated with contamination of food by ill or infected food employees. The person in charge and food employees should be familiar with and able to provide the following information through direct dialogue when interviewed by facility managers or regulatory officials. Also, when designing and implementing an employee health policy, the following information should be considered and addressed:

1. Does the establishment have an Employee Health Policy? If so, are the food employees aware of the employee health policy, and is it available in written format and readily available for food employees? (Note: A written Employee Health Policy is not a Food Code requirement unless the facility is operating under a pre-approved alternative procedure specified under ¶ 3-301.11(D)).
2. Does the establishment require conditional employees and food employees to report certain illnesses, conditions, symptoms, and exposures?
3. Are the reporting requirements explained to all employees?
4. What are the reporting requirements for conditional employees, food employees, and the food establishment manager?
5. Are conditional employees asked if they are experiencing certain symptoms or illnesses upon offer of employment? If so, which symptoms or illnesses?
6. If a food employee reports a diagnosis with one of the 5 listed pathogens in the Food Code, what questions are asked of the food employee? (The first question every food manager should ask a food employee who reports diagnosis with a listed pathogen is if the employee is currently having any symptoms.)
7. Who does the establishment notify when a food employee reports a diagnosis with one of the listed pathogens?
8. What gastrointestinal symptoms would require exclusion of a food employee from the food establishment?
9. What history of exposure is a conditional employee or food employee required to report?
10. If a food employee reports a gastrointestinal symptom, what criteria are used to allow the employee to return to work?

Responsibilities and Reporting Symptoms and Diagnosis	**2-201.11**	**Responsibility of the Person in Charge, Food Employees, and Conditional Employees.***

Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. The person in charge is responsible for ensuring all food employees and conditional employees are knowledgeable and understand their responsibility to report listed symptoms, diagnosis with an illness from a listed pathogen, or exposure to a listed pathogen to the person in charge. The person in charge is also responsible for reporting to the regulatory official if a food employee reports a diagnosis with a listed pathogen.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or has a history of exposure to a listed pathogen in this Code may transmit disease through the food being prepared. The person in charge must first be aware that a food employee or conditional employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

The person in charge may observe some of the symptoms that must be reported. However, food employees and conditional employees share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the listed symptoms, have a history of exposure to one of the listed pathogens, or have been diagnosed with an illness caused by a listed pathogen. Food employees must comply with restrictions or exclusions imposed upon them.

A conditional employee is a potential food employee to whom a job offer has been made, conditional on responses to subsequent medical questions or examinations. A conditional employee becomes a food employee as soon as the employee begins working, even if only on a restricted basis. When a conditional employee reports a listed diagnosis or symptom, the person in charge is responsible for ensuring that the conditional employee is prohibited from becoming a food employee until the criteria for reinstatement of an exclusion are met (as specified under section 2-201.13 of the Food Code). When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded symptomatic or diagnosed food employee (as specified under section 2-201.13 of the Food Code), the conditional employee may then begin working as a food employee.

Reporting Symptoms:

In order to protect the health of consumers and employees, information concerning the health status of conditional employees and food employees must be disclosed to the person in charge. The symptoms listed in the Code cover the common symptoms

experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. A food employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

The symptoms of vomiting, diarrhea, or jaundice serve as an indication that an individual may be infected with a fecal-oral route pathogen, and is likely to be excreting high levels of the infectious agent. When a food employee is shedding extremely high numbers of a pathogen through the stool or vomitus, there is greater chance of transmitting the pathogen to food products.

Sore throat with fever serves as an indication that the individual may be infected with *Streptococcus pyogenes. Streptococcus pyogenes* causes a common infection otherwise known as "streptococcal sore throat" or "strep throat." Streptococcal sore throat can spread from contaminated hands to food, which has been the source of explosive streptococcal sore throat outbreaks. Previous foodborne episodes with streptococcus sore throat have occurred in contaminated milk and egg products. Food products can be contaminated by infected food workers hands or from nasal discharges. Untreated individuals in uncomplicated cases can be communicable for 10-21 days, and untreated individuals with purulent discharges may be communicable for weeks or months.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing ***Staphylococcus aureus*** into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing ***Staphylococcus aureus*** into food.

If a food employee has an infected cut and bandages it and puts on a glove, the employee does not have to report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is required.

Title I of the Americans with Disabilities Act of 1990 (ADA)

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant's health status.

The ADA also requires that employers provide reasonable accommodation to qualified applicants and employees with disabilities. A reasonable accommodation is a change in the application process, in the way a job is done, or to other parts of the job that enables a person with a disability to have equal employment opportunities. ADA disabilities are serious, long-term conditions. Most people with diseases resulting from the pathogens listed in the Food Code do not have ADA disabilities because these diseases are usually short-term in duration. In addition, the gastrointestinal symptoms listed in the Food Code usually are not long-term and severe enough, in themselves, to be ADA disabilities. Of course, these symptoms may be linked to other conditions that may be serious enough to be ADA disabilities, like Crohn's disease or cancer.

A food employer may exclude any employee under the Food Code upon initially learning that the employee has *Salmonella* Typhi, or has a gastrointestinal symptom listed in the Food Code. The excluded employee may then ask for an ADA reasonable accommodation instead of the exclusion. In response, the employer's first step should be to ask the employee to establish that the employee is disabled by the disease or symptom (or that the symptom is caused by another ADA disability). If the employee successfully proves that the employee has an ADA disability, then the employer may continue to exclude the employee under the Food Code if:

- there is no reasonable accommodation at work that would eliminate the risk of transmitting the disease while also allowing the employee to work in a food handling position, or

- all reasonable accommodations would pose an undue hardship on the employer's business; and

- there is no vacant position **not involving food handling** for which the employee is qualified and to which the employee can be reassigned.

Example 1: A food employee working in the café of a department store informs the employer that the employee has been diagnosed with a disease caused by *Salmonella* Typhi. The employer immediately excludes the employee under the requirements of the Food Code. The employee then establishes that the disease is an ADA disability because it is severe and long-term and the employee requests reasonable accommodation instead of an exclusion. The employer determines that no reasonable accommodation would eliminate the risk of transmitting *Salmonella* Typhi through food and refuses to remove the exclusion. However, there is a vacant clerical position in another part of the store for which the employee is qualified. Unless the employer can establish that reassigning the employee to this position would be an undue hardship, the employer's failure to make the reassignment instead of continuing the exclusion would be a violation of the ADA.[1]

[1] Whether or not the employee in question is an individual with an ADA diability, in those jurisdictions where the Code is adopted, Food Code exclusions or restrictions must be removed when requirements for removal under § 2-201.13 of the Code are met.

Example 2: A food employee has diarrhea and is excluded. The employee establishes that the diarrhea is caused by Crohn's disease. This employee also establishes a serious longstanding history of Crohn's disease and is an individual with an ADA disability. Crohn's disease is not a communicable disease and cannot be transmitted through food. No reasonable accommodation is needed to eliminate the risk of transmitting the disease through the food supply, so the Food Code exclusion should be removed. Of course, the Food Code's provisions on personal cleanliness for hands and arms apply as usual, requiring employees to clean hands and exposed portions of arms after using the toilet room and in other specified circumstances (Subpart 2-301).

Somewhat different rules apply to conditional employees. If a conditional employee reports a disease or symptom listed in the Food Code and shows that the disease or symptom makes the conditional employee an individual with an ADA disability, the employer may withdraw the job offer only if:

- The job involves food handling; and
- The employer determines that either there is no reasonable accommodation that would eliminate the risk of transmitting the disease through food, or any such accommodation would be an undue hardship to the business.
- There is no need to offer the conditional employee a vacant position not involving food handling as a reasonable accommodation.

It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in Annex 2 that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission. See the Equal Employment Opportunity Commission's *How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers*, found at http://www.eeoc.gov/facts/restaurant_guide.html or http://www.eeoc.gov/facts/restaurant_guide_summary.html for detailed information about the interaction between the FDA Food Code and the ADA.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease that can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness. Applicants, to whom a conditional offer of employment is extended, and food employees are required to report their specific history of exposure, medical symptoms, and previous illnesses. The symptoms listed

may be indicative of a disease that is transmitted through the food supply by infected food employees.

As required by the ADA, the CDC published in the Federal Register on October 4, 2004, (Volume 69, Number 191) a list of infectious and communicable diseases that are transmitted through food. The CDC updates the list annually.
See "List of Infectious and Communicable Diseases which are Transmitted through the Food Supply" at
http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/pdf/04-22260.pdf). The list is divided into two parts: pathogens often transmitted and pathogens occasionally transmitted by infected persons who handle food.

The following Lists summarize the CDC list by comparing the common symptoms of each pathogen. Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. The CDC has no evidence that the HIV virus is transmissible via food. Therefore, a food employee positive for the HIV virus is not of concern unless suffering secondary illness listed below. The following Lists include all enterohemorrhagic or Shiga toxin-producing ***E. coli*** likely to occur in foods in the United States.

LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens.

	D	**F**	**V**	**J**	**S**
1. Noroviruses	D	F	V		
2. Hepatitis A virus	-	F	-	J	-
3. ***Salmonella* Typhi**	-	F	-	-	-
4. ***Shigella*** species	D	F	V	-	-
5. ***Staphylococcus aureus***	D	-	V	-	-
6. ***Streptococcus pyogenes***	-	F	-	-	S

LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons Who Handle Food, But Usually Transmitted by Contamination at the Source or in Food Processing or by Non-foodborne Routes.

	D	**F**	**V**	**J**	**S**
1. ***Campylobacter jejuni***	D	F	V	-	-
2. ***Cryptosporidium parvum***	D	-	-	-	-
3. ***Entamoeba histolytica***	D	F	-	-	-
4. Enterohemorrhagic ***Escherichia coli***	D	-	-	-	-
5. Enterotoxigenic ***Escherichia coli***	D	-	V	-	-
6. ***Giardia lamblia***	D	-	-	-	-
7. Non-typhoidal ***Salmonella***	D	F	V	-	-
8. ***Taenia solium***	-	-	-	-	-

9. ***Vibrio cholerae*** 01	D	-	V	-	-
10. ***Yersinia enterocolitica***	D	F	V	-	-

KEY: D = Diarrhea V = Vomiting S = Sore throat with fever
F = Fever J = Jaundice

The 5 Listed Pathogens:

The CDC has designated the 5 organisms listed in the Food Code as having high infectivity via contamination of food by infected food employees. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and/ or the severity of the medical consequences to those who become ill.

The following is taken from information provided in the 18th Edition of Control of Communicable Diseases Manual, the CDC website, and the FDA Bad Bug Book, and is provided as background information on pathogen virulence, infectivity, and common symptoms exhibited with infection of each of the 5 listed pathogens.

NOROVIRUS

Noroviruses (genus Norovirus, family Caliciviridae) are a group of small (27-40nm), round structured, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. Norovirus has also been commonly known as “Norwalk-like virus,” “Small Round-structured Virus,” and “Winter Vomiting Disease.”

The CDC estimates that Norovirus is the leading cause of foodborne illness in the United States. Transmission of Norovirus has been shown to occur most commonly through the fecal oral route, with contaminated food identified as a common vehicle of transmission. Exclusion of food employees exhibiting or reporting diarrhea symptoms is an essential intervention in controlling the transmission of Norovirus from infected food employees’ hands to RTE food items. Norovirus also has a high secondary attack rate (> 50%) via person-to-person contact.

Norovirus has also been reported to cause infection by airborne transmission when individuals are in close physical proximity to an infected individual vomiting in the facility. Therefore an infected individual vomiting in a food facility increases the risk of infecting employees and consumers. Foodborne illness outbreaks have occurred from consumers vomiting in the dining room, or employees vomiting on the premises. Removing food employees exhibiting or reporting vomiting symptoms from the food facility protects consumers and fellow workers from infection with Norovirus.

Incubation Period: Generally between 24 and 48 hours (median in outbreaks 33 to 36 hours), but cases can occur within 12 hours of exposure.

Symptoms and Complications: Acute-onset explosive (or projectile) vomiting, watery non-bloody diarrhea with abdominal cramps, nausea, and occasionally, a low grade fever. Symptoms usually last 24 to 60 hours. Vomiting is more common in children. Recovery is usually complete and there is no evidence of any serious long-term sequelae. Among the young and the elderly, dehydration is a common complication. There is no long-term immunity to Norovirus and individuals may be repeatedly infected throughout their lifetimes. There is no specific therapy for viral gastroenteritis. Symptomatic therapy consists of replacement of fluid loss by the administration of liquids orally, and in rare instances, through parenteral intravenous fluid therapy. Earlier feeding studies conducted on Norovirus have found that as many as 30% of individuals infected with Norovirus are asymptomatic.

Infectivity: Noroviruses are highly contagious, and it is thought that an inoculum of as few as 10 viral particles may be sufficient to infect an individual. Although pre-symptomatic shedding may occur, shedding usually begins with onset of symptoms and may continue for 2 weeks after recovery. However the degree of infectivity of prolonged shedding has not been determined. Norovirus is shed at high levels in the stool: 10^5 – 10^7/g or more.

***SALMONELLA* TYPHI**

Salmonella enterica subspecies *enterica* serovar Typhi (commonly *S.*Typhi) causes a systemic bacterial disease, with humans as the only host. This disease is relatively rare in the United States, with fewer than 500 sporadic cases occurring annually in the U.S. Worldwide, the annual estimated incidence of Typhoid fever is about 17 million cases with approximately 600,000 deaths. Currently, most cases of ***S.* Typhi** in industrialized nations are imported into the country from developing countries. Antibiotic-resistant strains have become prevalent in several areas of the world.

Incubation period: Depends on inoculum size and on host factors: from 3 days to over 60 days, with a usual range of 8 – 14 days.

Symptoms: Insidious onset of sustained fever, marked headache, malaise, anorexia, relative bradycardia, splenomegaly, and nonproductive cough in the early stage of the illness, rose spots on the trunk in 25% of white skinned patients and constipation more often than diarrhea in adults. The illness varies from mild illness with low-grade fever to severe clinical disease with abdominal discomfort and multiple complications.

Infectivity: The minimal infectious dose is estimated to be less than 1000 bacterial cells. An individual infected with ***S.* Typhi** is infectious as long as the bacilli appear in the excreta, usually from the first week throughout the convalescence; variable thereafter. About 10% of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%-5% become permanent carriers; fewer persons affected with paratyphoid organisms may become permanent gallbladder carriers.

ENTEROHEMORRHAGIC OR SHIGA TOXIN-PRODUCING ESCHERICHIA *COLI*

E. coli O157:H7 is the most commonly identified strain of Enterohemorrhagic ***Escherichia coli*** (EHEC) or Shiga toxin-producing ***Escherichia coli*** (STEC) as a cause of foodborne illness in the United States. ***E. coli*** O157:H7 is a zoonotic disease derived from cattle and other ruminants. However, ***E. coli*** O157:H7 also readily transmits from person-to-person, so contaminated raw ingredients and ill food employees both can be sources of foodborne disease. Other EHEC or STEC serotypes have been identified as a source of foodborne illness in the United States, however not as frequently as ***E. coli*** O157:H7. The other serogroups most commonly implicated as a cause of foodborne illness in the United States are 026, 0111, 0103, 045, and 0121.

The Food Code definition of STEC covers all ***E. coli*** identified in clinical laboratories that produce Shiga toxins. Nearly 200 O:H combinations of ***E. coli*** have been shown to produce Shiga toxins. The Food Code definition includes all STEC, including those that have not been specifically implicated in human disease such as hemorrhagic colitis (i.e., bloody diarrhea) or hemolytic uremic syndrome (HUS). A subset of STEC that has the capacity to both produce Shiga toxin and cause “attaching and effacing” lesions in the intestine is classified as “enterohemorrhagic” (EHEC). EHEC ***E. coli*** cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Virtually all human isolates of ***E. coli*** O157:H7 seotypes are EHEC.

Incubation period: From 2-10 days, with a median of 3-4 days.

Symptoms: The illness is characterized by severe cramping (abdominal pain) and diarrhea with a range from mild and nonbloody to stools that are virtually all blood. Occasionally vomiting occurs. Some individuals exhibit watery diarrhea only. Lack of fever in most patients can help to differentiate this infection from other enteric pathogens. About 8% of individuals with ***E. coli*** O157:H7 diarrhea progress to HUS. This rate varies for other serotypes of Enterohemorrhagic ***E. coli.***

Infectivity: The infectious dose is for example ***E. coli*** O157:H7 can be as low as 10 bacterial cells. Children under 5 years old are most frequently diagnosed with infection and are at greatest risk of developing HUS. The elderly also experience a greater risk of complications. The duration of excretion of Enterohemorrhagic ***E. coli*** in the stool is typically 1 week or less in adults, but can be up to 3 weeks in one-third of infected children.

SHIGELLA SPP.

Causes an acute bacterial disease, known as shigellosis, and primarily occurs in humans, but also occurs in other primates such as monkeys and chimpanzees. An

estimated 300,000 cases of shigellosis occur annually in the U.S. ***Shigella*** spp. consist of 4 species or serogroups, including ***S. flexneri***, ***S. boydii***, ***S. sonnei***, and ***S. dysenteriae***; which all differ in geographical distribution and pathogenicity. ***Shigella*** spp. are highly infectious and highly virulent. Outbreaks occur in overcrowding conditions, where personal hygiene is poor, including in institutions, such as prisons, mental hospitals, day care centers, and refugee camps, and also among men who have sex with men. Water and RTE foods contaminated by feces, frequently from food workers' hands, are common causes of disease transmission. Multidrug-resistant ***Shigella*** (including ***S. dysenteriae*** 1) have appeared worldwide. Concern over increasing antimicrobial resistance has led to reduced use of antimicrobial therapy in treating shigellosis.

Incubation period: Usually 1 – 3 days, but ranges from 12 to 96 hours, and up to 1 week for ***S. dysenteriae*** 1.

Symptoms and Complications: Abdominal pain, diarrhea, fever, nausea, and sometimes vomiting, tenesmus, toxaemia, and cramps. The stools typically contain blood, pus, or mucus resulting from mucosal ulcerations. The illness is usually self-limited, with an average duration of 4-7 days. Infections are also associated with rectal bleeding, drastic dehydration, and convulsions in young children. The fatality rate for ***Shigella dysenteriae*** 1 may be as high as 20% among hospitalized cases. Other complications can also occur, such as Reiter's disease, reactive arthritis, intestinal perforation, and hemolytic uremic syndrome.

Infectivity: The infectious dose for humans is low, with as few as 10 bacterial cells depending on age and condition of the host. Infectivity occurs during acute infection and until the infectious agent is no longer present in feces, usually within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may persist for months or longer.

HEPATITIS A VIRUS

Hepatitis A virus (HAV) is a 27-nanometer picornavirus (positive strand RNA, non-enveloped virus). The hepatitis A virus has been classified as a member of the family *Picornaviridae*. The exact pathogenesis of HAV infection is not understood, but the virus appears to invade from the intestinal tract and is subsequently transported to the liver. The hepatocytes are the site of viral replication and the virus is thought to be shed via the bile.

HAV is most commonly spread by the fecal-oral route through person-to-person contact. Risk factors for reported cases of hepatitis A include personal or sexual contact with another case, illegal drug use, homosexual male sex contact, and travel to an endemic country. Common source outbreaks also can occur through ingestion of water or food that has fecal contamination. However, the source of infection is not identified for approximately 50% of reported cases.

HAV infection is endemic in developing countries, and less common in industrialized countries with good environmental sanitation and hygienic practices. In the developing world, nearly all HAV infections occur in childhood and are asymptomatic or cause a mild illness. As a result, hepatitis A (symptomatic infection with jaundice) is rarely seen in the developing world. More than 90% of adults born in many developing countries are seropositive.

Children play an important role in the transmission of HAV and serve as a source of infection for others, because most children have asymptomatic infections or mild, unrecognized HAV infections. In the United States, the disease is most common among school-aged children and young adults. After correction for under-reporting and undiagnosed infections, an estimated 61,000 HAV infections (includes cases of hepatitis A as well as asymptomatic infections) occurred in 2003.

HAV Immunization: Immune globulin can be used to provide passive pre-exposure immunoprophylaxis against hepatitis A. Protection is immediately conferred to an exposed individual following administration of IG, and immunity is provided for 3-5 months following inoculation. IG is effective in preventing HAV infection when given as post-exposure immunoprophylaxis, if given within 14 days of exposure. When a food service worker with hepatitis A is identified, IG is often given to co-workers. Active immunoprophylaxis using hepatitis A vaccine (a formalin-inactivated, attenuated strain of HAV) has been shown to provide immunity in > 95% of those immunized, with minimal adverse reactions. Hepatitis A vaccination of food workers has been advocated, but has not been shown to be cost-effective and generally is not recommended in the United States, although it may be appropriate in some communities.

Incubation period: Average 28 – 30 days (range 15 – 50 days).

Symptoms and Complications: Illness usually begins with symptoms such as nausea/ vomiting, diarrhea, abdominal pain, fever, headache, and/or fatigue. Jaundice, dark urine or light colored stools might be present at onset, or follow illness symptoms within a few days. HAV infection of older children and adults is more likely to cause clinical illness with jaundice (i.e., hepatitis A); onset of illness is usually abrupt. In young adults, 76-97% have symptoms and 40-70% are jaundiced. Jaundice generally occurs 5-7 days after the onset of gastrointestinal symptoms. For asymptomatic infections, evidence of hepatitis may be detectable only through laboratory tests of liver infections such as alanine aminotransferase (ALT) tests. The disease varies in severity from a mild illness to a fulminant hepatitis, ranging from 1-2 weeks to several months in duration. In up to 10-15% of the reported cases, prolonged, relapsing hepatitis for up to 6 months occurs. The degree of severity often increases with age; however, most cases result in complete recovery, without sequelae or recurrence. The reported case fatality rate is 0.1% - 0.3% and can reach 1.8% for adults over 50 years old.

Diagnosis: Diagnosis of HAV infection requires specific serological testing for IgM anti-HAV. IgM anti-HAV becomes undetectectable within 6 months of illness onset for most

persons; however, some persons can remain IgM anti-HAV positive for years after acute infection. Total anti-HAV (the only other licensed serologic test) can be detected during acute infection but remains positive after recovery and for the remainder of the person's life.

Infectivity: Evidence indicates maximum infectivity during the latter half of the incubation period, continuing for a few days after onset of jaundice. Most cases are probably noninfectious after the first week of jaundice. Chronic shedding of HAV in feces has not been reported. HAV is shed at peak levels in the feces, one to two weeks before onset of symptoms, and shedding diminishes rapidly after liver dysfunction or symptoms appear. Liver dysfunction or symptoms occur at the same time circulating antibodies to HAV first appear. Immunity after infection probably lasts for life; immunity after vaccination is estimated to last for at least 20 years.

Reporting History of Exposure:

The reporting requirements for history of exposure are designed to identify employees who may be incubating an infection due to Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC/STEC, typhoid fever, or HAV.

Which employees who report exposure are restricted?

- Employees who work in a food establishment serving a highly susceptible population (HSP) facility.

What constitutes exposure?

- Consuming a food that caused illness in another consumer due to infection with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC/STEC, typhoid fever, or HAV.
- Attending an event or working in a setting where there is a known disease outbreak.
- Close contact with a household member who is ill and is diagnosed with a listed pathogen.

Why are other guidelines provided, in addition to restriction for employees serving an HSP who report exposure to hepatitis A virus?

- Employees who have had a hepatitis A illness in the past are most likely protected from infection by life-time immunity to hepatitis A infection.
- Immunity developed through immunization or IgG inoculation prevents hepatitis A infection in exposed employees.
- Our standard definition of HSP doesn't apply very well to HAV. Children under 6 years old who become infected with HAV are generally asymptomatic, and while a higher proportion of susceptible elderly who become infected have serious illness, most institutionalized elderly are protected from HAV by prior infection.

What is the period of restriction?

- The period of restriction begins with the most recent time of foodborne or household member exposure and lasts for the usual incubation period of the pathogen as defined in the Control of Communicable Diseases Manual. This is the time that the employee is most likely to begin shedding the pathogen.

    - For Norovirus, 48 hours after the most recent exposure
    - For ***Shigella*** spp., 3 days after the most recent exposure
    - For ***E. coli*** O157:H7 or other EHEC/STEC, 3 days after the most recent exposure
    - For typhoid fever (***S.* Typhi**), 14 days after the most recent exposure
    - For HAV, 30 days after the most recent exposure

What is the period of restriction when exposed to a diagnosed, ill household member?

- While the household member is symptomatic with an infection due to Norovirus, ***Shigella*** spp., ***E coli*** O157:H7 or other EHEC/STEC, typhoid fever (***S.* Typhi**) or HAV;
- Plus during the usual incubation period of the pathogen of concern:
    - For Norovirus, symptomatic period plus 48 hours
    - For ***Shigella*** spp., symptomatic period plus 3 days
    - For ***E. coli*** O157:H7 or other EHEC/STEC, symptomatic period plus 3 days
    - For typhoid fever (***S.* Typhi**), symptomatic period plus 14 days
    - For HAV, onset of jaundice plus 30 days

What is the appropriate response to a report of exposure to other food employees?

- Employees who report a history of exposure but who do not work in a HSP facility should be reminded of the requirements for reporting illness, avoidance of bare hand contact with RTE foods, and proper hand washing and personal hygiene.

2-201.12 Exclusions and Restrictions.*[2]

Refer to public health reasons for § 2-201.11 for actions to take with conditional employees.

It is necessary to exclude food employees symptomatic with diarrhea, vomiting, or jaundice, or suffering from a disease likely to be transmitted through contamination of food, because of the increased risk that the food being prepared will be contaminated such as with a pathogenic microorganism. However, if the food employee is suffering from vomiting or diarrhea symptoms, and the condition is from a non-infectious condition, Crohn's disease or an illness during early stages of a pregnancy, the risk of transmitting a pathogenic microorganism is minimal. In this case, the food employee may remain working in a full capacity if they can substantiate that the symptom is from a noninfectious condition. The food employee can substantiate this through providing to the person in charge medical documentation or other documentation proving that the symptom is from a noninfectious condition.

Because of the high infectivity (ability to invade and multiply) and/ or virulence (ability to produce severe disease), of typhoid fever (***Salmonella* Typhi**) and hepatitis A virus, a food employee diagnosed with an active case of illness caused by either of these two pathogens, whether asymptomatic or symptomatic, must be excluded from food establishments. The exclusion is based on the high infectivity, and/or the severe medical consequences to individuals infected with these organisms. A food employee diagnosed with an active case of illness caused by Norovirus, ***Shigella*** spp., or ***E. coli*** O157:H7 or other EHEC/STEC, is excluded if exhibiting symptoms of vomiting and diarrhea, and then allowed to work as the level of risk of pathogen transmission decreases (See section 2-201.12, Tables #1b, #2 and #3).

The degree of risk for a food employee or conditional employee who is diagnosed with an infection but asymptomatic with regard to symptoms, to transmit a foodborne pathogen decreases with the resolution of symptoms. This risk decreases even further for those employees that are diagnosed with a listed pathogen, but never developed symptoms. The decrease in risk is taken under consideration when excluding and restricting diagnosed food employees and results in a slight difference in the way food employees diagnosed with Norovirus, but asymptomatic with respect to gastrointestinal symptoms are handled (See section 2-201.12, Table #2).

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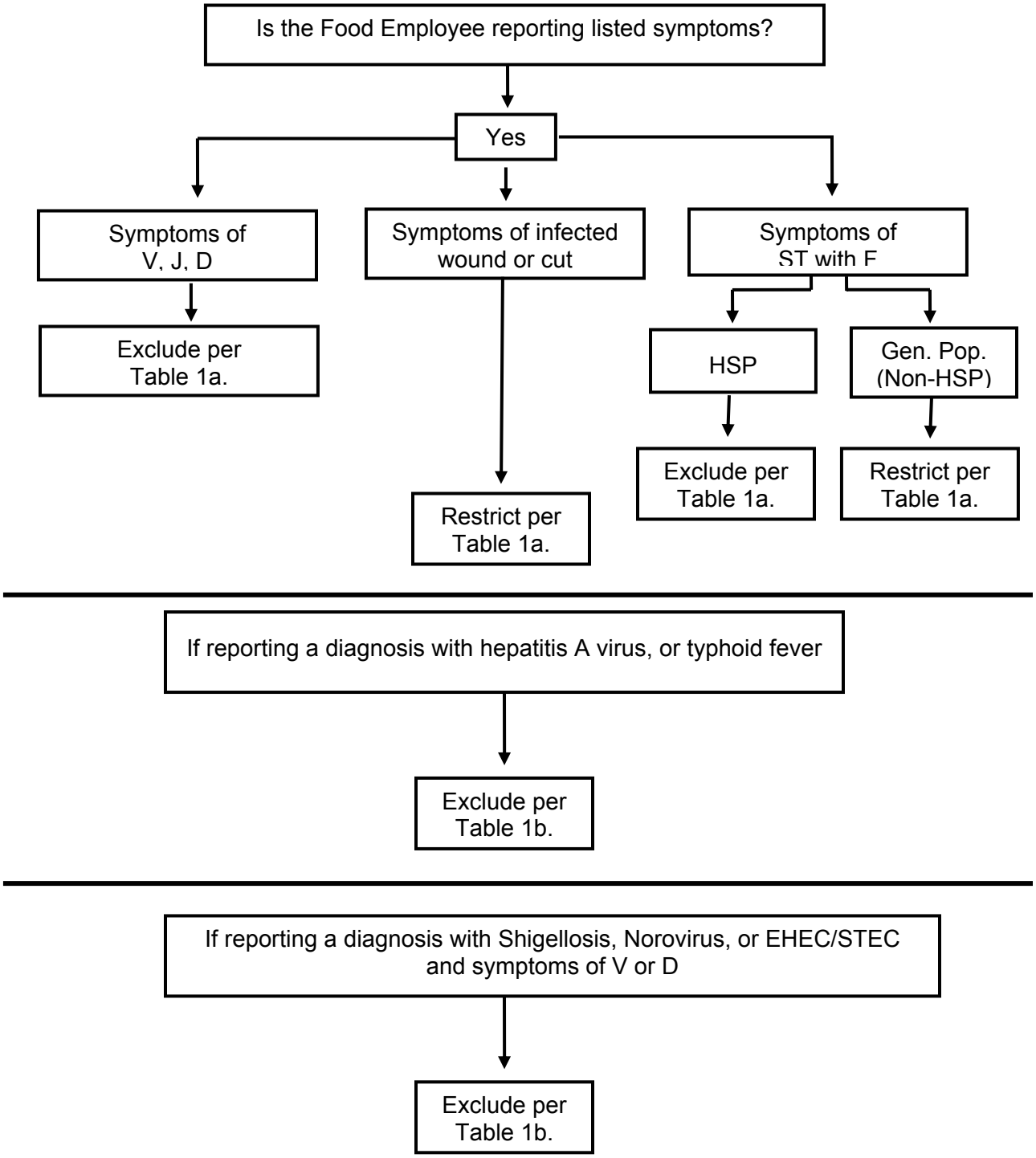
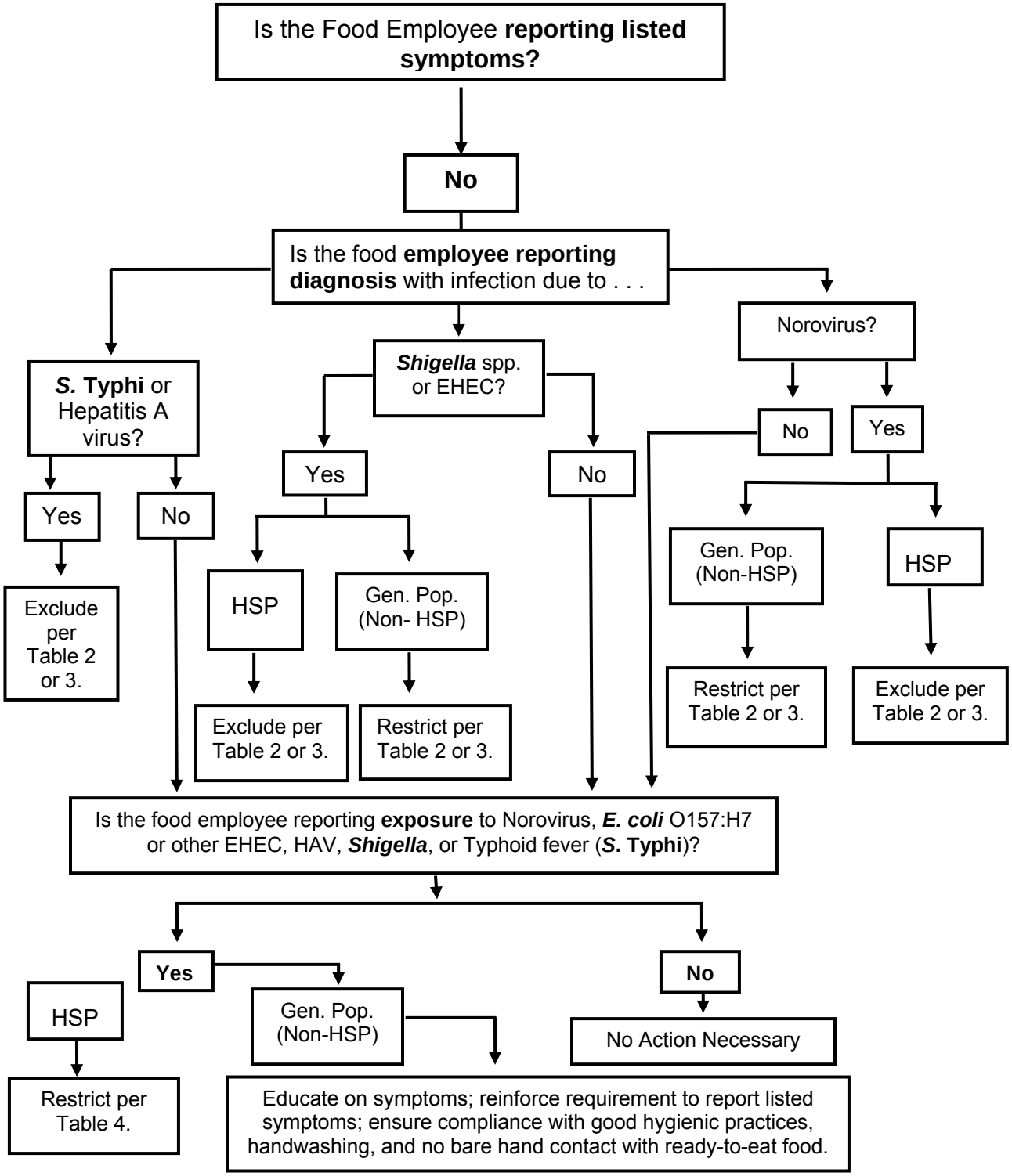
[2]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

2-201.11 / 2-201.12 Decision Tree 1. When to Exclude or Restrict a Food Employee Who Reports a Symptom and When to Exclude a Food Employee Who Reports a Diagnosis with Symptoms Under the Food Code



Key:
Listed Symptoms for Reporting: (V) Vomiting; (J) Jaundice; (D) Diarrhea; (ST with F) Sore Throat with Fever; (HSP) Highly Susceptible Population; (Gen. Pop.) General Population

2-201.11 / 2-201.12 Decision Tree 2. When to Exclude or Restrict a Food Employee Who is Asymptomatic and Reports a Listed Diagnosis and When to Restrict a Food Employee Who Reports a Listed Exposure Under the Food Code



Key:
(HSP) Highly Susceptible Population; (Gen. Pop.) General Population

2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

Food employees and conditional employees shall report symptoms immediately to the person in charge				
The person in charge shall prohibit a conditional employee that reports a listed symptom from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a symptomatic food employee.				
Symptom	**EXCLUSION/ OR RESTRICTION**		Removing symptomatic food employees from exclusion or restriction	**RA Approval Needed to Return to Work?**
	Facilities Serving a HSP	**Facilities not serving a HSP**		
Vomiting	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A)(1). ***Exceptions:*** If diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC, HAV, or typhoid fever ***(S.* Typhi*)*** (see Tables 1b & 2).	No if not diagnosed
Diarrhea	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A). ***Exceptions:*** If Diagnosed with Norovirus, ***E. coli*** O157:H7 or other EHEC, HAV, or ***S.* Typhi** (see Tables 1b & 2).	No if not diagnosed
Jaundice	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	When approval is obtained from the RA 2-201.13 (B), and: • Food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • Provides medical documentation 2-201.13(B)(3).	Yes
Sore Throat with Fever	**EXCLUDE** 2-201.12(G)(1)	**RESTRICT** 2-201.12(G)(2)	When food employee provides written medical documentation 201.13(G) (1)-(3).	No
Infected wound or pustular boil	**RESTRICT** 2-201.12(H)	**RESTRICT** 2-201.12(H)	When the infected wound or boil is properly covered 2-201.13(H)(1)-(3).	No

Key for Tables 1, 2, 3, and 4:
RA = Regulatory Authority
EHEC = Enterohemorrhagic, or Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees

Food employees and conditional employees shall report a listed diagnosis with symptoms immediately to the person in charge			
The person in charge shall notify the RA when a food employee is jaundiced or reports a listed diagnsis			
The person in charge shall prohibit a conditional employee that reports a listed diagnosis with symptoms from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed, symptomatic food employee.			
Diagnosis	**EXCLUSION Facilities Serving HSP or not Serving HSP**	Removing diagnosed, symptomatic food employees from exclusion	**RA Approval Needed to Return to Work?**
Hepatitis A virus	**EXCLUDE** if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms or more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (also see Table 2).	Yes
Typhoid Fever (***S.* Typhi**)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: • Food employee provides medical documentation, that states the food employee is free of a ***S.* Typhi** infection 2-201.13(C)(2) (also see Table 2).	Yes
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving Non-HSP facility: 2-201.13(A)(4)(a): May only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed below: • Approval is obtained from RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2) (also see Table 2).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility

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2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees (continued)

Diagnosis	EXCLUSION Facilities Serving HSP or not Serving HSP	Removing diagnosed, symptomatic food employees from exclusion	RA Approval Needed to Return to Work?
Norovirus	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving non-HSP facility: 2-201.13 (A)(2)(a): May only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed below: • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 2).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
Shigella spp.	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving Non-HSP facility: 2-201.13(A)(3)(a): May only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed below: 2. Serving HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements listed below: • Approval is obtained from the RA 2-201.13(E), and • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13)(E)(2) (also see Table 2).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility

2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge				
The person in charge shall notify the RA when a food employee reports a listed diagnosis				
The person in charge shall prohibit a conditional employee that reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.				
Pathogen Diagnosis	**Facilities Serving HSP**	**Facilities Not Serving HSP**	**Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction**	**RA Approval Required to Return to Work**
Typhoid fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11 (A)(3)	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: • Food employee provides medical documentation, that states the food employee is free of a ***S.* Typhi** infection 2-201.13)(C)(2) (also see Table 1b).	Yes
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	1. Serving Non-HSP facility: 2-201.13(A)(3)(a): May only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed below: 2. Serving HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements listed below: • Approval is obtained from the RA 2-201.13(E), and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(E)(3)(a) (also see Table 1b).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility

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2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms (continued)

Pathogen Diagnosis	Facilities Serving HSP	Facilities Not Serving HSP	Removing Diagnosed Food Employee with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work
Norovirus	**EXCLUDE** 2-201.12(D)(1)	**RESTRICT** 2-201.12(D)(2)	1. Serving Non-HSP facility: 2-201.13(A)(2)(a): May only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed below: • Approval is obtained from the RA 2-201.13(D), and: • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 1b).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** 2-201.12(F)(1)	**RESTRICT** 2-201.12(F)(2)	1. Serving Non-HSP facility: 2-201.13(A)(4)(a): May only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed below: • Approval is obtained from the RA 2-201.13(F), and: • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility

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2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms (continued)

Pathogen Diagnosis	Facilities Serving HSP	Facilities Not Serving HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work
Hepatitis A virus	**EXCLUDE** if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	**EXCLUDE** if within 14 days of any sumptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (see also Table 1b).	Yes

2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge				
The person in charge shall notify the RA when a food employee reports a listed diagnosis				
The person in charge shall prohibit a conditional employee that reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee				
Pathogen Diagnosis	**Facilities Serving HSP**	**Facilities Not Serving HSP**	**Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction**	**RA Approval Required to Return to Work**
Typhoid Fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11 (A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: Food employee provides medical documentation, specifying that the food employee is free of a ***S.* Typhi** infection 2-201.13(C)(2).	Yes
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	Remains excluded or restricted until approval is obtained from the RA, and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee was last diagnosed 2-201.13(E)(3).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
Norovirus	**EXCLUDE** 2-201.12(D)(1)	**RESTRICT** 2-201.12(D)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee was diagnosed 2-201.13(D)(3).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility

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2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms (continued)

Pathogen Diagnosis	Facilities Serving HSP	Facilities Not Serving HSP	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** 2-201.12(F)(1)	**RESTRICT** 2-201.12(F)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(F), and: • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee was diagnosed 2-201.13(F)(3).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	**EXCLUDE** 2-201.12(B)(3)	**EXCLUDE** 2-201.12(B)(3)	When approval is obtained from the RA 2-201.13(B), and • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3).	Yes

Key for Tables 1, 2, 3, and 4:
RA = Regulatory Authority
EHEC = Enterohemorrhagic, or Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

Food employees and conditional employees shall report a listed exposure to the person in charge				
The person in charge shall prohibit a conditional employee who reports a listed exposure from becoming a food employee in a facility serving a HSP until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of an exposed food employee				
The person in charge shall reinforce and ensure compliance with good hygienic practices, symptom reporting requirements, proper handwashing and no BHC with RTE foods for all food employees that report a listed exposure				
Pathogen Diagnosis	**Facilities Serving HSP**	**Facilities Not Serving HSP**	**When Can the Restricted Food Employee Return to Work?**	**RA Approval needed**
Typhoid Fever (***S.* Typhi**)	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(3) When 14 calendar days have passed since the last exposure, or more than 14 days has passed since the food employee's household contact became asymptomatic.	No
Shigella spp.	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 days have passed since the food employee's household contact became asymptomatic.	No
Norovirus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no bare hand contact with RTE foods.	2-201.13(I)(1) When more than 48 hours have passed since the last exposure, or more than 48 hours has passed since the food employee's household contact became asymptomatic.	No
E. coli O157:H7 or other EHEC/ STEC	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no bare hand contact with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 calendar days has passed since the food employee's household contact became asymptomatic.	No
Hepatitis A virus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no bare hand contact with RTE foods.	2-201.13(I)(4) When any of the following conditions is met: * The food employee is immune to HAV infection because of a prior illness from HAV, vaccination against HAV, or IgG administration; or * More than 30 calendar days have passed since the last exposure; or since the food employee's household contact became jaundiced; or * The food employee does not use an alternative procedure that allows BHC with RTE food until at least 30 days after the potential exposure, and the employee receives additional training.	No

Key for Table 4: GHP = Good Hygienic Practices; RTE = Ready-to-Eat foods; BHC = Bare Hand Contact

2-201.12 Exclusion and Restrictions (continued)[3]

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by ***Salmonella* Enteritidis**. Over 70% of the deaths in outbreaks attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active gastrointestinal symptoms, followed by diagnosis and history of exposure.

The history of exposure that must be reported applies only to the 5 organisms listed.

Upon being notified of the history of exposure, the person in charge should immediately:

1. Discuss the traditional modes of transmission of fecal-oral route pathogens.

2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.

3. Review the symptoms listed in the Code that require immediate exclusion from the food establishment.

4. Remind food employees of their responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.

5. Ensure that the food employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

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[3]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

A restricted food employee may work in an area of the food establishment that houses packaged food, wrapped single-service or single-use articles, or soiled food equipment or utensils. Examples of activities that a restricted person might do include working at the cash register, seating patrons, bussing tables, stocking canned or other packaged foods, or working in a non-food cleaning or maintenance capacity consistent with the criteria in the definition of the term "restricted." A food employee who is restricted from working in one food establishment may not work in an unrestricted capacity in another food establishment, but could work unrestricted in another retail store that is not a food establishment. A restricted food employee may enter a food establishment as a consumer.

An excluded individual may not work as a food employee on the premises of any food establishment.

2-201.13 Removal of Exclusions and Restrictions.[4]

Food employees diagnosed with Norovirus, hepatitis A virus**,** ***Shigella*** spp., ***E.* coli** O157:H7 or other EHEC, and symptomatic with diarrhea, vomiting, or jaundice, are excluded under subparagraph 2-201.12 (A)(2) or 2-201.12(B)(2). However these symptomatic, diagnosed food employees differ from symptomatic, undiagnosed food employees in the requirements that must be met before returning to work in a full capacity after symptoms resolve.

The person in charge may allow undiagnosed food employees who are initially symptomatic and whose symptoms have resolved to return to work in a full capacity 24 hours after symptoms resolve.

However, diagnosis with a listed pathogen invokes additional requirements before the person in charge may allow diagnosed food employees to return to work in full capacity.

Asymptomatic food employees diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC may not return to work in a full capacity 24 hours after symptoms resolve. The person in charge may only allow these food employees to work on a restricted basis 24 hours after symptoms resolve and they may only allow this if not in a food establishment that serves a highly susceptible population. These restricted food employees remain restricted until they are medically cleared or otherwise meet the criteria for removal from restriction as specified under subparagraphs 2-201.13(D) (1)-(2); 2-201.13(E)(1)-(2); or 2-201.13(F)(1)-(2).

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[4]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

In a food establishment that serves a highly susceptible population, food employees who are diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC and initially symptomatic with vomiting or diarrhea, may not work on a restricted basis after being asymptomatic for at least 24 hours. These food employees must remain excluded until they are medically cleared or otherwise meet the criteria for removal from exclusion from a highly susceptible population under subparagraph 2-201.13(D)(1)-(2), 2-201.13(E)(1)-(2), or 2-201.13 (F)(1)-(2).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1) - (4).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraph 2-201.13(B)(1)-(3). A food employee with an anicteric infection with the hepatitis A virus has a mild form of hepatitis A without jaundice. Food employees diagnosed with an anicteric infection with the hepatitis A virus are excluded if they are within 14 days of any symptoms. Anicteric, diagnosed food employees may be removed from exclusion if more than 14 days have passed since they became symptomatic, or if medically cleared. Asymptomatic food employees diagnosed with an active infection with the hepatitis A virus are also excluded until medically cleared.

Food employees diagnosed with typhoid fever (caused by a ***Salmonella* Typhi** infection) are always excluded, even without expressing gastrointestinal symptoms, since these symptoms are not typically exhibited with typhoid fever. Outbreaks of foodborne illness involving typhoid fever (***Salmonella* Typhi**) have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness. The high virulence combined with the extremely high infectivity of ***S*. Typhi** warrant exclusion from the food establishment until the food employee has been cleared by a physician or has completed antibiotic therapy.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through diagnosis, or laboratory confirmation of their stools to have Norovirus, or any one of the three bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

Despite lacking specific epidemiological evidence of transmission through food contaminated by food employees infected with ***E. coli*** O157:H7 or other EHEC/STEC bacteria are included with the 5 listed pathogens in the Food Code. This is because of the documented ease of transmission from person-to-person in a day care setting and because characteristics of foodborne outbreaks suggest a low infectious dose and the potential for the organism to be transmitted through food contaminated by soiled hands. The severity and consequences of infection, including hemolytic uremic syndrome

(HUS), associated with Shiga toxin-producing ***E. coli*** warrant the institution of disease interventions.

The risk that food employees who are asymptomatic shedders will transmit a communicable disease varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism. Restriction in a food establishment that does not serve a highly susceptible population affords protection for the general population and the immune-suppressed subset of the general population provided there is adequate attention to personal hygiene and avoidance of bare-hand contact with RTE foods.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the three bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases Manual."

Hands and Arms **2-301.11 Clean Condition.***

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

2-301.12 Cleaning Procedure.*

Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to RTE food as well as other pathogens that can be transmitted from environmental sources. Many employees fail to wash their hands as often as necessary and even those who do may use flawed techniques.

In the case of a food worker with one hand or a hand-like prosthesis, the Equal Employment Opportunity Commission has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable the food worker with one hand to adequately generate the necessary friction to achieve the intent of this requirement.

The greatest concentration of microbes exists around and under the fingernails of the hands. The area under the fingernails, known as the “subungal space”, has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to decontaminate. Fingernail brushes, if used properly, have been found to be effective tools in decontaminating this area of the hand. Proper use of single-use fingernail brushes, or designated individual fingernail brushes for each employee, during the handwashing procedure can achieve up to a 5-log reduction in microorganisms on the hands.

There are two different types of microbes on the hands, transient and resident microbes. Transient microbes consist of contaminating pathogens which are loosely attached to the skin surface and do not survive or multiply. A moderate number of these organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin and they are not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential contamination in food service.

All aspects of proper handwashing are important in reducing microbial transients on the hands. However, friction and water have been found to play the most important role. This is why the amount of time spent scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

Research has shown a minimum 10-15 second scrub is necessary to remove transient pathogens from the hands and when an antimicrobial soap is used, a minimum of 15 seconds is required. Soap is important for the surfactant effect in removing soil from the hands and a warm water temperature is important in achieving the maximum surfactant effect of the soap.

Every stage in handwashing is equally important and has an additive effect in transient microbial reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When done properly, each stage of handwashing further decreases the transient microbial load on the hands. It is equally important to avoid recontaminating hands by avoiding direct hand contact with heavily contaminated environmental sources, such as manually operated handwashing sink faucets, paper towel dispensers, and rest room door handles after the handwashing procedure. This can be accomplished by obtaining a paper towel from its dispenser before the handwashing procedure, then, after handwashing, using the paper towel to operate the hand sink faucet handles and restroom door handles.

Handwashing done properly can result in a 2-3 log reduction in transient bacteria and a 2-log reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens, (i.e., $> 10^4$ microbes, as found on hands contaminated with bodily wastes and infected bodily fluids) handwashing may be ineffective in completely

decontaminating the hands. Therefore, a further intervention such as a barrier between hands and ready-to-eat food is necessary.

2-301.13 Special Handwash Procedures.*

This section is reserved.

In earlier editions of the Code, FDA's model contained a provision for a Special Procedure in certain situations. Pursuant to a 1996 Conference for Food Protection (CFP) Recommendation, the text of this Code provision is removed and the section is reserved. It is FDA's intent to further research the matter and to submit the findings to the CFP for reconsideration of the matter.

2-301.14 When to Wash.*

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

2-301.15 Where to Wash.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing sinks are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

2-301.16 Hand Antiseptics.

In the 2005 Food Code, the use of the term “hand sanitizer” was replaced by the term “hand antiseptic” to eliminate confusion with the term “sanitizer,” a defined term in the Food Code, and to more closely reflect the terminology used in the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994.

The term “sanitizer” is typically used to describe control of bacterial contamination of inert objects or articles, or equipment and utensils, and other cleaned food-contact surfaces. The Food Code definition of “sanitizer” requires a minimum microbial reduction of 5 logs, which is equal to a 99.999% reduction. The FDA bases the 5-log reduction on the AOAC International’s “Official Methods of Analysis 2003,” which requires a minimum 5-log reduction in microorganisms to achieve “sanitization.”

Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement. However, removing microorganisms from human skin is a totally different process and sterilization of human skin is nearly impossible to achieve without damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms than the 5-log reduction required for “sanitization.” Therefore, the effect achieved from using antimicrobial hand agents is not consistent with the definition of “sanitization” in the Food Code.

The word “antiseptic” is a Greek term, meaning “against putrefaction”, and eventually evolved into a second definition, meaning, “a substance used to destroy pathogenic microorganisms.” The term “antiseptic” is often used to describe agents used on skin to prevent infection of the skin.

“Antiseptic” is defined under section 201 (o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 (o)), as: “The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation of a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.”

Section 333.403 of the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994, defines a “health-care antiseptic” as an antiseptic-containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination. An “antiseptic handwash” or “health-care personnel handwash drug product” is defined in Section 333.403 of the Monograph as an antiseptic containing preparation designed for frequent use; it reduces the number of transient microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is a broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin.

Replacing the term “hand sanitizer” with the term “hand antiseptic” allows the use of a more scientifically appropriate term that is used to describe reduction of microorganisms on the skin and will improve clarification and regulation of these products.

The provisions of § 2-301.16 are intended to ensure that an antimicrobial product applied to the hands is 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food.

Because of the need to protect workers and to ensure safe food, hand antiseptics must comply with both the human drug and the food safety provisions of the law. The prohibition against bare hand contact contained in ¶ 3-301.11(B) applies only to an exposed ready-to-eat food.

As a Drug Product

There are two means by which a hand antiseptic is considered to be safe and effective when applied to human skin:

1. A hand antiseptic may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. This document is maintained by the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. Also known as the "Orange Book," this document provides "product-specific" listings rather than listings by compound. It is published annually with monthly supplements and is available at http://www.fda.gov/cder/ob/default.htm. However, as of the end of 1998, no hand antiseptics are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand antiseptic active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand antiseptic products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand antiseptics and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975, for hand antiseptic use by food handlers, are being evaluated under the Over-the-Counter (OTC) Drug Review by FDA's Center for Drug Evaluation and Research. However, as of May 2005, a final OTC drug monograph for these products has not been finalized. Therefore, FDA has not made a final determination that any of these products are generally recognized as safe and effective (GRAS/E).

GRAS/E antimicrobial ingredients for hand sanitizer use by food handlers will be identified in a future final monograph issued under the OTC Drug Review. Information about whether a specific product is covered by the proposed monograph may be obtained from the tentative final monograph (TFM) for "Health Care Antiseptic Drug Products for OTC Human Use; Proposed Rule." This TFM, which was published in the

Federal Register of June 17, 1994 (59 FR 31402), describes the inclusion of hand sanitizers in this Review on page 31440 under Comment 28 of Part II. Information about whether a specific product is included in this proposed monograph may also be available from the manufacturer.

Questions regarding acceptability of a hand antiseptic with respect to OTC compliance may be directed to the Division of New Drugs and Labeling Compliance (HFD-310), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

<u>As a Food Additive</u>

To be subject to regulation under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the substances in a hand antiseptic must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the substances in a hand antiseptic are reasonably expected to become a component of food based upon the product's intended use, circumstances under which those substances may be legally used include the following:

1. The intended use of a substance may be exempted from regulation as a food additive under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. A review by FDA's Center for Food Safety and Applied Nutrition is required in order to determine whether such an exemption can be granted.

2. A substance may be regulated for the intended use as a food additive under 21 CFR 174 – *Indirect Food Additives – General*, and be listed along with conditions of safe use in 21 CFR 178 - *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers*.

3. The intended use of a substance, including substances that contact food such as those in hand antiseptics, may be "generally recognized as safe (GRAS)" within the meaning of the FFDCA. A partial listing of substances with food uses that are generally recognized as safe may be found in CFR Parts 182, 184, and 186. These lists are not exhaustive because the FFDCA allows for independent GRAS determinations.

   For the use of a substance to be GRAS within the meaning of the FFDCA, there must be publicly available data that demonstrate that the substance is safe for its intended use. There also must be a basis to conclude that there is a consensus among qualified experts that these publicly available data establish safety. If the use of a substance in food is GRAS, it is not subject to premarket review by FDA. While there is no legal requirement to notify FDA of an independent GRAS

determination, a number of firms have chosen to do so with the expectation of receiving a response letter from FDA (see FDA's Inventory of GRAS Notices at http://www.cfsan.fda.gov/~rdb/opa-gras.html. Although such a letter does not affirm the independent GRAS determination, it is an opportunity for the firm to receive comment from FDA regarding the materials supporting its determination.

4. A substance may be the subject of a Food Contact Substance Notification that became effective in accordance with the FFDCA Section 409 (h). Substances that are the subject of an effective food-contact substance notification are listed, along with conditions of safe use, in the FDA Inventory of Effective Premarket Notifications for Food Contact Substances. This list is available on-line at http://www.cfsan.fda.gov/~dms/opa-fcn.html. A food-contact substance that is the subject of an effective notification submitted under FFDCA 409(h) does not include similar or identical substances manufactured or prepared by any person other than the manufacturer identified in that notification.

The Division of Food Contact Substance Notifications does not certify or provide approvals for specific products. However, if the intended use of a substance in contact with food meets the requirements of 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*, FDA may provide a letter to a firm stating that the intended use of this product is exempt from regulation as a food additive. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of substances in hand antiseptics as food additives may be directed to the Division of Food Contact Substance Notifications, HFS-275, 5100 Paint Branch Parkway, College Park, MD 20740. It may be helpful or necessary to provide label/promotional information when inquiring about a specific substance.

Fingernails **2-302.11** **Maintenance.**

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

Jewelry **2-303.11** **Prohibition.**

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

The term “jewelry” generally refers to the ornaments worn for personal adornment and medical alert bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for transmitting disease-causing organisms to food. If a food worker wears a medical alert or medical information bracelet, the conflict between this need and the Food Code’s requirements can be resolved through reasonable accommodation in accordance with the Americans with Disabilities Act. The person in charge should discuss the Food Code requirement with the employee and together they can work out an acceptable alternative to a bracelet. For example, the medical alert information could be worn in the form of a necklace or anklet to provide the necessary medical information without posing a risk to food. Alternatives to medical alert bracelets are available through a number of different companies (*e.g.,* an internet search using the term “medical alert jewelry” leads to numerous suppliers).

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing **2-304.11** **Clean Condition.**

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Food Contamination Prevention **2-401.11** **Eating, Drinking, or Using Tobacco.***

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

2-401.12 Discharges from the Eyes, Nose, and Mouth.*

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

Hair Restraints **2-402.11 Effectiveness.**

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

Animals **2-403.11 Handling Prohibition.***

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

Chapter 3 Food

Condition **3-101.11 Safe, Unadulterated, and Honestly Presented.***

Sources **3-201.11 Compliance with Food Law.***

Refer to the public health reason for § 3-401.11.

Source

A primary line of defense in ensuring that food meets the requirements of § 3-101.11 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of

farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat treatment nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by cer`tification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Fish

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling or other information should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Juice

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices.

On July 18, 2001 FDA announced a final rule designed to improve the safety of fruit and vegetable juice and juice products. Under the rule, juice processors must use Hazard Analysis and Critical Control Point (HACCP) principles for juice processing. Processors making shelf-stable juices or concentrates that use a single thermal processing step are exempt from the microbial hazard requirements of the HACCP regulation. Retail establishments where packaged juice is made and only sold directly to consumers (such as juice bars) ae not required to comply with this regulation.

Rather, the Food Code requires fresh fruit or vegetable juices that are packaged at retail (untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods) to be processed under HACCP with a 5 log reduction in pathogens of concern OR bear the warning statement as specified in 21 CFR Section 101.17(g). That statement is: “WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the eldersly, and persons with weakened immune systems.” Refer to Chapter 1 for the definition of juice. It is important to note that the definition of “juice” includes puréed fruits and vegetables, which are commonly prepared for service to highly susceptible populations.

Food establishments that serve a highly susceptible population (HSP) cannot serve prepackaged juice that bears the warning label and they must serve only pasteurized

juice. For juice only, this population includes children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care.

Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5 log reduction nor a warning statement or other consumer advisory (juice is not an animal food and therefore not covered by section 3-603.11) when prepared and served at retail. Usually the juice is served by the glass or in small batches compared to a commercial juice processor. The risk of using "drops" and damaged fruits or vegetables is much less at retail because of buyer specs that provide higher quality produce, meaning that fruits for juicing are less likely to be of a lower quality or damaged.

Additional information is available in the document, "Guidance for Industry. Warning and Notice Statement: Labeling of Juice Products, Small Entity Compliance Guide" which can be found on the FDA Web Page http://www.cfsan.fda.gov/~dms/juicguid.html or obtained from the FDA Office of Nutritional Products Labeling and Dietary Supplements.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by Federal regulation to label the product with safe food handling instructions. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and prelabeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling Guidance for Irradiated Raw Meat and Meat Products

In December 1999, the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) issued a final regulation to permit the use of ionizing radiation to reduce foodborne pathogens, including *Escherichia coli O*157:H7, and extend the shelf life of raw refrigerated and frozen meat and meat products (Irradiation of Meat Food Products 64 *Federal Register* 72150, December 23, 1999).

The final regulations are published in Title 9 of the Code of Federal Regulations (9 CFR 424.21 Use of food ingredients and sources of radiation and provide that raw refrigerated products may receive a maximum absorbed dose of no more than 4.5 kGy, and that frozen product receive no more than 7.0 kGy, in accordance with the FDA restrictions provided for in Title 21 of the Code of Federal Regulations (21 CFR 179.26(a) Ionizing radiation for the treatment of food, (a) Energy sources). The regulations further require that all irradiated meat and meat products bear labeling that reflects that the product was irradiated, or that the product contains an irradiated meat

or poultry product. This labeling requirement is applicable even at retail facilities where irradiated coarse ground beef might be finely ground for retail sale, or in cases where irradiated product is combined with other non-irradiated meat or poultry product for retail sale.

In cases where the entire package of product is irradiated, the labeling must include both a statement and the international symbol, called the radura. Additionally, the product name must include the word “irradiated,” or the labeling must bear a disclosure statement such as, “treated with radiation” or “treated by irradiation.” If either statement is used, the logo must be placed in conjunction with the statement. If an irradiated meat or meat product is used to formulate a multi-ingredient product with other non-irradiated components, the irradiated meat ingredient must be identified as such in the ingredients statement, but the logo is not required. For example, the ingredients statement for a Chicken and Beef Sausage product that contains irradiated beef would be, Ingredients: chicken, irradiated beef, seasonings (salt, pepper, spice), and the logo would not be required to be present.

All labels for products produced at federally inspected establishments bearing statements about irradiation must be submitted to USDA/FSIS for evaluation and approval prior to use.

Optional labeling statements about the purpose of the irradiation process may be included on the labeling of irradiated products provided they are not false or misleading and have been evaluated first by USDA/FSIS. If such statements indicate a specific benefit from irradiation, such as a reduction of microbial pathogens, such statements must be substantiated by processing documentation and validated through the processing and Hazard Analysis and Critical Control Point (HACCP) system. Such validation and documentation of the HACCP system would only be applicable in federally inspected establishments.

Because irradiation can substantially reduce and, in some situations, eliminate any detectable level of pathogenic bacteria, it is important that the meat products be held at the proper refrigerated temperatures to prevent growth of any pathogens present, and that the packaging is not compromised. Although co-mingling irradiated beef with non-irradiated meat or poultry is not prohibited under the current regulations, USDA/FSIS believes that such a process would decrease the benefit of irradiation by potentially exposing the irradiated product to pathogenic bacteria. While FSIS considers such comingling to be highly unlikely, if it did occur, a statement advising the consumer that the product contains both irradiated and non-irradiated components would be required.

The Radura, International Symbol:

Further information about labeling irradiated raw meat is available through Directive 7700.1, Irradiation of Meat and Poultry Products, on the USDA/FSIS website at http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/7700-1.htm. Irradiation Questions & Answers can be found at http://www.fsis.usda.gov/oppde/larc/policies/iradqa.pdf.

Labeling for Raw Shell Eggs

The Code of Federal Regulations 21 CFR 101.17 **Food Labeling warning, notice, and safe handling statements**, paragraph (h) *Shell* eggs state in subparagraph (1), "The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement: 'SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.'" Further, in subparagraph (4) it states, "Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (h) of this section."

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

Refer also to public health reason for § 3-602.11.

3-201.12 Food in a Hermetically Sealed Container.*

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of ***Clostridium botulinum***, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is

canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.13 Fluid Milk and Milk Products.*

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Listeria monocytogenes***, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

3-201.14 Fish.*

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

RECREATIONALLY CAUGHT FISH

Recreationally caught fish received for sale or service may be approved by the regulatory authority. The EPA recognizes that fish are a healthy part of our diet and recognizes fishing as an all-American recreational pastime, however, they add the cautionary note that some individuals, such as pregnant women and small children, may need to limit their intake of certain noncommercial fish. Recreationally caught fish may contain possible contaminants that may pose health risks. Fish advisories can be found in EPA Listing of Fish Advisories the EPA website at: http://www.epa.go/waterscience/fish.

States issue fish consumption advisories if elevated concentrations of chemicals such as mercury or dioxin are found in local fish. For most people, the risk from mercury by eating fish is not a health concern. Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. Therefore, the FDA and the EPA recently advised women who may become pregnant, pregnant women, nursing mothers, and young children to avoid some types of fish and eat fish and shellfish that are lower in mercury. (http://www.epa.gov/waterscience/fishadvice/advice.html).

State-issued advisories apply primarily to non-commercial fish obtained through sport, recreation, and subsistence activities. Each advisory is different; it may recommend unrestricted, limited, or totally restricted consumption; may be targeted to everyone or limited to women, children, or other people at risk; and may apply to certain species or sizes of fish or a specific waterbody.

States may issue safe-eating guidelines in addition to issuing fish advisories. A fish advisory is issued to warn the public of the potential human health risks from chemical contamination of certain species from particular types of waterbodies such as lakes, rivers, and/ or coastal waters within the State. In contrast, a safe-eating guideline is issued to inform the public that fish from specific waterbodies have been tested for chemical contaminants and the fish from these waters are safe to eat without consumption restrictions.

Regulatory authorities are encouraged to monitor and review the National Listing of Fish Advisories (See August 2004 EPA Fact Sheet at http://www.epa.gov/waterscience/fish/advisories/factsheet.pdf as well as the local listings, as part of the decision-making process regarding the approval of recreationally caught fish being used in food establishments.

3-201.15 Molluscan Shellfish.*

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as ***Vibrio vulnificus***, ***Vibrio parahaemolyticus***, ***Vibrio cholerae***, and ***Listeria monocytogenes*** that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant

occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving Federal and State public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

3-201.16 Wild Mushrooms.*

Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that include individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups. If a food establishment chooses to sell wild mushrooms, management must recognize and address the need for a sound identification program for providing safe wild mushrooms.

Regulatory authorities have expressed their difficulty in determining what constitutes a "wild mushroom identification expert" and enforcing the Food Code provisions associated with it. In 1998, the Conference for Food Protection (CFP) attempted to alleviate this problem through the formation of a committee that was charged with determining what constitutes a wild mushroom expert. However, the committee was unable to provide this information in a practical, useful manner for State and local regulators within the constraints of the Food Code. The 2000 CFP recommended and FDA accepted the committee's alternative solution that a brochure be developed that will provide information on what constitutes a wild mushroom expert, and to replace "identification by a wild mushroom expert" with "written buyer specifications."

The CFP's recommendation attempts to provide the necessary information in a practical, useful manner for all stakeholders, and yet still convey the highest level of public health protection. The CFP committee suggested that written buyer specifications place more responsibility on the food establishment to ensure that wild mushrooms are obtained from a safe source, and also provides State and local regulators a template to use in ensuring wild mushrooms sold at retail are obtained from a safe source.

However, the recommendation for written buyer specifications will not replace Food Code paragraph 3-201.16(A) until the brochure is developed and accepted by the CFP and FDA. In the interim, the following guidance is provided regarding the identification of wild mushrooms:

A food establishment that sells or serves mushroom species picked in the wild shall have a written buyer specification that requires identification of:

(1) The Latin binomial name, the author of the name, and the common name of the mushroom species,
(2) That the mushroom was identified while in the fresh state,
(3) The name of the person who identified the mushroom,
(4) A statement as to the qualifications and training of the identifier, specifically related to mushroom identification.

Additional information can be found on the California Poison Control web site: http://www.calpoison.org/public/mushrooms.html.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.17 Game Animals.*

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the

human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

Specifications for Receiving **3-202.11 Temperature.***

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. USDA published a final rule (63 FR 45663, August 27, 1998 Shell Eggs; Refrigeration and Labeling Requirements) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2ºC (45ºF).

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of ***Staphylococcus aureus***). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

3-202.12 Additives.*

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

Food and Color additives must be used in compliance with a federal food, or color additive regulation, an effective food-contact notification, or a threshold of regulation exemption. Such regulations, notifications, and exemptions are generally composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties, and *limitations* on the conditions of use. In order for a food, or color additive use to be in compliance, the use must comply with all three criteria.

Federal Food Additive regulations are found in Title 21 CFR, Parts 172-180. Color additive regulations are found in Title 21 CFR Parts 73-Subpart A, 74-Subpart A, 81 and 82. Effective food-contact notifications are listed at http://vm.cfsan.fda.gov/~dms/opa-fcn.html, and threshold of regulation exemptions are listed at http://www.cfsan.fda.gov/~dms/opa-torx.html.

Other substances that are added to food include those prior sanctioned for use in food by either the FDA or USDA, or those generally recognized as safe for their intended use in food. Some of these are listed in Title 21 CFR Parts 181-186, Title 9 CFR Section 424.21(b) and at http://www.cfsan.fda.gov/~rdb/opa-gras.html. Tolerances and exemptions from tolerance for pesticide chemical residues in or on food are found in Title 40 CFR Part 180. Substances that are prohibited form use in human food are listed in Title 21 CFR Part 189.

3-202.13 Eggs.*

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg may be restricted because it is a/an:

(i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.

(iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

(v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

On December 5, 2000 Federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

The labeling rule became effective September 4, 2001, and the refrigeration rule became effective June 4, 2001. These rules are one part of a larger farm-to-table approach for ensuring the safety of our nation's egg supply. The public health goal is a 50 percent reduction in all salmonellosis and a 50 percent reduction in ***Salmonellae* Enteritidis** illnesses by 2010.

3-202.14 Eggs and Milk Products, Pasteurized.*

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these potentially hazardous foods (time/temperature control for safety foods). Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

3-202.15 Package Integrity.*

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as ***Clostridium botulinum*** may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed.

Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

3-202.16 Ice.*

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

3-202.17 Shucked Shellfish, Packaging and Identification.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

3-202.18 Shellstock Identification.*

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

3-202.19 Shellstock, Condition.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

3-202.110 Juice Treated.

Refer to public health reason for § 3-801.11.

Original Containers and Records

3-203.11 Molluscan Shellfish, Original Container.

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated

lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

When shucked shellfish are prepackaged in consumer self service containers, the labeling information as specified under section 3-202.17 must be recorded on a log sheet to correlate with the date of sale of the consumer sized containers.

3-203.12 Shellstock, Maintaining Identification.*

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product	14 days
Incubation period	56 days
Medical diagnosis and confirmation	5 days
Reporting	5 days
Epidemiological investigation	10 days
Total	90 days

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.*

In November 1999, the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) concluded that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended exclusion/restriction of ill food workers as the first preventative strategy and recognized that this intervention has limitations, such as trying to identify and manage asymptomatic food workers.

The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route, identified by the NACMCF, include exclusion/restriction of ill food workers; proper handwashing; and no bare hand contact with ready-to-eat foods. Each of these factors is inadequate when utilized independently and may not be effective. However, when all three factors are combined and utilized properly, the transmission of fecal-oral pathogens can be controlled. Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as specified in the Food Code, may not be an adequate intervention to prevent the transmission of pathogenic microbes to ready-to-eat foods via hand contact with ready-to-eat foods.

Handwashing as specified in the Food Code will reduce microbial contamination of the hands by 2-3 logs.

Food employees and conditional employees infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at levels up to 10^8 viral particles or oocysts per gram of feces. Having a high potential contamination level on the hands combined with a very low infectious dose necessary to cause infection are the reasons that FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-oral pathogens. The infective dose for ***Giardia*** and ***Cryptosporidium*** is believed to be as low as 1-10 oocysts, and as few as 10 virus particles can infect an individual with Norovirus or hepatitis A.

The CDC now estimates that Norovirus is the leading cause of foodborne illness in the United States. Contaminated hands are a significant factor in the transmission of enteric viruses, including Norovirus and hepatitis A virus. Further, contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial contamination of the hands, especially in the subungal space of the fingers, a basic 2-3 log reduction handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.14.

3-301.11(D) Prior Approval for Food Employees to Touch Ready-to-Eat Food with Bare Hands

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause.[1] Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

[1]Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks – United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used. Any alternative to this requirement must convincingly address how food employees will be managed to preclude food contamination and how management will ensure that thorough handwashing occurs after employees use the toilet.

Because highly susceptible populations include persons who are immunocompromised, the very young and elderly, establishments serving these populations may not use alternatives to the no bare hand contact with ready-to-eat food requirement.

Acceptability of an alternative procedure to no bare hand contact requires prior approval from the regulatory authority based on the food establishment having a written employee health policy that details how the establishment complies with management of ill employees as specified under sections 2-201.11 - .13 and management of handwashing practices as specified under Part 2-3 of the Code. The approval should also be based on evidence provided through written procedures and documentation that at least all of the following are addressed:

(A) **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in section 2-301.14, including after using the toilet and between tasks that may recontaminate the hands.

(B) **Hygienic Practices** as specified in Part 2-4.

(C) **Employee Health** regarding:

(1) **Reporting of diseases and medical conditions,** and

(2) **Exclusions and restrictions,** i.e., that food employees and conditional employees report their health status as specified in section 2-201.11; ill food employees are restricted or excluded as specified in section 2-201.12; and the exclusions and restrictions are removed as specified in section 2-201.13;

(D) **How the alternative practices and procedures will control the hazard through an active managerial control program.** Such a program includes monitoring and verifying the institution of the provisions described in paragraphs A-C above and satisfies the following:

(1) The public health hazard associated with bare hand contact specific to the food establishment operation is identified and understood. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

(2) The ready-to-eat foods that will be contacted with bare hands are identified and both procedures and practices are in place so that food employees wash their hands before returning to their work station and cross-contamination from touching raw and ready-to-eat food is precluded.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

(3) Institution of an effective training program for food employees that emphasizes not working when ill with any of the gastrointestinal symptoms listed in the Code, and explains good hygienic practices, proper handwashing procedures, and safe food preparation procedures. This should include a documented training plan that specifies how management responsibility for training has been designated, training program content, and the frequency of administration including periodic refresher sessions.

(E) The alternative procedure should clearly describe monitoring, documentation, and verification actions to ensure that the practices and procedures are followed. Corrective actions need to be predetermined for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

(F) Documentation of the practices, procedures, and corrective actions related to an alternative to no bare hand contact with ready-to-eat food must be maintained and readily available at the food establishment at all times for use by the person in charge and for review by the regulatory authority.

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food – Protection Separation, Packaging, and Segregation.*

With regard to the storage of raw animal foods as specified under subparagraph 3-302.11(A)(2), it is the intent of this Code to require separation based on anticipated microbial load and raw animal food type (species). Raw animal foods shall be

separated based on a succession of cooking temperatures since cooking temperatures as specified under § 3-401.11 are based on thermal destruction data and anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are required to be cooked to an internal temperature of 145°F for 15 seconds, shall be stored above or away from raw poultry, which is required to be cooked to an internal temperature of 165°F for 15 seconds due to its considerably higher anticipated microbial load. In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.*

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism ***Salmonella* Enteritidis** may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

3-302.14 Protection from Unapproved Additives.*

Refer to the public health reason for § 3-202.12.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

3-302.15 Washing Fruits and Vegetables.

Pathogenic organisms and chemicals may be present on the exterior surfaces of raw fruits and vegetables. Washing removes the majority of organisms and/or chemicals present. If nondrinking water is used, the fruits and vegetables could become contaminated.

Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations.

On October 26, 1998 a voluntary guidance document which addresses practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents. The “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” is available from FDA’s Food Safety Initiative staff and also on the Internet at http://www.fda.gov/dms/prodguid.html.

Preventing Contamination from Ice Used as a Coolant

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

3-303.12 Storage or Display of Food in Contact with Ice and Water.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Preventing Contamination From Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.*

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Probe-type price or identification tags are defined as a utensil. This means that if such tags are for multiuse, they must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction. Probe-type price or product identification tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and maintained.

The Food Code defines gloves as a "utensil" and therefore gloves must meet the applicable requirements related to utensil construction, cleaning, and storage.

3-304.12 In-Use Utensils, Between-Use Storage.

Refer to the public health reason for § 3-304.11.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely

stored in hot water maintained at 135°F or above during intermittent use because microbial growth is controlled at such temperatures.

A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to determine if a utensil is improperly designed for the task or whether a food employee is misusing an appropriately designed utensil.

3-304.13 Linens and Napkins, Use Limitation.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

3-304.14 Wiping Cloths, Use Limitation.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution at all times, with the proper sanitizer concentration in the solution. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

3-304.15 Gloves, Use Limitation.

Refer to the public health reason for § 3-304.11.

Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable requirements related to utensil construction, good repair, cleaning, and storage.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food. Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves. Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants enter the inside of the glove.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

Natural Rubber Latex (NRL) Gloves

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2, 3-304.15). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively reviewing its current policy on the use of disposable NRL gloves in food operations in light of the possible transmission of the latex protein via food. To gain additional information regarding allergic reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been collecting reports of such reactions from consumers who have contacted the Agency. Several offices within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and other related efforts will be used to determine if policy changes regarding the use of latex in food operations, based on food safety considerations, are warranted.

The FDA, Office of Food Additive Safety, Division of Food Contact Notification, reviews gloves submitted for food-contact use in the food industry on the basis of the glove's formulation or components. FDA regulates NRL gloves used for medical purposes only.

FDA is aware of the following information related to occupational hazards (not food safety hazards) associated with the use of NRL gloves:

- The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication number 97-135) which is found at http://www.cdc.gov/niosh/latexalt.html.

- The American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement discouraging the routine use of NRL gloves by food handlers. (1997) http://www.acaal.org/public/physicians/joint.htm.

  The AAAAI provides information on latex allergies on the web at http://www.aaaai.org/patients/resources/fastfacts/latex_allergy.stm.

  The ACAAI provides information on latex allergies on the web at http://www.acaai.org/public/facts/latex.htm.

- An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves for food handling..." (1999) http://www.osha.gov/dts/tib/tib_data/tib19990412.html.

OSHA addresses gloves in the following Federal regulation, which can be found at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9788.

OSHA Regulations (Standards - 29 CFR)
Standard Number: 1910.138
Standard Title: Hand Protection.
SubPart Number: I
SubPart Title: Personal Protective Equipment

(a) General requirements. Employers shall select and require employees to use appropriate hand protection when employees' hands are exposed to hazards such as those from skin absorption of harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns; thermal burns; and harmful temperature extremes.

(b) Selection. Employers shall base the selection of the appropriate hand protection on an evaluation of the performance characteristics of the hand protection relative to the task(s) to be performed, conditions present, duration of use, and the hazards and potential hazards identified.

3-304.16 Using Clean Tableware for Second Portions and Refills.

Refer to the public health reason for § 3-304.11.

3-304.17 Refilling Returnables.

Refer to the public health reason for § 3-304.11.

Preventing Contamination from the Premises

3-305.11 Food Storage.
3-305.12 Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

3-305.13 Vended Potentially Hazardous Food (Time/Temperature Control for Safety Food), Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended potentially hazardous food (time/temperature control for safety food) allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, many potentially hazardous foods (time/temperature control for safety foods) are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

3-305.14 Food Preparation.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

Preventing Contamination by Consumers

3-306.11 Food Display.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

3-306.12 Condiments, Protection.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

3-306.13 Consumer Self-Service Operations.*

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are potentially hazardous foods (time/temperature control for safety foods) and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

3-306.14 Returned Food and Re-Service or Sale.*

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous (time/temperature control safety foods) and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

Preventing Contamination from Other Sources **3-307.11 Miscellaneous Sources of Contamination.**

This Code section provides a category in which to capture sources of contamination not specifically delineated in Subparts 3-301 through 306. Codes prior to 1993 had such a provision for addressing food contamination for reasons other than those elsewhere specified. Regardless of its specificity, a Code can not anticipate all the diverse means by which food can become contaminated after receipt.

Cooking

3-401.11 Raw Animal Foods.*
3-401.12 Microwave Cooking.*
3-401.13 Plant Food Cooking for Hot Holding.

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has reached 54.4°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has reached 62.8°C (145°F). Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, lamb roasts and cooked corned beef can be prepared using one of the time and temperature combinations listed in the chart in § 3-401.11 to meet a 6.5-$\log_{10}$ reduction of Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time. The source of the time and temperature parameters is from the USDA/FSIS Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/oa/fr/95033F-a.htm.

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Part 3-4 of this Code are based on the destruction of *Salmonellae*. This organism, if present in raw shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats including commercially raised game animal meat, specified as acceptable for cooking at this temperature and time parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods. Part 3-4 includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at

63°C(145°F), a time span of 15 seconds will provide a 3D reduction of ***Salmonella* Enteritidis** in eggs.

The requirements specified under ¶ 3-401.11(D) acknowledge the rights of an informed consumer to order and consume foods as preferred by that consumer based on the consumer's health status and understanding of the risks associated with eating raw or partially-cooked animal foods.

In consumer self-service operations, such as buffets, salad bars, sushi bars, or display cases, the consumer advisory as specified under section 3-603.11 must be posted or available at the self-service unit where the raw or partially cooked food is held for service and readily accessible to consumers prior to making their food selections. In a catered situation, such as a wedding reception, guests are responsible for making their own requests or selections.

Slow-cooked roasts - Heating Deviations and Slow Come Up Time

(Source: USDA/FSIS Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/oa/fr/95033F-a.htm

Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious that even recooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins, such as those of ***Staphylococcus aureus***, are extremely heat stable and are not inactivated by normal recooking temperatures.

Further, the sampling of product following a heating deviation may not yield sufficient information to determine the safety of the product in question. Heating deviations can favor the multiplication of many types of bacteria. It would be difficult and expensive to sample for all of them. Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an oven in which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The USDA/FSIS determined that within a 6-hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded 5-logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed. Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) and USDA. Paragraph 3-401.11(C) includes their recommendations.

USDA comments included, “For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork, and lamb are not included.”

NACMCF comments included, “Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145°F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready-to-eat food.”

As reflected in the definition of “whole-muscle, intact beef steak,” marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Code allowance for undercooking without a consumer advisory is negated.

Pork

In pork, ***Trichinella spiralis***, ***Toxoplasma gondii***, and ***Taenia solium***, parasites causing foodborne illness, are inactivated at temperatures below 145°F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145°F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145°F for 15 seconds.

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animals foods because when cooked to a temperature greater than 68°C (155°F), ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 Heat-Processing and Stabilization Requirements for Uncurred Meat Patties (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing ***Escherichia coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee for Microbiological Criteria for Foods' (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated on page 7, in Option (A), that:

> "Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157°F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158°F requirement."

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158°F for less than one second is an adequate cook based on the following:

> 1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetative enteric pathogens;
>
> 2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and
>
> 3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C (165°F) or above for 15 seconds yield greater than a 7D reduction.

3-401.12 Microwave Cooking.*

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°C (165°F) in all parts of

the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C (165°F) throughout the food.

"The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction. These factors are exemplified by moisture and salt contents of foods, which play a far more important role in microwave than conventional heating." (Reference: Heddelson and Doores, see Annex 2)

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 60°C (140°F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

Freezing **3-402.11 Parasite Destruction.***

Refer to the public health reason for § 3-201.11.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

The recommended control strategies refer to the ambient air temperature during freezing and to the length of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held after it is solid frozen, whichever it appropriate. The parasite hazard is not considered to be reasonably likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that contains the egg mass) and rinsed.

In response to information provided to the FDA Office of Seafood, the Fish and Fisheries Products Hazards and Controls Guidance lists certain species of tuna as not

being susceptible to parasites of concern and therefore exempted from the freezing requirements that apply to other fish species that are consumed raw.

The Fish and Fisheries Products Hazards and Controls Guidance states that species that normally have parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when raised on pelleted food in an aquaculture operation. On the other hand, aquacultured fish that are fed processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species do not normally have a parasite hazard. Feed must not contain any live parasites. For example, the use of fresh fish meat in feed could transmit such parasites. Only heat treated feed or feed otherwise produced in a manner that would kill parasite intermediate stages infective to the aquacultured fish, such as most pelleted feeds, should be used.

3-402.12 Records, Creation and Retention.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

While the Country of Origin Labeling requirements, http://www.ams.usda.gov/COOL/ effective Sept. 30, 2004, mandate identification of wild and farm-raised fish and shellfish, the requirements do not address contents of pelleted feed used in the aquaculture operation. Documentation must be available in the food establishment from the source-through-purchase specifications or labeling that pelleted feed used did not contain fresh fish or plankton. Follow the guidance provided in The Fish and Fisheries Products Hazards and Controls Guidance Table #3-1 - Potential Vertebrate Species Related Hazards and Table #3-2 - Potential Invertebrate Species Related Hazards.

Reheating **3-403.11 Reheating for Hot Holding.***

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of ***Clostridium perfringens*** that may grow in meat, poultry, or gravy if these products were improperly cooled. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being held at improper holding temperatures or improperly cooled, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by ***Staphylococcus aureus***, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Refer also to the public health reason for § 3-401.12.

3-404.11 Treating Juice.

Refer to the public health reason for § 3-801.11.

Temperature and Time Control	**3-501.11**	**Frozen Food.**
	3-501.12	**Potentially Hazardous Food (Time/Tempurture Control for Safety Food), Slacking.**
	3-501.13	**Thawing.**

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

3-501.14 Cooling.*

Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of potentially hazardous foods (time/temperature control for safety foods) has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, potentially hazardous foods (time/temperature control for safety foods) are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21°C - 52°C (70°F - 125°F), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

The Food Code provision for cooling provides for cooling from 135ºF to 41°F or 45°F in 6 hours, with cooling from 135ºF to 70°F in 2 hours. The 6-hour cooling parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Code. The initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might involve cooling from 135ºF to 70ºF in 1 hour, in which case 5 hours remain for cooling from 70ºF to 41ºF or 45ºF. Conversely, if cooling from 135ºF to 41°F or 45°F is achieved in 6 hours, but the initial cooling to 70ºF took 3 hours, the food safety hazards may not be adequately controlled.
If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as ***Clostridium perfringens*** or ***Bacillus cereus*** should be killed or inactivated. However, under substandard sanitary conditions, other

pathogens such as ***Salmonella*** or ***Listeria monocytogenes*** may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions.

Shell Eggs

FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not found the ionizing radiation process to be unsafe for shell eggs. However, shell eggs that have been subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell egg pasteurization requires the egg to have been subjected to a 5-log kill process for ***Salmonella* Enteritidis**, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction. Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot be guaranteed that ***Salmonella* Enteritidis** will be eliminated in all treated eggs. Further, irradiated eggs must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a potentially hazardous food (time/temperature control for safety food) after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a potentially hazardous food (time/temperature control for safety food) after cooling because pathogens, which may be present in the water, may pass through the egg shell during cooling.

***Salmonella* Enteritidis** has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

On December 5, 2000 federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of maintaining an ambient air temperature of 45°F. With the newly established Federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of ***Salmonella*** spp. should be shortened. Additionally, this requirement negates the need to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

CFSAN/FSIS Joint Position Paper on Cooling

The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of ***Clostridium botulinum*** and ***Clostridium perfringens*** and other spore-forming bacteria. Furthermore, these organisms can thrive in the warm product since other competing organisms have been eliminated. Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells can multiply to hazardous levels. The presence of sufficient numbers of ***C. botulinum*** or other spore-forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these organisms will provide the greatest amount of safety.

The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of ***C. botulinum*** and no more than 1 log growth of ***C. perfringens***. The performance standard of no more than 1 log growth of ***C. perfringens*** was based on the following reasons:

1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater of ***C. perfringens*** per gram as one of the criteria for incriminating ***C. perfringens*** as a causative agent of foodborne illness in finished product. However, foods responsible for ***C. perfringens*** outbreaks were found usually to contain 10^6 vegetative ***C. perfringens*** cells per gram. In FSIS microbiological raw product surveys, samples were found to contain more than 1000 ***C. perfringens***

per gram. There is some probability that greater than 10^4 ***C. perfringens*** per gram can occur in the raw product on rare occasions. It is a conservative assumption that the great majority of ***C. perfringens*** in the raw product are spores.

2. Heating activates spores that, during cooling, become vegetative cells that can multiply to hazardous levels. If there are more than 10^4 ***C. perfringens*** (spores) per gram on raw product, it is possible that there may be more than 10^4 vegetative ***C. perfringens*** per gram in the product if it is improperly cooled after cooking.

3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was determined that a limit of no more than 1 $\log_{10}$ growth of ***C. perfringens*** would be appropriate to ensure that there would be no more than 10^5 ***C. perfringens*** per gram on the finished product after cooling.

4. The performance standard was discussed with experts on clostridia research. The experts agreed that limiting the relative growth of ***C. perfringens*** to no more than 1 $\log_{10}$ would be reasonable and somewhat conservative with respect to product safety. (64 FR 732, January 6, 1999, Performance Standards for the Production of Certain Meat and Meat Products).

The FSIS compliance guideline for the cooling performance standards, which can be found at http://www.fsis.usda.gov/oa/fr/95033F-b.htm Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization), is that product must be cooled from 130ºF to 80°F in 1.5 hours and from 80ºF to 40°F in 5 hours. This cooling rate can be applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and poultry products. The guideline results in continuous and rapid cooling of the product in the temperature range where the spore-forming organisms can grow rapidly.

The former USDA guideline of cooling from 120ºF to 55°F in no more than 6 hours is also included in the new compliance guidelines. In using this guideline, chilling should begin within 90 minutes after the cooking cycle is completed, and cooling should continue until product reaches 40°F. The 6-hour rule begins when the product reaches 120ºF, and product should not be shipped until the product reaches 40°F. This older cooling guideline results in a significantly smaller margin of safety, especially if the product is non-intact. In using this older guideline, the establishment has to ensure that cooling is as rapid as possible, especially between 120ºF and 80°F, and should monitor the cooling closely to prevent any deviation. If product remains between these temperatures for more than an hour, compliance with the performance standard is less certain.

The FSIS cooling guideline **for meat and poultry products containing 100 ppm added nitrite** is 130ºF to 80°F in 5 hours and from 80ºF to 45°F in 10 hours, a total of 15 hours cooling time. This cooling process provides a narrow margin of safety. In case of cooling deviations, the establishment should assume that their process has exceeded the performance standard for controlling the growth of ***C. perfringens***, and

should take corrective action. However, the **presence of nitrite** should ensure compliance with the performance standard for ***C. botulinum***.

The Food Code provision for cooling is similar, though not identical to the FSIS cooling compliance guidelines. It provides for cooling from 135ºF to 70°F in 2 hours and from 135ºF to 41°F or 45°F in 6 hours and is based on the same food safety concerns as FSIS' guidance. The Food Code provides prescriptive cooling time/temperature combinations without a HACCP plan in place. Federally inspected meat and poultry establishments are required to implement a HACCP plan for their operations.

The Conference for Food Protection (CFP) at its 2000 meeting recommended that FSIS and FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the data on safe cooling times for cooked, potentially hazardous foods (time/temperature control for safety foods). The review would include data from a study, submitted to the CFP, showing that cooling of a meat product from 130ºF to 45°F can safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the study, continuous cooling of a meat product from 130ºF to 45°F in 15 hours permitted about 1 log growth of ***C. perfringens***.

In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data referenced in the CFP recommendation do not support a change in the FSIS guidance or the Food Code § 3-501.14 and considered it inadvisable to ask the NACMCF to undertake the task requested for several reasons:

1. The study did not address growth of ***C. botulinum****.*

2. The results are from a carefully controlled laboratory study in which cooling of the product was steady and continuous, conditions difficult to maintain in most commercial processing or retail environments even with data loggers and other control mechanisms in place.

3. The study was done only on ground beef and may not be applicable to other meat and poultry or to other potentially hazardous foods (time/temperature control for safety foods).

As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position paper to clarify their joint position on the cooling issues.

3-501.15 Cooling Methods.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time

required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

3-501.16 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding.*

Bacterial growth and/or toxin production can occur if potentially hazardous food (time/temperature control for safety food) remains in the temperature "Danger Zone" of 5°C to 57°C (41°F to 135°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

Cold Holding

Except for raw shell eggs, control of the growth of ***Listeria monocytogenes*** (*Lm*) is the basis for the list of cold holding temperature and time combinations in paragraph 3-501.17(A). The list addresses time, in addition to temperature, as a control for the growth of *Lm* in refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food). The Code provisions for cold holding focus on environmental conditions that allow 1 log of growth of *Lm*, and do not set an acceptable number of *Lm* in food. Neither do they imply that *Lm* is in the product.

The times and temperatures in the 1999 Food Code were based on the USDA Pathogen Modeling Program (PMP), which is conservative in estimating how soon *Lm* begins to grow and how fast. The PMP was based largely on observations of microbial growth in broth cultures, but some observations in specific foods were also included. The PMP allows for some variation in temperature, pH, and water activity, and gives a conservative estimate of safe times and temperatures for holding foods. The 1999 Food Code estimated safe times and temperatures that would allow 3 logs of growth, based on the PMP.

During 2000, CFSAN researched published literature and compiled a listing of the growth potential of *Lm* in various food commodities using real food data. Based on this information, the 1999 Food Code times and temperatures of 41ºF for 7 days and 45ºF for 4 days were validated, but the underlying performance standard changed for the commodities studied. The research-based, food-specific times and temperatures allow

no more than 1 log of growth instead of the 3 log growth predicted in the PMP. This more stringent performance standard of 1 log is consistent with the USDA/FSIS performance standard and the fact that the infectious dose of *Lm* remains unknown.

FDA concluded that the 1999 Code time/temperature criteria hold true and provide both a greater level of safety and a more realistic basis for regulatory requirements without compromising public health protection.

In October 2003, FDA, in cooperation with the USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (risk assessment). This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

The risk assessment identified several broad factors that affect consumer exposure to *Lm* at the time of food consumption. Two of these factors, refrigerated storage temperature and duration of refrigerated storage before consumption, have a direct bearing on cold holding time/temperature combinations used in food establishments.

FDA continues to have concerns about the potential for growth of *Lm* in refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food), prepared and packaged in a food processing plant and held in a food establishment. Data from the risk assessment (see the following Annex 3 3-501.16 Table 1) show a significant reduction in the projected cases of listeriosis when refrigerated storage is limited to 41ºF. Based on these data and conclusions from the risk assessment, FDA continues to recommend that food establishments limit the cold storage of potentially hazardous (time/temperature control for safety), ready-to-eat foods to a maximum temperature of 41ºF.

3-501.16 – Table 1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures*

Maximum Refrigerator Temperature	Cases of Listeriosis[a]		
	Median	5th Percentile	95th Percentile
Baseline[b]	2105	3/4[c]	3/4[c]
7 ˚C (45 ˚F) maximum	656	331	761
5 ˚C (41 ˚F) maximum	28	1	126

[a]Values for the median, upper and lower uncertainty levels.
[b]The baseline uses the full empirical distribution of refrigerator temperatures from the Audits International (1999) survey.
[c]The baseline number of cases of listeriosis is fixed based on CDC surveillance data.
*The scenario assumed the distribution of storage times is the same for all three temperature sets.
Source: Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003. Table VI-1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures.

Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998 Refrigeration and Labeling Requirements for Shell Eggs) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7ºC (45ºF). This regulation, however, does not apply to eggs while held at all retail establishments. FDA is concerned that without continued refrigeration up until the time that the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of ***Salmonella* Enteritidis** to occur. The agency reviewed research indicating that ***Salmonella Enteritidis*** multiplies at temperatures of 10ºC (50ºF) and above but can be inhibited at lower temperatures, e.g., 8ºC (46ºF), 7ºC (45ºF), and 4ºC (39ºF). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air temperature of 7ºC (45ºF) for eggs stored and displayed at retail establishments. Amended Federal regulations 21 CFR Part 115.50 issued on December 5, 2000 and became effective on June 4, 2001.

Although Congress did not expressly preempt State law in this area, FDA found preemption is needed because State and local laws that are less stringent than the Federal requirements will not support the important public health goals of these regulations. FDA does not believe that preemption of State and local refrigeration and labeling requirements that are the same as or more stringent than the requirements of these regulations is necessary, as enforcement of such State and local requirements will support the food safety goals of these regulations. Accordingly, the preemptive effect of this rule is limited to State or local requirements that are not as stringent as the

requirements of these regulations; requirements that are the same as or more stringent than FDA's requirements remain in effect.

Hot Holding

In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommended that the minimum hot holding temperature specified in the Food Code:

- Be greater than the upper limit of the range of temperatures at which ***Clostridium perfringens*** and ***Bacillus cereus*** may grow; and
- Provide a margin of safety that accounts for variations in food matrices, variations in temperature throughout a food product, and the capability of hot holding equipment to consistently maintain product at a desired target temperature.

C. perfringens has been reported to grow at temperatures up to 52°C (126°F). Growth at this upper limit requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that lag phase duration and generation times are shorter at incubation temperatures below 49°C (120°F) than at 52°C (125°F). Studies also suggest that temperatures that preclude the growth of ***C. perfringens*** also preclude the growth of ***B. cereus***.

CDC estimates that approximately 250,000 foodborne illness cases can be attributed to ***C. perfringens*** and ***B. cereus*** each year in the United States. These spore-forming pathogens have been implicated in foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an important public health intervention.

Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food Protection meeting, FDA believes that maintaining food at a temperature of 57°C (135°F) or greater during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure in the prevention of foodborne illness.

3-501.17	**Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.***
3-501.18	**Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Disposition.***

Refer to Annex 7, Chart 4-C.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as ***Listeria monocytogenes***, is significantly slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to public health in ready-to-eat foods.

The date by which the food must be consumed takes into consideration the differences in growth of ***Listeria monocytogenes*** at 5°C (41°F) and 7°C (45°F). Based on a predictive growth curve modeling program for ***Listeria monocytogenes***, ready-to-eat, potentially hazardous food (time/temperature control for safety food) may be kept at 5°C (41°F) a total of 7 days or at 7°C (45°F) a total of 4 days. Therefore, the period of time allowed before consumption is shortened for food in refrigerators incapable of maintaining food at 5°C (41°F) but capable of maintaining it at 7°C (45°F) or below. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for ***Listeria monocytogenes*** to multiply, before freezing and after thawing. Potentially hazardous (time/temperature control for safety) refrigerated foods must be consumed, sold or discarded by the expiration date.

Date marking is the mechanism by which the Food Code requires active managerial control of the temperature and time combinations for cold holding. Industry must implement a system of identifying the date or day by which the food must be consumed, sold, or discarded. Date marking requirements apply to containers of processed food that have been opened and to food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food establishment. This provision applies to both bulk and display containers. It is not the intent of the Food Code to require date marking on the labels of consumer size packages.

A date marking system may be used which places information on the food, such as on an overwrap or on the food container, which identifies the first day of preparation, or alternatively, may identify the last day that the food may be sold or consumed on the premises. A date marking system may use calendar dates, days of the week, color-coded marks, or other effective means, provided the system is disclosed to the Regulatory Authority upon request, during inspections.

FDA/USDA/CDC *Listeria monocytogenes* Risk Assessment

In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

In examining these closely, FDA showed that 5 factors are important in measuring the public health impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of consumption of a ready-to-eat food; (2) frequency and levels of ***L. monocytogenes*** in a ready-to-eat food; (3) potential of the food to support growth

of the bacterium during refrigeration; (4) refrigerated storage temperature; and (5) duration of refrigerated storage before consumption.

Based on these 5 factors, the 23 categories of ready-to-eat foods were ranked according to their relative risk of contamination and growth of ***Listeria monocytogenes***. The risk categories used were: very high risk; high risk; moderate risk; low risk; and very low risk.

Impact of the Listeria monocytogenes Risk Assessment on Date Marking

Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on very high and high risk foods, while at the same time, exempting foods that present a very low, or low risk of contamination and growth of ***Listeria monocytogenes***. Based on this evaluation, date marking provisions of the Food Code do not apply to the following foods:

Deli Salads Prepared and Packaged in a Food Processing Plant

Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato salad, and macaroni salad, manufactured according to 21 CFR 110. According to data from the risk assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of ***Listeria monocytogenes***. There are estimates that 85% of all deli salads are prepared and packaged in a food processing plant and do not support growth. Based on discussions with deli salad manufacturers and trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli salads to add one or more preservatives that inhibit the growth of ***Listeria monocytogenes***. Based on their wide use within this segment of the industry and their effectiveness at inhibiting the growth of ***Listeria monocytogenes***, all deli salads prepared and packaged in a food processing plant are exempt from date marking. However, all deli salads prepared in a food establishment require date marking.

Hard and Semi-Soft Cheeses

In December, 1999, FDA issued an exemption from date marking for certain types of hard and semi-soft cheeses (http://www.cfsan.fda.gov/~ear/ret-chdt.html), based on the presence of several factors that may control the growth of ***Listeria monocytogenes***. These factors may include organic acids, preservatives, competing microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are exempt from date marking.

List of Some Hard and Semi-Soft Cheeses Exempt from Datemarking	
Asadero	Asiago soft
Abertam	Battelmatt
Appenzeller	Bellelay (blue veined)
Asiago medium or old	Blue
Bra	Brick
Cheddar	Camosum
Christalinna	Chantelle
Colby	Edam
Cotija Anejo	Fontina
Cotija	Gorgonzola (blue veined)
Coon	Gouda
Derby	Havarti
Emmentaler	Konigskase
English Dairy	Limburger
Gex (blue veined)	Milano
Gloucester	Manchego
Gjetost	Monterey
Gruyere	Muenster
Herve	Oka
Lapland	Port du Salut
Lorraine	Provolone
Oaxaca	Queso de Bola
Parmesan	Queso de la Tierra
Pecorino	Robbiole
Queso Anejo	Roquefort (blue veined)
Queso Chihuahua	Samsoe
Queso de Prensa	Tilsiter
Romanello	Trappist
Romano	
Reggiano	
Sapsago	
Sassenage (blue veined)	
Stilton (blue veined)	
Swiss	
Tignard (blue veined)	
Vize	
Wensleydale (blue veined)	

Cultured Dairy Products

Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation. Data from the risk assessment

show that ***Listeria monocytogenes*** does not grow in these foods and therefore, these products are exempt from date marking.

Preserved Fish Products

Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products, manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or acidity of these products does not allow for the growth of ***Listeria monocytogenes*** and therefore, these products are exempt from date marking. This exemption does not apply to hot or cold smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved on-site, in a food establishment, such as ceviche.

USDA-regulated products

Date marking provisions of the Food Code do not apply to shelf stable ready-to-eat meat and poultry products. Shelf stable ready-to-eat meat and poultry products are not required by USDA to be labeled "Keep Refrigerated." For these products, the nitrite and salt in the cure and the lower pH resulting from fermentation give additional protection against microbial growth. Some fermented sausages and salt-cured products are shelf stable, do not require refrigeration, and do not bear the label "Keep Refrigerated." To be shelf stable, a product manufactured under USDA inspection must have a process that results in a product that meets one of the recognized objective criteria for shelf stability, such as water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are exempt from the Food Code date marking requirements.

Shelf stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date marked. Shelf stable salt-cured products such as prosciutto, country cured ham, or Parma ham do not require refrigeration or Food Code date marking. Other salt-cured products include basturma, breasaola, coppa, and capocolla.
Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the USDA-required label "Keep Refrigerated." Examples of these products are cooked bologna, cooked salami, and sliced country ham which are ready-to-eat fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

Regarding the exemption from date marking for shelf-stable sausages in a casing, the exemption does not apply if the casing is removed. The intact casing on shelf-stable sausages may be overwrapped to protect the cut face of the sausage. With shelf stable (not potentially hazardous (time/temperature control safety)) sausages, the intact casing provides a barrier to contamination (although not an absolute one), the exposed face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face is exposed. The coagulated protein that occurs on the surface of some nonshelf stable cooked sausages is not a casing.

Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do need to be date marked.

If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment, the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is not required by USDA/FSIS and if applied, would not supercede or replace date marking requirements established by the Food Code or by State/local authorities that apply after the food is opened in a retail establishment.

Manufacturer's use-by dates

It is not the intent of this provision to give a product an extended shelf life beyond that intended by the manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are voluntarily placed on food packages.

Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer's use-by date is its recommendation for using the product while its quality is at its best. Although it is a guide for quality, it could be based on food safety reasons. It is recommended that food establishments consider the manufacturer's information as good guidance to follow to maintain the quality (taste, smell, and appearance) and salability of the product. If the product becomes inferior quality-wise due to time in storage, it is possible that safety concerns are not far behind.

It is not the intention of this provision that either the manufacturer's date or the date marked by the food establishment be placed on consumer packages.

3-501.19 Using Time as a Public Health Control.*

The 2000 Conference for Food Protection (CFP) meeting recommended that FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the Food Code provision that addresses using time alone as a public health control, section 3-501.19. In response to the CFP recommendation, FDA in consultation with USDA/FSIS, determined that there is sufficient scientific information available to support the current provision in the Food Code without requesting consideration by the NACMCF. As an alternative response, FDA informed the CFP that it would provide the following position paper on using time alone as a public health control.

Position Paper

Food Code section 3-501.19 allows potentially hazardous food (time/temperature control for safety) food that is ready-to-eat (RTE) to be stored without temperature control for up to 4 hours, after which it must be discarded or consumed or for up to 6

hours for refrigerated food, if the food is 5°C (41°F) when initially removed from temperature control, and as long as the food temperature does not exceed 21°C (70°F). The following information is provided to explain the reasoning in allowing time alone to be used as a public health control for food safety.

Background information

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during its equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Holding Cold Food Without Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, ***Listeria monocytogenes*** is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of ***L. monocytogenes*** warrants concern for potentially hazardous (time/temperature control for safety foods) RTE foods. Although the FDA and USDA have a zero tolerance for ***L. monocytogenes*** in RTE food, conditions are permitted in the Food Code that would allow ***L. monocytogenes*** cells 1 log of growth (3.3 generations). ***Salmonella*** is also a concern especially with products containing eggs. However ***L. monocytogenes*** grows more rapidly than ***Salmonella*** at refrigeration and room temperatures. By ensuring minimal ***Listeria*** growth in food, the threat from ***Salmonella*** would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow ***B. cereus*** to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

For food refrigerated at 41ºF or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of ***L. monocytogenes*** remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for ***L. monocytogenes*** in food were not found, however published values at 68ºF and 70°F in egg and milk products confirmed slow ***L. monocytogenes*** growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, ***L. monocytogenes*** would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth

rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly.

Unfortunately there are no models that take changing temperatures into consideration when predicting growth. Likewise there are very few published papers dealing with the growth of organisms in food during warming. The conservative nature of the 4-hour limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 75°F.

It is important to note that potentially hazardous (time/temperature control for safety) foods held without cold holding temperature control for a period of 4 hours do not have any temperature control or monitoring. These foods can reach any temperature when held at ambient air temperatures as long as they are discarded or consumed within the four hours.

Holding Hot Food without Temperature Control

The second scenario for food without temperature control exists when food is cooked according to Food Code recommendations, then kept at room temperature for 4 hours before discarding. Foodborne pathogens of concern for an uncontrolled temperature scenario are sporeformers including ***Clostridium perfringens*** and ***Bacillus cereus***. Food cooked according to Food Code guidelines should be free of vegetative cells. However, the heat requirements are not sufficient to kill spores of ***C. perfringens*** or ***B. cereus*** and may actually serve as a heat shock that activates the spores. ***B. cereus*** is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. ***C. perfringens*** is found commonly in outbreaks attributed to inadequate hot holding of beef and poultry. Despite the prevalence of both spores in nature, ***C. perfringens*** cases are estimated to be more numerous than ***B. cereus*** cases by a factor of 10.

B. cereus can produce emetic toxin in food, and the optimum temperature for the production of toxin is between 77°F and 86°F. However, the time needed to produce the toxin is longer than the time the food will be exposed to any temperature range with a 4-hour holding limit. Both ***C. perfringens*** and ***B. cereus*** produce enterotoxin inside the intestine of the infected host if substantial numbers of vegetative cells are present in the food (10^{5-7} CFU/g). Although the reported levels of both spores in raw foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in food.

During the time without temperature control, the temperature of the food could decrease slowly enough to expose spores of both organisms to optimal growth conditions for a significant length of time. Like warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of foods prepared it would be impossible to generalize how fast a typical product loses temperature after cooking. As with

warming, it is prudent to imagine a worst-case scenario where heat loss is slowed. A beef roast slow cooked to 130°F for the appropriate time according to the Food Code was used as consideration for possible spore growth. Cooking roast beef to 130°F can create an anaerobic environment in both the meat and gravy. The low internal temperature creates a small temperature differential with the environment (assumed at 75°F), allowing for a slower decrease in the food's temperature.

After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or rolled meat product would lose heat quickly enough to discourage significant growth of either ***C. perfringens*** or ***B. cereus***. If all spores were distributed on the surface of the product by either pre- or post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe. Likewise, products that are stirred or products that lose heat faster than a roast would also be considered safe.

FDA intends to do research regarding food products that may have spores in the center of the product, and further evaluate if there are potential hazards that may be associated with them while held without temperature control for 4 hours.

---------- End of position paper ---------

At the 2004 meeting of the CFP, a committee submitted and the Conference accepted a document that examined scientific research related to the growth of ***Listeria monocytogenes***, and the influence of time and temperature on its growth. The CFP committee report is found at http://www.foodprotect.org/doc/04_issues/folder_attachments/III-008a%finalreport-timeasapublichealthcontrol.pdf.

The 2004 CFP report stated that the USDA-PMP program can be used as a tool to estimate time periods for a 1-log increase in growth for ***Listeria monocytogenes*** in ideal (laboratory media) growth conditions. Using this modeling approach, at 41°F, 45°F, and 50°F, the time for a 1-log increase was, 87.8, 53.9, and 34.7 hours, respectively. At room temperature (70°F) a 1-log increase was noted at 5.2 hours and at ideal growth temperatures (95°F), the reported time for a 1-log increase was 3.0 hours. In general, the data from the USDA-PMP program provides very conservative growth data and, in most cases, growth would be expected to be less rapid in a food system. This table does provide comparative information relative to growth rates at different holding temperatures in the event that time was used as a factor in managing food safely.

The report further recommended that food could safely be held for up to 6 hours without external temperature control as long as the food temperature did not exceed 70°F. Based on that report and data from the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003, the Food Code allows potentially hazardous food (time/temperature control for safety) food to be stored up to 6 hours without external

temperature control provided that the food temperature does not exceed 70°F and the food is discarded or consumed at the end of the 6 hours.

Raw eggs

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with ***Salmonella* Enteritidis**, that the use of time as a public health control in institutional settings is not allowed.

Specialized Processing Methods **3-502.11 Variance Requirement.***

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

The concept of variances may be new to some regulatory authorities. Some jurisdictions may not have a formal process to respond to industry requests for variances, although informal allowances may have been allowed in specific situations. Recognizing the opportunity to use the variance process may require additional rulemaking, or at least policy development, at the jurisdictional level. Rulemaking can be used to outline the procedures for a variance request, including the information required in section 8-103.11. In addition, the rulemaking process can address the regulatory authority's responsibility to consider an industry's variance application and an appeals process in case a variance is not given due consideration or is denied. The Conference for Food Protection Variance Committee recommended that regulatory agencies adopt a variance review process. General guidance regarding administrative procedures is given below.

Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request. From any variance request there may emerge a set of complex issues and scientific competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within

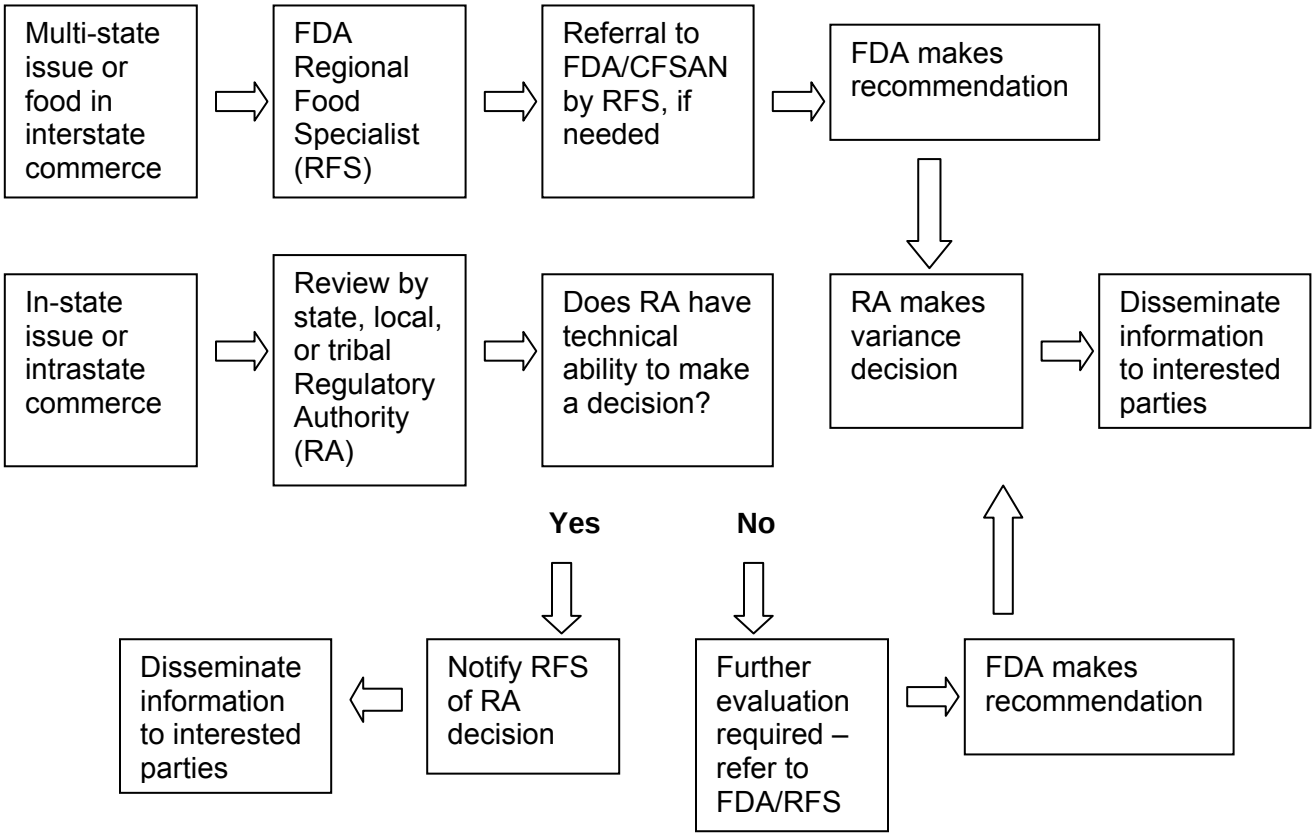
the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.

Except for the Interstate Travel Program, FDA generally does not directly regulate retail and food service establishments, including entertaining variances for that segment of the industry. FDA is still exploring processes for handling variances on a national basis such as those received from national chain businesses. In conjunction with the 2000 CFP Variance Committee, FDA will continue to explore ways to provide assistance and guidance to regulators regarding access to scientific and technical resources in order to make science-based decisions regarding variances.

FDA recommends that regulatory authorities develop a written administrative process that is consistent with, and addresses the information contained in, Food Code sections 8-103.10, 8-103.11, and 8-103.12, and follow a process consistent with the recommendations of the CFP Variance Committee as shown in its flow chart.

3-501.11 Chart 1 – A Model Flow Process for State Regulators to Address Variances

Developed by the CFP Variance Committee



Model Administrative Procedures for Regulators to Address Variances

1) Designate an agency team and assign a leader to address variance requests.

2) Establish an agency review process leading to approval or denial of variance applications. For food safety issues, include recommendations for consulting with food processing authorities, food scientists, academia, professional organizations, other government agencies including the FDA Regional Food Specialist, or other experts external to the agency.

3) Set reasonable timelines for decision making. Determine if the variance application addresses an intrastate or interstate issue.

   a) For variances that have interstate or national implications, especially those that address food safety, regulators are urged to contact and work closely with their FDA Regional Food Specialist to determine if a national policy related to the issue exists. Regulators are encouraged to be consistent with national policies, guidelines, or opinions.

b) For variances that address intrastate issues, regulators are also encouraged to determine if other State or national guidance exists, and to stay consistent with it.

4) Make the agency's decision. Inform the applicant.

   a) If the variance request is approved, determine the starting date and document all special provisions with which the applicant must comply.
   b) If the variance request is denied, inform the applicant as to the reasons for the denial, the applicant's right to appeal, and the appeal process.

5) Inform other interested parties, including the FDA Regional Food Specialist.

   a) For variances having interstate or national implications, especially those that address food safety, regulators are urged to inform their FDA Regional Food Specialist so that FDA is aware of, and can appropriately disseminate the information regarding food safety variances that may affect food establishments in other jurisdictions, such as national chains.

   b) For variances that address intrastate issues, regulators are encouraged to share the information as if it were an interstate issue.

6) Document all agency actions and decisions in the facility's file. Consider including documentation of special variance provisions on the establishment's permit to operate.

7) If the variance is approved, inform the inspector assigned to that facility and train the inspector on the variance provisions, including the implementation of the industry's HACCP plan, if required.

8) Establish procedures to periodically review the status of the variance, determine if it successfully accomplishes its public health objective, and ensure that a health hazard or nuisance does not result from its implementation.

9) Establish written procedures for withdrawing approval of the variance if it is not successful.

3-502.12 Reduced Oxygen Packaging, Criteria.*

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic.

This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cm^2/m^3/24 hours or greater. A reduced oxygen atmosphere will result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.

Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic ***C. botulinum*** and ***L. monocytogenes*** are able to multiply well below 5°C (41°F). For this reason, ***C. botulinum*** and ***L. monocytogenes*** become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

The control of ***C. botulinum*** *or* ***L. monocytogenes*** when using ROP is usually accomplished using multiple hurdles or barriers to growth. Subparagraph 3-502.12 (B)(2) identifies secondary barriers that will control the growth of ***C. botulinum*** and ***L. monocytogenes*** when used in conjunction with a food storage temperature of 5°C (41°F) or less. They include a_w of 0.91 or less; pH of 4.6 or less; cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high levels of competing microorganisms. ***C. botulinum*** will not produce toxin below an a_w of 0.91. Nitrite, used in meat and poultry curing, inhibits the outgrowth of ***C. botulinum*** spores. Most foodborne pathogens do not compete well with other microorganisms, therefore foods that have a high level of spoilage organisms or lactic acid bacteria can safely be packaged using ROP.

Naturally fermented cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following: a lower pH, production of organic acids, and natural antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient air temperatures. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue,

Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of ***L. monocytogenes*** under modified atmosphere conditions.

When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of ***C. botulinum*** and ***L. monocytogenes***. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures of 1°C (34°F) or less to inhibit growth and/or toxin production of any surviving pathogens is essential. Since there are no other controlling factors for ***C. botulinum*** and ***L. monocytogenes*** in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate.

New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide products at 1°C (34°F) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures which can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Time is also a factor that must be considered in ROP. The 14 day “use by” date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer’s “sell by” or “use by” date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 34°F or less with stringent temperature monitoring and recording requirements. These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook chill processes.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors in these cheeses plus the normal refrigeration temperature of 41°F or less to maintain safety.

A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing procedures. ***C. botulinum*** and ***L. monocytogenes*** are potential hazards which must be controlled in most foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used.

When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under 3-502.11 providing evidence that the ROP methodology intended for use is safe.

Unfrozen raw fish and other seafood are specifically excluded from ROP because of these products' natural association with ***C. botulinum*** type E which grows at or above 3°C (37-38°F). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.

Accurate	**3-601.11**	**Standards of Identity.**
Representation	**3-601.12**	**Honestly Presented.**
Labeling	**3-602.11**	**Food Labels.**
	3-602.12	**Other Forms of Information.**

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Recent illnesses and deaths from Shiga toxin-producing ***Escherichia coli*** have occurred across the United States as a result of people eating hamburgers that were contaminated and then undercooked. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures.

Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997. The following attempts to provide guidance regarding those requirements and exemptions as they relate to the retail environment and to alert regulators to authority that has been given to them by the Nutrition Labeling and

Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a comprehensive understanding of the labeling requirements.

I. The following foods need not comply with nutrition labeling in the CFR referenced in subparagraph 3-602.11(B)(5) if they do not bear a nutrient claim, health claim, or other nutrition information:

(A) Foods packaged in a food establishment if:

(1) The food establishment has total annual sales to consumers of no more than $500,000 (or no more than $50,000 in food sales alone), and

(2) The label of the food does not bear a reference to the manufacturer or processor other than the food establishment;

(B) Low-volume food products if:

(1) The annual sales are less than 100,000 units for which a notification claiming exemption has been filed with FDA's Office of Nutritional Products Labeling and Dietary Supplements Food Labeling by a small business with less than 100 full-time equivalent employees, or

(2) The annual sales are less than 10,000 units by a small business with less than 10 full-time equivalent employees;

(C) Foods served in food establishments with facilities for immediate consumption such as restaurants, cafeterias, and mobile food establishments, and foods sold only in those establishments;

(D) Foods similar to those specified in the preceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:

(1) Ready-to-eat but not necessarily for immediate consumption,

(2) Prepared primarily in the food establishment from which it is sold, and

(3) Not offered for sale outside the food establishment;

(E) Foods of no nutritional significance such as coffee;

(F) Bulk food for further manufacturing or repacking; and

(G) Raw fruits, vegetables, and fish.

II. Game animal meats shall provide nutrition information which may be provided by labeling displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some other appropriate device.

III. Food packaged in a food processing plant or another food establishment, shall meet the requirements specified in § 3-602.11 and enforcement by the regulatory authority is authorized in the NLEA, Section 4. State Enforcement.

In 1998, 21 CFR Part 73, Section 73.75 was amended to address canthaxanthin as a color additive for salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout, cutthroat trout, and brown trout. This color additive may be in the feed that is fed to aquacultured fish, and when those fish are placed into a bulk container for shipment, the bulk container must bear a label declaring the presence of canthaxanthin. That same label information must be displayed at retail when those fish are offered for sale.

The 21 CFR Section 73.75(d)(4) requires that the presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2) and 101.100(a)(2). For additional information, see the Federal Register announcement 63 FR 14814, March 27, 1998, Listing of Color Additives Exempt from Certification; Canthaxanthin.

On August 2, 2004, President Bush signed into law the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282). This new law amended Sections 201 and 403 of the Federal Food, Drug, and Cosmetic Act to establish food allergen labeling requirements for all packaged foods regulated by FDA. The new provisions require that all affected packages of food labeled on or after January 1, 2006 must identify on the label the names of the food sources of any major food allergens (i.e., the following eight foods and any protein derived from them: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans) used as ingredients in the food. The names of the food sources are the same as the names of the eight foods that are major food allergens, with the exception that for fish, crustacean shellfish, and tree nuts, their respective food source names are the specific species of fish (e.g., bass, flounder, or cod), the specific species of crustacean shellfish (e.g., crab, lobster, or shrimp), and the specific types of tree nuts (e.g., almonds, pecans, or walnuts).

Consumer Advisory	**3-603.11**	**Consumption of Raw or Undercooked Animal Foods.***

Refer to the public health reason for § 3-401.11.

Purpose:

At issue is the role of government agencies, the regulated industry, and others in providing notice to consumers that animal-derived foods that are not subjected to

adequate heat treatment pose a risk because they may contain biological agents that cause foodborne disease. The deliverance of a balanced message that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk in perspective based on the consumer's health status and the food being consumed is part of the challenge. Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect behavior. The following information is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Background:

Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA included a codified provision for a point-of-purchase consumer advisory and stated in Annex 3:

> "FDA has requested comments and will consider the responses as well as other information that is available related to the risks involved and methods of risk communication to determine what action may be necessary by FDA to effectively inform consumers."

Consumer Focus Groups:

During 1996 - 1998, FDA conducted two different consumer focus group studies. Because the first set of focus groups (conducted before the 1997 Code) were not receptive to the language recommended at the 1996 Conference for Food Protection (CFP) meeting, that language was not included in the 1997 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer acceptance and receptiveness to menu-based advisories emerged.

It became apparent that there is a general appreciation for **"disclosure"** of what consumers view as "hidden ingredients," for example, whether a particular menu item contains raw egg. In addition to disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a **"reminder"** that consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the food establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a disclosure and reminder are**

provided, as described in § 3-603.11 of the Code. **Disclosure is** achieved when there is clear identification of animal-derived foods that are sold or served raw or undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such raw or undercooked ingredients. A third option for the consumer "reminder" was added later. The **reminder is** a notice about the relationship between thorough cooking and food safety.

Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a menu statement that advises consumers that food safety information about the disclosed items is available upon request. Essential criteria for such written information are available, with a downloadable model brochure, on the CFSAN Web Page at http://www.cfsan.fda.gov/~fc99guid.html. All brochures must meet these essential criteria. The other option is a short notice alerting consumers to the increased risk of consuming the disclosed menu items.

In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8, 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

The information contained in both the disclosure and reminder should be publicly available and readable so that consumers have benefit of the total message (disclosure and reminder) before making their order selections.

It is not possible to anticipate all conceivable situations. Therefore, there will always be need for discussion between the food establishment and the Regulatory Authority as to the most effective way to meet the objectives of satisfactory compliance.

The *Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code* (section 3-603.11 in the FDA Model Food Code), is a resource intended to assist regulators and industry in the implementation of the Consumer Advisory provision. It is recommended that it be used in conjunction with the FDA Food Code. It is available on the FDA/CFSAN web page at http://www.cfsan.fda.gov/~dms/fc99guid.html.

Locating the Advisory:

Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure and the reminder need to accompany the information from which the consumer makes a selection. That information could appear in many forms such as a menu, a placarded listing of available choices, or a table tent.

Educational Messages:

Educational messages are usually longer, more didactic in nature, and targeted to consumers who have been alerted to the food safety concern and take the initiative to

obtain more detailed information. It is expected that, in most cases, educational messages that are provided pursuant to § 3-603.11 (i.e., in situations where the option for referring the consumer to additional information is chosen), will be embodied in brochures that will not be read at the site where the immediate food choice is being made. Nonetheless, such messages are viewed as an important facet of arming consumers with the information needed to make informed decisions and, because the information is being requested by the consumer, it would be expected to play a role in subsequent choices.

Applicability:

Food Establishments:

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

"... Otherwise Processed to Eliminate Pathogens... ":

This phrase is included in § 3-603.11 to encompass new technologies and pathogen control/reduction regimens as they are developed and validated as fulfilling a specific performance standard for pathogens of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the Food Code, the level of pathogen reduction that is required before a raw or undercooked animal food is allowed to be offered without a consumer advisory must be equivalent to the levels provided by § 3-401.11 for the type of food being prepared.

The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions achieved in ¶¶ 3-401.11(A) and (B). Irradiated poultry provides a 3D kill which does not provide the level of protection of the 7D kill that results from the cooking regimen in the Food Code. Therefore, irradiated meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is intended that future Food Code revisions will address time/temperature requirements that take into consideration the pathogen reduction that occurs with irradiated foods.

Recognition of Other Processes:

Animal-derived foods may undergo validated processes that target a specific pathogen. In such instances, along with the required consumer advisory may appear additional language that accurately describes the process and what it achieves. For example, a technology for reducing ***Vibrio vulnificus*** in oysters to nondetectable levels has been

validated. FDA concurs that shellfish subjected to that process can be labeled with a truthful claim that appropriately describes the product. That is, a statement could be made such as, "pasteurized to reduce ***Vibrio vulnificus***" or "temperature treated to reduce ***Vibrio vulnificus.***" Such a claim must be in accordance with labeling laws and regulations, accurate, and not misleading. The claim would not, however, negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.

Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked ready-to-eat form. For example, a raw bar serving molluscan shellfish on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder, option #3, which would highlight the increased risk incurred when persons with certain medical conditions ingest shellfish that has not been adequately heat treated.

Terminology:

It should be noted that the actual on-site (e.g., on-the-menu) advisory language differs from the language in the codified provision, § 3-603.11. In the insert page for § 3-603.11, the **Reminder** options 2 and 3 use terms for foods that are less specific than the terms used in the actual code section. That is, the words "meat" rather than "beef, lamb, and pork" and "seafood" rather than "fish" are used. Categorical terms like "meat" are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, "milk" is not mentioned in the actual on-site advisory language. The sale or transportation of final packaged form of unpasteurized milk into interstate commerce is specifically prohibited by 21 CFR 1240.61. Also the consumption of raw milk is not recommended by FDA (this statement is in the form of an official FDA position statement found at http://www.cfsan.fda.gov/~ear/mi-03-4.html. Nonetheless, approximately 27 states allow unpasteurized milk in intrastate commerce which usually involves direct dairy farm-to-consumer procurement.

In the event that a food establishment governed by § 3-603.11 of this Code operates in conjunction with a dairy farm in a State that allows the in-State sale or service of unpasteurized milk, or in the case where a State allows unpasteurized milk to be marketed via retail-level food establishments, consumers need to be advised of the risk associated with drinking unpasteurized milk. In these situations, the actual advisory language needs to be amended to include milk (refer to Consumer Advisory Reminder, paragraph 3-603.11(C), options 2 or 3).

Molluscan Shellstock:

In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be provided when a seafood department or seafood market offers raw molluscan shellstock for sale or service. There is a risk of death from ***Vibrio*** infections from consuming raw molluscan shellstock for persons who have certain medical conditions.

Disposition	**3-701.11**	**Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.***

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Additional Safeguards	**3-801.11**	**Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.***

Refer to the public health reason for § 3-201.11.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of a “juice” means it is served as such or used as an ingredient in beverages. Puréed fruits and vegetables, which are commonly prepared as food for service to highly susceptible populations, are not juices and do not require HACCP plans or compliance with 21 CFR Part 120. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as ***Cryptosporidium***, Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Vibrio cholera***. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly susceptible population.

In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile products (canned juices) are acceptable for service to a highly susceptible population. Persons providing pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food safety.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of ***Salmonella* Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a ***Salmonella* Enteritidis** control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of ***Salmonella* Enteritidis** in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to ***Salmonella* Enteritidis**.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. Further information is available at the FDA website, http://www.fda.gov, by entering "sprouts" in the search window.

Although the Code's allowance for the Regulatory Authority to grant a variance (refer to §§ 8-103.10 - .12, 8-201.14, and 8-304.11) is applicable to all Code provisions, variance requests related to the preparation of food for highly susceptible populations must be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operating plan that implements good retail practices. Variances that will impact a highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population.

Subparagraph 3-801.11(F)(3) requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and

conservative and require a cooking temperature and time to ensure destruction of ***Salmonella* Enteritidis**.

3-801.11(G) and (H) Re-service of food

The Food Code addresses two issues concerning persons in isolation:

1. Contamination from an isolated patient to others outside.

The re-service of any food including unopened, original, intact packages in sound condition, of non-potentially hazardous food (temperature controlled for safety) from a person in isolation or quarantine for use by anyone else (other patients, clients, or consumers) is not permitted. The "isolation or quarantine" terminology in the Code text refers to a patient-care setting that isolates the patient, thereby preventing spread of key pathogens to other patients and healthcare workers. Once food packages come to a contact isolation room, they stay there until the patient uses or discards them. If packages of food are still in the room when the patient is discharged or moved from isolation, they must be discarded.

2. Contamination from the outside into a room with a patient in a "protective environment" isolation setting which protects the patient from contacting pathogens from other patients, healthcare workers, or other persons.

Packages of food from any patients, clients or other consumers should not be re-served to persons in protective environment isolation. Precautions similar to the isolation setting apply to this setting, i.e., once an unopened, original, intact package of condiment is delivered to this patient, the package stays there until used or discarded. New (not re-served) packages of food should be delivered to this patient each time.

To summarize the key difference between the two scenarios:

- Food packages served to patients in contact isolation may not be re-served to other patients because of the potential for disease transmission to other patients.

- Patients in protective environments should not be re-served with food packages from other patients because of the potential for disease transmission to the protective environment patient.

Chapter 4 Equipment, Utensils, and Linens

Multiuse **4-101.11 Characteristics.***

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be

transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

4-101.12 Cast Iron, Use Limitation.

Equipment and utensils constructed of cast iron meet the requirement of durability as intended in section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces the residues in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.

4-101.13 Lead, Use Limitation.

Historically, lead has been used in the formulation or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

FDA has established maximum levels (see FDA Compliance Policy Guide Section 545.450 Pottery (Ceramics); Imported and Domestic – Lead Contamination (CPG 7117.07) for leachable lead in ceramicware, and pieces that exceed these levels are subject to recall or other agency enforcement action. The levels are based on how frequently a piece of ceramicware is used, the type and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs, and pitchers have the most stringent action level, 0.5 parts per million, because they can be expected to hold food longer, allowing more time for lead to leach. Also, a pitcher may be used to hold fruit juice. And a coffee mug is generally used every day to hold a hot acidic beverage, often several times a day.

The FDA allows use of lead glazes because they're the most durable, but regulates them tightly to ensure their safety. Commercial manufacturers employ extremely strict and effective manufacturing controls that keep the lead from leaching during use. Small potters often can't control the firing of lead glazes as well so their ceramics are more likely to leach illegal lead levels, although many do use lead-free glazes.

In 21 CFR 109.16, FDA requires high-lead-leaching decorative ceramicware to be permanently labeled that it's not for food use and may poison food. Such items bought outside the United States may not be so labeled, potentially posing serious risk if used for food.

Pewter refers to a number of silver-gray alloys of tin containing various amounts of antimony, copper, and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys.

4-101.14 Copper, Use Limitation.*

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 2½ hours or more. After boiling, the wort is cooled, inoculated with brewers yeast, and fermented. The use of copper equipment during the prefermentation and fermentation steps typically result in some leaching of copper.

Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.

Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel-lined copper equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer following the hot brewing steps in the beer making process. Some also use pitch-coated oak vats or glass-lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for successful fermentation.

4-101.15 Galvanized Metal, Use Limitation.*

Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized containers into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized container.

4-101.16 Sponges, Use Limitation.

Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

4-101.17 Wood, Use Limitation.

The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

4-101.18 Nonstick Coatings, Use Limitation.

Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of this material as safe for food-contact surfaces. The Agency has determined that neither the particles that may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this nonstick finish may be scratched by sharp or rough-edged kitchen tools, the

manufacturer's recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or cleaners avoided.

4-101.19 Nonfood-Contact Surfaces.

Nonfood-contact surfaces of equipment routinely exposed to splash or food debris are required to be constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and insects.

Single-Service and Single-Use **4-102.11 Characteristics.***

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

Durability and Strength **4-201.11 Equipment and Utensils.**

Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they can not maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

4-201.12 Food Temperature Measuring Devices.*

Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

Cleanability **4-202.11 Food-Contact Surfaces.***

The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks,

chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

4-202.12 CIP Equipment.

Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas which are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

4-202.13 "V" Threads, Use Limitation.

V-type threads present a surface which is difficult to clean routinely; therefore, they are not allowed on food-contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on the high temperatures that are used in this equipment. The high temperature in effect sterilizes the equipment, including debris in the "V" threads.

4-202.14 Hot Oil Filtering Equipment.

To facilitate and ensure effective cleaning of this equipment, Code requirements, §§ 4-202.11 and 4-202.12 must be followed. The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible for replacement. Filtering the oil reduces the likelihood that off-odors, tastes, and possibly toxic compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is necessary for the filter to be accessible for replacement.

4-202.15 Can Openers.

Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced because they can no longer be adequately cleaned and sanitized. Can openers must be designed to facilitate replacement.

4-202.16 Nonfood-Contact Surfaces.

Hard-to-clean areas could result in the attraction and harborage of insects and rodents and allow the growth of foodborne pathogenic microorganisms. Well-designed equipment enhances the ability to keep nonfood-contact surfaces clean.

4-202.17 Kick Plates, Removable.

The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation does not meet Code requirements, debris could accumulate and create a situation that may attract insects and rodents.

Accuracy **4-203.11 Temperature Measuring Devices, Food.**

The Metric Conversion Act of 1975 (amended 1988, 1996, and 2004, 15 USC 205a et seq) requires that all Federal government regulations use the Celsius scale for temperature measurement. The Fahrenheit scale is included in the Code for those jurisdictions using the Fahrenheit scale for temperature measurement.

The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves. The accuracy specified for a particular food temperature measuring device is applicable to its entire range of use, that is, from refrigeration through cooking temperatures if the device is intended for such use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance.

The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988, 1996, and 2004, 15 USC 205a et seq) which requires the use of metric values. The $\pm$ 1.5^{o}C requirement is more stringent than the 3°F previously required since $\pm$ 1.5^{o}C is equivalent to $\pm$ 2.7^{o}F. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers.

If Fahrenheit thermometers are used, the 3°F requirement applies because of the calibrated intervals of Fahrenheit thermometers.

The accuracy specified for a particular air or water temperature measuring device is applicable to its intended range of use. For example, a cold holding unit may have a

temperature measuring device that measures from a specified frozen temperature to 20°C (68°F). The device must be accurate to specifications within that use range.

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Flow pressure is a very important factor with respect to the efficacy of sanitization. A pressure below the design pressure results in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

Functionality **4-204.11 Ventilation Hood Systems, Drip Prevention.**

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drippage are no longer clean.

4-204.12 Equipment Openings, Closures and Deflectors.

Equipment openings and covers must be designed to protect stored or prepared food from contaminants and foreign matter that may fall into the food. The requirement for an opening to be flanged upward and for the cover to overlap the opening and be sloped to drain prevents contaminants, especially liquids, from entering the food-contact area.

Some equipment may have parts that extend into the food-contact areas. If these parts are not provided with a watertight joint at the point of entry into the food-contact area, liquids may contaminate the food by adhering to shafts or other parts and running or dripping into the food.

An apron on parts extending into the food-contact area is an acceptable alternative to the watertight seal. If the apron is not properly designed and installed, condensation, drips, and dust may gain access to the food.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

This requirement is intended to protect both the machine-dispensed, unpackaged, liquid foods and the machine components from contamination. Barriers need to be provided so that the only liquid entering the food container is the liquid intended to be dispensed when the machine's mechanism is activated. Recessing of the machine's components and self-closing doors prevent contamination of machine ports by people, dust, insects,

or rodents. If the equipment components become contaminated, the product itself will be exposed to possible contamination.

A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the food.

4-204.14 Vending Machine, Vending Stage Closure.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

4-204.15 Bearings and Gear Boxes, Leakproof.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

4-204.16 Beverage Tubing, Separation.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines.

Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

4-204.18 Condenser Unit, Separation.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

4-204.19 Can Openers on Vending Machines.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

4-204.110 Molluscan Shellfish Tanks.

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

4-204.111 Vending Machines, Automatic Shutoff.*

Failure to store potentially hazardous (time/temperature control for safety) food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control," provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

4-204.112 Temperature Measuring Devices.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a

location that is representative of the actual storage temperature of the unit to ensure that all potentially hazardous (time/temperature control for safety) foods are stored at least at the minimum temperature required in Chapter 3.

Installing an air thermometer in some open display refrigerators can be difficult without physically impairing the usability of the case and interfering with cleaning and sanitation. Use of a temperature monitoring system that uses probe-like sensors that are placed in material resembling the density of food is an acceptable alternative. Thus, the direct temperature of the substitute product is measured by use of this product mimicking method.

A permanent temperature measuring device is required in any unit storing potentially hazardous (time/temperature control for safety) food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining potentially hazardous (time/temperature control for safety) foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

4-204.114 Warewashing Machines, Internal Baffles.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

The presence of adequate detergents and sanitizers is necessary to effect clean and sanitized utensils and equipment. The automatic dispensing of these chemical agents, plus a method such as a flow indicator, flashing light, buzzer, or visible open air delivery

system that alerts the operator that the chemicals are no longer being dispensed, ensures that utensils are subjected to an efficacious cleaning and sanitizing regimen.

4-204.118 Warewashing Machines, Flow Pressure Device.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. (See discussion in Public Health Reason for section 4-203.13.) It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

4-204.121 Vending Machines, Liquid Waste Products.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

4-204.122 Case Lot Handling Equipment, Moveability.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity.

4-204.123 Vending Machine Doors and Openings.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests.

Acceptability **4-205.10 Food Equipment, Certification and Classification.**

Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has been stipulated that:

"For food equipment programs, standards that establish sanitation requirements shall be specified government standards or standards that have been ratified by a public health approval step. ANSI shall verify that this requirement has been met by communicating with appropriate standards developing organizations and governmental public health bodies."

The term certified is used when an item of food equipment has been evaluated against an organization's own standard. The term classified is used when one organization evaluates an item of food equipment against a standard developed by another organization.

Equipment **4-301.11 Cooling, Heating, and Holding Capacities.**

The ability of equipment to cool, heat, and maintain potentially hazardous (time/temperature control for safety) foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;

2. Removal of any abrasive and removal or dilution of cleaning chemicals; and

3. Sanitization.

Refer also to the public health reason for § 4-603.16.

4-301.13 Drainboards.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

4-301.14 Ventilation Hood Systems, Adequacy.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Refer also to the public health reason for § 4-204.11.

4-301.15 Clothes Washers and Dryers.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Refer also to the public health reason for § 4-401.11.

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked potentially hazardous (time/temperature control for safety) food.

4-302.12 Food Temperature Measuring Devices.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

When determining the temperature of thin foods, those having a thickness less than 13 mm (1/2 inch), it is particularly important to use a temperature sensing probe designed for that purpose. Bimetal, bayonet style thermometers are not suitable for accurately measuring the temperature of thin foods such as hamburger patties because of the large diameter of the probe and the inability to accurately sense the temperature at the

tip of the probe. However, temperature measurements in thin foods can be accurately determined using a small-diameter probe 1.5 mm (0.059 inch), or less, connected to a device such as thermocouple thermometer.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

4-302.14 Sanitizing Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:

1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and

2. Too much sanitizer in the final rinse water could be toxic.

Location **4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.**

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

Installation **4-402.11 Fixed Equipment, Spacing or Sealing.**

This section is designed to ensure that fixed equipment is installed in a way that:

1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;

2. Ensures that equipment that is subject to moisture is sealed;

3. Prevents the harborage of insects and rodents; and

4. Provides accessibility for the monitoring of pests.

4-402.12 Fixed Equipment, Elevation or Sealing.

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

Equipment **4-501.11 Good Repair and Proper Adjustment.**

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding potentially hazardous (time/temperature control for safety) foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Exposure time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4-501.12 Cutting Surfaces.

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

4-501.13 Microwave Ovens.

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

4-501.14 Warewashing Equipment, Cleaning Frequency.

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940.

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

With respect to chemical sanitization, section 4-501.114 addresses the proper make-up of the sanitizing <u>solution</u>, i.e., chemical concentration, pH, and temperature at the required <u>minimum</u> levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the <u>maximum</u> hardness level. If these minimums (maximum hardness) are not as specified, then this provision is violated.

By contrast, paragraph 4-703.11(C) addresses exposure <u>time</u> in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met.

Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is <u>approved</u> and listed for that use under 40 CFR 180.194. If the chemical used is not thus listed, this section is violated.

The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the “Limits” provided for that product under its 40 CFR 180.940 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for “food-

contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils," each listing adding a Limit that states, "When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quarternary compound. If a sanitarian determined that a solution of any of these quats was at 600 ppm, section 7-204.11 would be violated.

To summarize, a too weak sanitizing solution would be a violation of section 4-501.114. A too strong solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use chemical sanitizers.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

4-501.16 Warewashing Sinks, Use Limitation.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

4-501.17 Warewashing Equipment, Cleaning Agents.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

4-501.18 Warewashing Equipment, Clean Solutions.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110°F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.*

If the temperature during the hot water sanitizing step is less than 77°C (171°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

The temperature of hot water delivered from a warewasher sanitizing rinse manifold must be maintained according to the equipment manufacturer’s specifications and temperature limits specified in this section to ensure surfaces of multiuse utensils such as kitchenware and tableware accumulate enough heat to destroy pathogens that may remain on such surfaces after cleaning.

The surface temperature must reach at least 71ºC (160ºF) as measured by an irreversible registering temperature measuring device to affect sanitization. When the sanitizing rinse temperature exceeds 90ºC (194ºF) at the manifold, the water becomes volatile and begins to vaporize reducing its ability to convey sufficient heat to utensil surfaces. The lower temperature limits of 74ºC (165ºF) for a stationary rack, single temperature machine, and 82ºC (180ºF) for other machines are based on the sanitizing rinse contact time required to achieve the 71ºC (160ºF) utensil surface temperature.

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.*

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction Act of 1998, Federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 40 CFR 180.940 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code.

With respect to chemical sanitization, section 4-501.114 addresses the proper make-up of the sanitizing solution, i.e., chemical concentration, pH, and temperature at the required maximum levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these minimums (maximum hardness) are not as specified, then this provision is violated.

By contrast, paragraph 4-703.11(C) addresses exposure time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met.

Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940 If the chemical used is not thus listed, this section is violated.

The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the "Limits" provided for that product under its 40 CFR 180.940 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for “food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils,” each listing adding a Limit that states, “When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound.” If a sanitarian determined that a solution of any of these quats was at 600 ppm, section 7-204.11 would be violated.

To summarize, a too weak sanitizing solution would be a violation of section 4-501.114. A too strong solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use chemical sanitizers.

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

Utensils and Temperature and Pressure Measuring Devices

4-502.11 Good Repair and Calibration.

A utensil or food temperature measuring device can act as a source of contamination to the food it contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

4-502.12 Single-Service and Single-Use Articles, Required Use.*

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

4-502.14 Shells, Use Limitation.

The reuse of mollusk and crustacean shells as multiuse utensils is not allowed in food establishments. This prohibition does not apply to the removal of the oyster or other species from the shell for preparation, then returning the same animal to the same shell for service.

The shell itself may be potentially unsafe for use as a food utensil because of residues from natural and environmental contamination occurring after the mollusk or crustacean is removed. In addition, natural shells are not durable or easily cleanable as specified under section 4-502.13. When mollusk or crustacean shells (from commercial sources) are re-used by filling them with shucked shellfish, the food is considered misleading and not honestly presented.

Objective **4-601.11** **Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.***

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Frequency **4-602.11** **Equipment Food-Contact Surfaces and Utensils.***

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for potentially hazardous (time/temperature control for safety) foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary to clean every four hours. However, the time period between cleaning equipment and utensils may not exceed 24 hours. A time-temperature chart is provided in subparagraph 4-602.11(D)(2) to accommodate operations that use equipment and utensils in a refrigerated room or area that maintains a temperature between 41°F or less and 55°F.

Surfaces of utensils and equipment contacting food that is not potentially hazardous (time/temperature control for safety food) such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

Regarding the possible adulteration from one species of meat to another between cleaning of food-contact surfaces, USDA/FSIS does not automatically consider species adulteration as a health hazard. FSIS stated in an Advance Notice of Proposed

Rulemaking that species adulteration falls into a gray area between safety and economic adulteration (65 FR 14486, March 17, 2000, Other Consumer Protection Activities). FSIS will review public comments received on the species adulteration issue and further review the scientific literature and risk assessment mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is generally considered by FSIS as an economic issue. However, investigations by FSIS of species adulteration incidents may include a determination regarding the impact of species adulteration as a health hazard on a case-by-case basis.

4-602.12 Cooking and Baking Equipment.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in § 4-602.11.

4-602.13 Nonfood-Contact Surfaces.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

Methods **4-603.11 Dry Cleaning.**

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not potentially hazardous (time/temperature control for safety foods). Under some circumstances, attempts at wet cleaning may create microbiological concerns.

4-603.12 Precleaning.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

4-603.14 Wet Cleaning.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

Some pieces of equipment are fixed or too large to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

4-603.16 Rinsing Procedures.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

4-603.17 Returnables, Cleaning for Refilling.*

The refilling of consumer-owned beverage containers introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned containers is limited to beverages that are not potentially hazardous (time/temperature control for safety) foods. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Objective **4-701.10 Food-Contact Surfaces and Utensils.**

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

Frequency **4-702.11 Before Use After Cleaning.***

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

Methods **4-703.11** **Hot Water and Chemical.***

Efficacious sanitization depends on warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as rinse pressure, temperature, and chemical concentration are used in combination with time to achieve sanitization.

When surface temperatures of utensils passing through warewashing machines using hot water for sanitizing do not reach the required 71ºC (160ºF), it is important to understand the factors affecting the decreased surface temperature. A comparison should be made between the machine manufacturer's operating instructions and the machine's actual wash and rinse temperatures and final rinse pressure. The actual temperatures and rinse pressure should be consistent with the machine manufacturer's operating instructions and within limits specified in §§ 4-501.112 and 4-501.113.

If either the temperature or pressure of the final rinse spray is higher than the specified upper limit, spray droplets may disperse and begin to vaporize resulting in less heat delivery to utensil surfaces. Temperatures below the specified limit will not convey the needed heat to surfaces. Pressures below the specified limit will result in incomplete coverage of the heat-conveying sanitizing rinse across utensil surfaces.

Objective **4-801.11** **Clean Linens.**

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

Frequency **4-802.11** **Specifications.**

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Methods **4-803.11** **Storage of Soiled Linens**.

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

4-803.12 Mechanical Washing.

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

4-803.13 Use of Laundry Facilities.

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

Drying **4-901.11 Equipment and Utensils, Air-Drying Required.**

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

4-901.12 Wiping Cloths, Air-Drying Locations.

Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

Lubricating and Reassembling **4-902.11 Food-Contact Surfaces.**

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4-902.12 Equipment.

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

Storing **4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.**

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

4-903.12 Prohibitions.

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

Preventing Contamination

4-904.11 Kitchenware and Tableware.
4-904.12 Soiled and Clean Tableware.
4-904.13 Preset Tableware.

The presentation or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

Chapter 5 Water, Plumbing, and Waste

Source

5-101.11 Approved System.*

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

5-101.12 System Flushing and Disinfection.*

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

5-101.13 Bottled Drinking Water.*

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

Quality

5-102.11 Standards.*

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

5-102.12 Nondrinking Water.*

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological or chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

5-102.13 Sampling.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

5-102.14 Sample Report.

The most recent water sampling report must be kept on file to document a safe water supply.

Quantity and Availability

5-103.11 Capacity.*

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization can not be reached. Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

5-103.12 Pressure.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

Distribution, Delivery, and Retention **5-104.11 System.**

Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

5-104.12 Alternative Water Supply.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

Materials **5-201.11 Approved.***

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

Design, Construction, and Installation **5-202.11 Approved System and Cleanable Fixtures.***

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing

sinks that are not easily cleanable may lead to the contamination of food products.

5-202.12 Handwashing Facility, Installation.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of 40°C ± 2°C (100 to 108°F).

An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

5-202.13 Backflow Prevention, Air Gap.*

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

5-202.14 Backflow Prevention Device, Design Standard.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system. Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative. To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

5-202.15 Conditioning Device, Design.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

Numbers and Capacities

5-203.11 Handwashing Facilities.*

Because handwashing is such an important factor in the prevention of foodborne illness, sufficient facilities must be available to make handwashing not only possible, but likely.

5-203.12 Toilets and Urinals.*

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

5-203.13 Service Sink.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

5-203.14 Backflow Prevention Device, When Required.*

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

5-203.15 Backflow Prevention Device, Carbonator.*

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If carbon dioxide backs up into a copper water line, carbonic acid will dissolve some of the copper. The water containing the dissolved copper will subsequently be used in dispensing soft drinks and the first few customers receiving the drinks are likely to suffer with the symptoms of copper poisoning.

An air gap or a vented backflow prevention device meeting ASSE Standard No. 1022 will prevent this occurrence, thereby reducing incidences of copper poisoning.

Location and Placement **5-204.11 Handwashing Sinks.***

Hands are probably the most common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. Some employees are unlikely to wash their hands unless properly equipped handwashing facilities are accessible in the immediate work area. Facilities which are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the facility unavailable for regular employee use. Nothing must block the approach to a handwashing facility thereby discouraging its use, and the facility must be kept clean and well stocked with soap and sanitary towels to encourage frequent use.

5-204.12 Backflow Prevention Device, Location.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

5-204.13 Conditioning Device, Location.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

Operation and Maintenance **5-205.11 Using a Handwashing Sink.**

Facilities must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing facility encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing facilities by employees returning from the toilet or from duties which have contaminated their hands.

5-205.12 Prohibiting a Cross Connection.*

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

5-205.13 Scheduling Inspection and Service for a Water System Device.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

Cleaning **5-205.14 Water Reservoir of Fogging Devices, Cleaning.***

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as ***Legionella pneumophila.*** This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

5-205.15 System Maintained in Good Repair.*

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation of warewashing equipment or other equipment which depends on sufficient volume and pressure to perform its intended functions.

Materials **5-301.11 Approved.**

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

Design and Construction	**5-302.11**	**Enclosed System, Sloped to Drain.**
	5-302.12	**Inspection and Cleaning Port, Protected and Secured.**

The tank must be a closed system from the filling inlet to the outlet to prevent contamination of water. It is important that the bottom of the tank be sloped to the outlet to allow the tank to drain completely, to facilitate the proper cleaning and disinfection of the tank, and to prevent the retention of water or solutions after cleaning.

Some tanks are designed with an access opening to facilitate the cleaning and servicing of the water tank. The access must be constructed to prevent the opening from becoming a source of contamination of the water.

5-302.13 "V" Type Threads, Use Limitation.

V-type threads are difficult to clean if contaminated with food or waste. To prevent the contamination of the drinking water, this type of thread should only be used on water tank inlets and outlets if the connection is permanent which eliminates exposed, difficult-to-clean threads.

5-302.14 Tank Vent, Protected.

Water tanks are equipped with a vent to preclude distortion during filling or draining. The vent should be equipped with a suitable screen or filter to protect the tank against the entry of insects or other vermin that may contaminate the water supply.

5-302.15 Inlet and Outlet, Sloped to Drain.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

5-302.16 Hose, Construction and Identification.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

Numbers and Capacities	**5-303.11**	**Filter, Compressed Air.**

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

5-303.12 Protective Cover or Device.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

5-303.13 Mobile Food Establishment Tank Inlet.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

Operation and Maintenance

5-304.11 System Flushing and Disinfection.*

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

5-304.12 Using a Pump and Hoses, Backflow Prevention.

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system. Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

5-304.14 Tank, Pump, and Hoses, Dedication.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

Mobile Holding Tank **5-401.11 Capacity and Drainage.**

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

Retention, Drainage, and Delivery **5-402.10 Establishment Drainage System.**

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

5-402.11 Backflow Prevention.*

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

The exception in paragraph 5-402.11(B) allows for a direct connection to the sanitary sewer system for floor drains originating in refrigerated spaces that are constructed as an integral part of the building structure. Examples of refrigerated spaces that are considered an integral part of the building include refrigerated prep rooms, meat cutting rooms, and refrigerated storage rooms. The exception specifically targets refrigerated spaces that are considered an integral part of the building. It does not apply to prefabricated walk-in refrigerators and freezers with prefabricated floors. It is not intended to apply to pieces of equipment, including those which may be located in a refrigerated room and which indirectly drain to a floor drain within the room. Drainage from equipment is addressed under paragraph 5-402.11(A).

5-402.12 Grease Trap.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

5-402.13 Conveying Sewage.*
5-402.14 Removing Mobile Food Establishment Waste.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

5-402.15 Flushing a Waste Retention Tank.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

Disposal Facility

5-403.11 Approved Sewage Disposal System.*

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

5-403.12 Other Liquid Waste and Rainwater.

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

Facilities on the Premises	**5-501.10**	**Indoor Storage Area.**
	5-501.11	**Outdoor Storage Surface.**
	5-501.12	**Outdoor Enclosure.**
	5-501.13	**Receptacles.**
	5-501.14	**Receptacles in Vending Machines.**
	5-501.15	**Outside Receptacles.**
	5-501.16	**Storage Areas, Rooms, and Receptacles, Capacity and Availability.**
	5-501.17	**Toilet Room Receptacle, Covered.**
	5-501.18	**Cleaning Implements and Supplies.**
	5-501.19	**Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.**
	5-501.110	**Storage Refuse, Recyclables, and Returnables.**
	5-501.111	**Areas, Enclosures, and Receptacles, Good Repair.**
	5-501.112	**Outside Storage Prohibitions.**
	5-501.113	**Covering Receptacles.**
	5-501.114	**Using Drain Plugs.**
	5-501.115	**Maintaining Refuse Areas and Enclosures.**
	5-501.116	**Cleaning Receptacles.**

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents. Proper equipment and supplies must be made available to accomplish thorough and

proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

Removal **5-502.11 Frequency.**
5-502.12 Receptacles or Vehicles.

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

Facilities for Disposal and Recycling **5-503.11 Community or Individual Facility.**

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Chapter 6 Physical Facilities

Indoor Areas **6-101.11 Surface Characteristics.**

Floors, walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture are intended to ensure that the cleanability of these surfaces is retained.

Although food served from temporary food establishments is subject to the same potential for contamination as food served in permanent establishments, the limited capabilities and short duration of operation are recognized by less stringent requirements for surface characteristics.

Outdoor Areas **6-102.11 Surface Characteristics.**

The requirements concerning surface characteristics of outdoor areas are intended to facilitate maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide durable exterior building surfaces, and prevent the attracting,

harboring, or breeding of insects, rodents, and other pests where refuse, recyclables, or returnables are stored.

Cleanability **6-201.11 Floors, Walls, and Ceilings.**
6-201.12 Floors, Walls, and Ceilings, Utility Lines.

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, therebypreventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as ***Listeria monocytogenes***.

6-201.14 Floor Carpeting, Restrictions and Installation.

Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely.

6-201.15 Floor Covering, Mats and Duckboards.

Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

6-201.16 Wall and Ceiling Coverings and Coatings.
6-201.17 Walls and Ceilings, Attachments.
6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

Functionality **6-202.11 Light Bulbs, Protective Shielding.**

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment,

utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

6-202.13 Insect Control Devices, Design and Installation.

Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Code requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

6-202.14 Toilet Rooms, Enclosed.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

6-202.15 Outer Openings, Protected.

Insects and rodents are vectors of disease-causing microorganisms which may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

In the National Fire Protection Association's NFPA 101, Life Safety Code®, 2003 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

The intent of subparagraph 6-202.15(A)(3) is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self-closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self-closing device. Doors not requiring a self-closing device include exterior emergency exit doors that open into a public way from a fire and that meet the criteria in ¶ 6-202.15(C).

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibited.
6-202.112 Living or Sleeping Quarters, Separation.

Areas or facilities that are not compatible with sanitary food establishment operations must be located or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

Handwashing Sinks **6-301.10 Minimum Number.**

Refer to the public health reason for § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

6-301.12 Hand Drying Provision.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

6-301.14 Handwashing Signage.

A sign or poster is required to remind food employees to wash their hands.

6-301.20 Disposable Towels, Waste Receptacle.

Waste receptacles at handwashing sinks are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

Toilets and Urinals **6-302.10 Minimum Number.**

Refer to the public health reason for § 5-203.12.

6-302.11 Toilet Tissue, Availability.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

Lighting **6-303.11 Intensity.**

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

Ventilation **6-304.11 Mechanical.**

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

Dressing Areas and Lockers **6-305.11 Designation.**

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

Service Sinks **6-306.10 Availability.**

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Handwashing Sinks **6-401.10** **Conveniently Located.**

Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

Toilet Rooms **6-402.11** **Convenience and Accessibility.**

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

Employee Accommodations **6-403.11** **Designated Areas**.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

Distressed Merchandise **6-404.11** **Segregation and Location.**

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

Refuse, Recyclables, and Returnables **6-405.10** **Receptacles, Waste Handling Units, and Designated Storage Areas.**

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

Premises, Structures, Attachments,* and *Fixtures, - Methods

6-501.11 Repairing.

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

6-501.12 Cleaning, Frequency and Restrictions.

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

6-501.13 Cleaning Floors, Dustless Methods.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.*

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

6-501.16 Drying Mops.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

6-501.18 Maintaining and Using Handwashing Sinks.

Handwashing facilities are critical to food protection and must be maintained in operating order at all times so they will be used.

Refer also to the public health reason for § 5-205.11.

6-501.19 Closing Toilet Room Doors.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

6-501.110 Using Dressing Rooms and Lockers.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

6-501.111 Controlling Pests.*

Insects and other pests are capable of transmitting disease to man by contaminating food and food-contact surfaces. Effective measures must be taken to control their presence in food establishments.

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

6-501.113 Storing Maintenance Tools.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

6-501.115 Prohibiting Animals.*

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with service animals are required under § 2-301.14 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for “service animal” is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. 12101 et seq.). A service animal performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by “seeing eye dogs”; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.

Under Title III of the ADA, privately owned businesses that serve the public are prohibited from discriminating against individuals with disabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all, are licensed or certified and have identification papers.

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the Federal agency which has the lead in these matters, in documents such as, "Commonly Asked Questions About Service Animals in Places of Business"; "The Americans with Disabilities Act Questions and Answers"; "A Guide to Disability Rights Laws"; and "Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement." The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is http://www.usdoj.gov/crt/ada/adahom1.htm.

Chapter 7 Poisonous or Toxic Materials

Original Containers **7-101.11** **Identifying Information, Prominence.***

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

Working Containers **7-102.11** **Common Name.***

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Storage **7-201.11** **Separation.***

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

Presence and Use **7-202.11 Restriction.***

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

7-202.12 Conditions of Use.*

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted use pesticides are applied.

Container Prohibitions **7-203.11 Poisonous or Toxic Material Containers.***

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

Chemicals **7-204.11** **Sanitizers, Criteria.***

See explanation in § 4-501.114.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

7-204.12 **Chemicals for Washing Fruits and Vegetables, Criteria.***
7-204.13 **Boiler Water Additives, Criteria.***
7-204.14 **Drying Agents, Criteria.***

If the chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are listed in the CFR can be used.

Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition. Wash chemicals, boiler water additives, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR.

21 CFR Section 173.315 specifically identifies chemicals that may be used in washing fruits and vegetables, but it **does not specify any maximum level** (2000 ppm or otherwise) of chemical usage for sodium hypochlorite. FDA acknowledges the use of sodium hypochlorite on fruits and vegetables and also allows calcium hypochlorite to be used interchangeably with sodium hypochlorite under 21 CFR 173.315.

Boiler water additives that may be safely used in the preparation of steam that may contact food, and their condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

Lubricants **7-205.11** **Incidental Food Contact, Criteria.***

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

Pesticides **7-206.11** **Restricted Use Pesticides, Criteria.***
7-206.12 **Rodent Bait Stations.***

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

7-206.13 **Tracking Powders, Pest Control and Monitoring.***

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

Medicines **7-207.11** **Restriction and Storage.***

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage.

There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

7-207.12 **Refrigerated Medicines, Storage.***

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

First Aid Supplies **7-208.11** **Storage.***

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

Other Personal Care Items	**7-209.11**	**Storage.**

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

Storage and Display	**7-301.11**	**Separation.***

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

Chapter 8 Compliance and Enforcement

Construction	**8-201.12**	**Contents of the Plans and Specifications.**
Inspection and Approval	**8-203.10**	**Preoperational Inspections.**

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this FDA/CFP Food Establishment Plan Review Guide – 2000 has been used in the FDA State Training Team Plan Review courses. It can be accessed through http://www.cfsan.fda.gov/~dms/prev-toc.html.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operating procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

(1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,

(2) Food is received from approved sources as specified under § 3-201.11,

(3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,

(4) Potentially hazardous (time/temperature control for safety) food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under §§ 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with ¶ 2-103.11(L) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

8-402.10 Competency of Inspectors.

Regulatory agencies are encouraged to use Standard #2 of the draft *FDA's Recommended National Retail Food Regulatory Program Standards* (http://www.cfsan.fda.gov/~dms/ret-toc.html) to ensure employees who inspect food establishments are properly trained. Regulatory inspectors are also encouraged to seek food safety certification through a nationally recognized and accredited program.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

See discussion in Annex 3, § 2-201.12.

Annex

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

1. ACTIVE MANAGERIAL CONTROL
2. INTRODUCTION TO HACCP
3. THE HACCP PRINCIPLES
4. THE PROCESS APPROACH – A PRACTICAL APPLICATION OF HACCP AT RETAIL TO ACHIEVE ACTIVE MANAGERIAL CONTROL
5. FDA RETAIL HACCP MANUALS
6. ADVANTAGES OF THE HACCP PRINCIPLES
7. SUMMARY
8. ACKNOWLEDGEMENTS
9. RESOURCES AND REFERENCES

1. ACTIVE MANAGERIAL CONTROL

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

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

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

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

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

(C) How can foodborne illness be reduced?

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

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

In 1998, FDA initiated a project designed to determine the incidence of foodborne illness risk factors in retail and food service establishments. Inspections focusing on the occurrence of foodborne illness risk factors were conducted in establishments throughout the United States. The results of this project are published in the 2000 *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, commonly referred to as the "FDA Baseline Report." The Baseline Report is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/retrsk.html. The data collection project was repeated in 2003 and the results are published in the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).* This second report is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/retrsk2.html . An additional data collection project is planned for 2008.
The CDC Surveillance Report and the results from the FDA Baseline Report and second data collection project, support the concept that operators of retail and food service establishments must be proactive and implement food safety management systems that will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors. By reducing the occurrence of foodborne illness risk factors, foodborne illness can also be reduced.

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

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

Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

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

- Certified food protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for performing critical operational steps in a food preparation process, such as cooling
- Recipe cards that contain the specific steps for preparing a food item and the food safety critical limits, such as final cooking temperatures, that need to be monitored and verified
- Purchase specifications
- Equipment and facility design and maintenance
- Monitoring procedures
- Record keeping
- Employee health policy for restricting or excluding ill employees
- Manager and employee training
- On-going quality control and assurance
- Specific goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors.

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

2. INTRODUCTION TO HACCP

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

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

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

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

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

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

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

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

(B) What are the Seven HACCP Principles?

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

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

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

(C) What are Prerequisite Programs?

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

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

Basic prerequisite programs should be in place to:

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

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

3. THE HACCP PRINCIPLES

(A) Principle #1: Conduct a Hazard Analysis

(1) What is a food safety hazard?

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

(2) What are biological hazards?

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

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

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

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

HAZARD	***ASSOCIATED FOODS***	***CONTROL MEASURES***
Bacteria		
Bacillus cereus (intoxication caused by heat stable, preformed emetic toxin and infection by heat labile, diarrheal toxin)	Meat, poultry, starchy foods (rice, potatoes), puddings, soups, cooked vegetables	Cooking, cooling, cold holding, hot holding
Campylobacter jejuni	Poultry, raw milk	Cooking, handwashing, prevention of cross-contamination
Clostridium botulinum	Vacuum-packed foods, reduced oxygen packaged foods, under-processed canned foods, garlic-in-oil mixtures, time/temperature abused baked potatoes/sautéed onions	Thermal processing (time + pressure), cooling, cold holding, hot holding, acidification and drying, etc.
Clostridium perfringens	Cooked meat and poultry, Cooked meat and poultry products including casseroles, gravies	Cooling, cold holding, reheating, hot holding
E. coli O157:H7 (other shiga toxin-producing *E. coli*)	Raw ground beef, raw seed sprouts, raw milk, unpasteurized juice, foods contaminated by infected food workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing, prevention of cross-contamination, pasteurization or treatment of juice
Listeria monocytogenes	Raw meat and poultry, fresh soft cheese, paté, smoked seafood, deli meats, deli salads	Cooking, date marking, cold holding, handwashing, prevention of cross-contamination
Salmonella spp.	Meat and poultry, seafood, eggs, raw seed sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, use of pasteurized eggs, employee health policy, no bare hand contact with RTE foods, handwashing, pasteurization or treatment of juice
Shigella spp.	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing
Staphylococcus aureus (preformed heat stable toxin)	RTE PHF foods touched by bare hands after cooking and further time/temperature abused	Cooling, cold holding, hot holding, no bare hand contact with RTE food, handwashing
Vibrio spp.	Seafood, shellfish	Cooking, approved source, prevention of cross-contamination, cold holding
Parasites		
Anisakis simplex	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, freezing
Taenia spp.	Beef and pork	Cooking
Trichinella spiralis	Pork, bear, and seal meat	Cooking
Viruses		
Hepatitis A and E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing
Other Viruses (Rotavirus, Norovirus, Reovirus)	Any food contaminated by infected worker via fecal-oral route	No bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing

RTE = ready-to-eat
PHF = potentially hazardous food (time/temperature control for safety food)

(3) What are Chemical Hazards?

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

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

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

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

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

(4) Food Allergens As Food Safety Hazards

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

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

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

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

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

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

Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures		
Chemical Hazards	**Associated Foods**	**Control measures**
Naturally Occurring:		
Scombrotoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies bonito, mackerel; Also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature abused prior to arrival in facility.
Ciguatoxin	Reef fin fish from extreme SE US, Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, and snappers	Ensure fin fish have not been caught: • Purchase fish from approved sources. • Fish should not be harvested from an area that is subject to an adverse advisory.
Tetrodoxin	Puffer fish (Fugu; Blowfish)	Do not consume these fish.
Mycotoxins Aflatoxin	Corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination.	Check condition at receiving; do not use moldy or decomposed food.
Patulin	Apple juice products	Buyer Specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing.
Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved source.
Shellfish toxins Paralytic shellfish poisoning (PSP)	Molluscan shellfish from NE and NW coastal regions; mackerel, viscera of lobsters and Dungeness, tanner, and red rock crabs	Ensure molluscan shellfish are: • from an approved source; and • properly tagged and labeled.
Diarrhetic shellfish poisoning (DSP)	Molluscan shellfish in Japan, western Europe, Chile, NZ, eastern Canada	
Neurotoxin shellfish poisoning (NSP)	Molluscan shellfish from Gulf of Mexico	
Amnesic shellfish poisoning (ASP)	Molluscan shellfish from NE and NW coasts of NA; viscera of Dungeness, tanner, red rock crabs and anchovies.	

Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures		
Chemical Hazards	**Associated Foods**	**Control measures**
Naturally Occurring:		
Pyrrolizidine alkaloids	Plants food containing these alkaloids. Most commonly found in members of the Borginaceae, Compositae, and Leguminosae families.	Do not consume of food or medicinals contaminated with these alkaloids.
Phtyohaemmagglutinin	Raw red kidney beans (Undercooked beans may be more toxic than raw beans)	Soak in water for at least 5 hours. Pour away the water. Boil briskly in fresh water, with occasional stirring, for at least 10 minutes.
Added Chemicals*:*		
Environmental contaminants: Pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
PCBs	Fish	Comply with fish advisories.
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.
Toxic elements/compounds Mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel and swordfish. Grains treated with mercury based fungicides	Pregnant women/women of childbearing age/nursing mothers, and young children should not eat shark, swordfish, king mackerel or tilefish because they contain high levels of mercury. Do not use mercury containing fungicides on grains or animals.
Copper	High acid foods and beverages	Do not store high acid foods in copper utensils; use backflow prevention device on beverage vending machines.
Lead	High acid food and beverages	Do not use vessels containing lead.
Preservatives and Food Additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Fresh fruits and Vegetables Shrimp Lobster Wine	Sulfiting agents added to a product in a processing plant must be declared on labeling. Do not use on raw produce in food establishments.

Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures		
Chemical Hazards	**Associated Foods**	**Control measures**
Naturally Occurring:		
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach Meat and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrates.
Flavor enhancers Monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.
Allergens	Foods containing or contacted by: Milk Egg Fish Crustacean shellfish Tree nuts Wheat Peanuts Soybeans	Use a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients.

(5) What are Physical Hazards?

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

Annex 4, Table 3. Main Materials of Concern as Physical Hazards and Common Sources[a, b]		
Material	**Injury Potential**	**Sources**
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

[a] Adapted from Corlett (1991).

[b] Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

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

The purpose of hazard analysis is to develop a list of food safety hazards that are reasonably likely to cause illness or injury if not effectively controlled.

(7) How is the hazard analysis conducted?

The process of conducting a hazard analysis involves two stages:

1. Hazard Identification
2. Hazard Evaluation

Hazard identification can be thought of as a brain storming session. This stage focuses on identifying the food safety hazards that might be present in the food given the food preparation process used, the handling of the food, the facility, and general characteristics of the food itself. During this stage, a review is made of the ingredients used in the product, the activities conducted at each step in the process, the equipment used, the final product, and its method of storage and distribution, as well as the intended use and consumers of the product. Based on this review, a list of potential biological, chemical, or physical hazards is made at each stage in the food preparation process.

In stage two, the hazard evaluation, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. The purpose of this stage is to determine which of the potential hazards listed in stage one of the hazard analysis warrant control in the HACCP plan. Severity is the seriousness of the consequences of exposure to the hazard. Considerations made when determining the severity of a hazard include understanding the impact of the medical condition caused by the illness, as well as the magnitude and duration of the illness or injury. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. Hazards that are not reasonably likely to occur are not considered in a HACCP plan. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage, and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled.

Upon completion of the hazard analysis, a list of significant hazards that must be considered in the HACCP plan is made, along with any measure(s) that can be used to control the hazards. These measures, called control measures, are actions or activities that can be used to prevent, eliminate, or reduce a hazard. Some control measures are not essential to food safety, while others are. Control measures essential to food safety like proper cooking, cooling, and refrigeration of ready-to-eat, potentially hazardous foods (time/temperature control for safety foods) are usually applied at critical control points (CCPs) in the HACCP plan (discussed later). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. Likewise, more than one hazard may be addressed by a specific control measure (e.g., proper cooking).

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

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

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

(2) Are quality issues considered when determining CCPs?

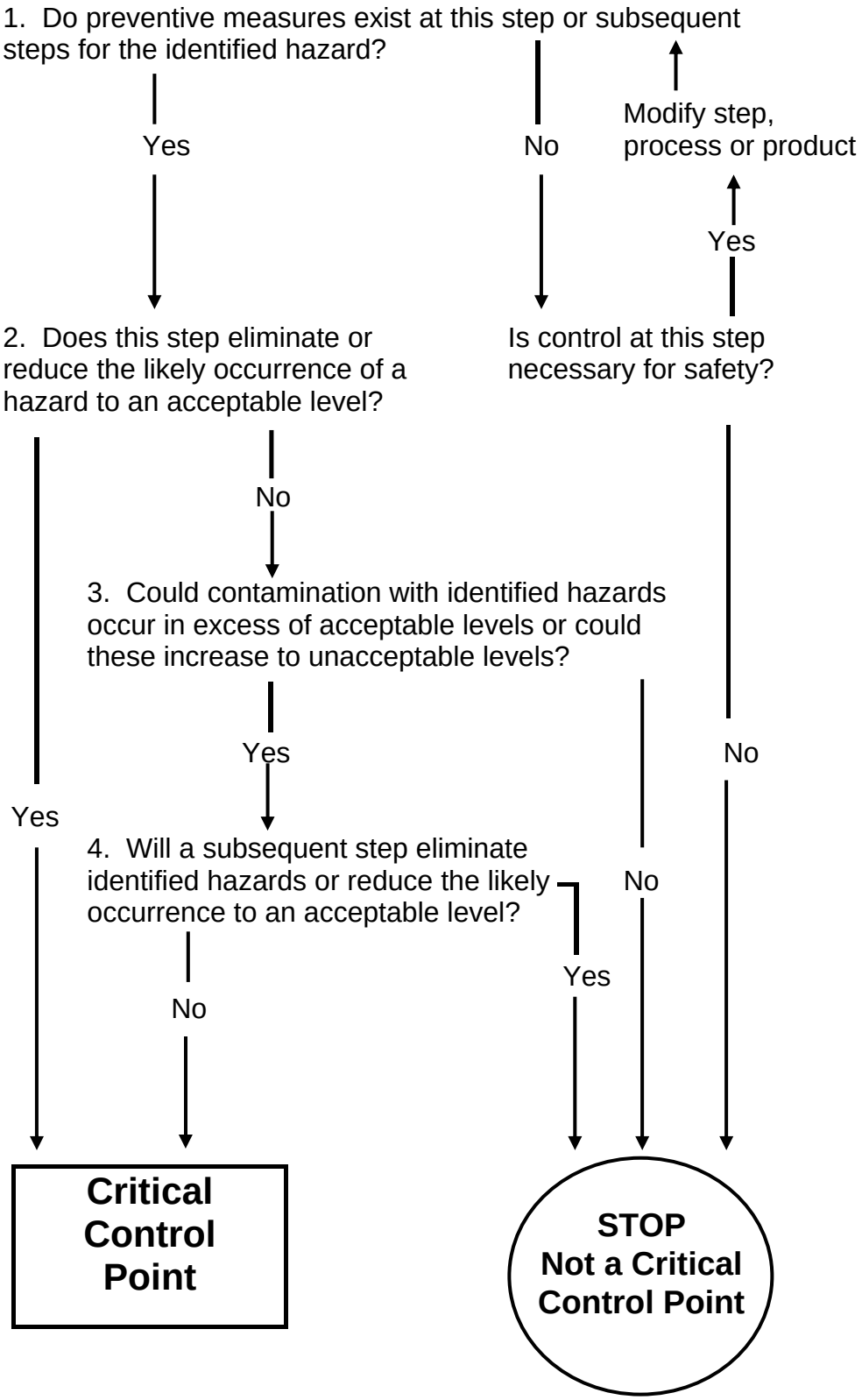
CCPs are only used to address issues with product safety. Actions taken on the part of the establishment such as first-in first-out (FIFO) or refrigerating nonpotentially hazardous foods (time/temperature control for safety foods) are to ensure food quality rather than food safety

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

(3) Are the CCPs the same for everyone?

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

Annex 4 – CCP Decision Tree 1



Decision Tree adapted from NACMCF.

(C) Principle #3: Establish Critical Limits

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

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

(2) What are examples of critical limits?

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

(D) Principle #4: Establish Monitoring Procedures

(1) What is the purpose of monitoring?

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

(2) What are examples of monitoring activities?

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

(3) How is monitoring conducted?

Typically, monitoring activities fall under two broad categories:

- measurements
- observations

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

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

(4) How often is monitoring conducted?

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

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

(5) Who conducts monitoring?

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

(E) Principle #5: Establish Corrective Actions

(1) What are corrective actions?

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

(F) Principle #6: Establish Verification Procedures

(1) What is verification?

Verification includes those activities, other than monitoring, that determine the validity of the HACCP plan and show that the system is operating according to the plan. Validation is a component of verification which focuses on collecting and evaluating scientific and technical information to determine if the HACCP system, when properly implemented, will effectively control the hazards. Clear instructions should be developed detailing who is responsible for conducting verification, the frequency of verification, and the procedures used.

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

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

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

(G) Principle #7: Establish Record Keeping Procedures

(1) Why are records important?

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) What is the Process Approach?

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

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

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

The flow of food in a retail or food service establishment is the path that food follows from receiving through service or sale to the consumer. Several activities or stages make up the flow of food and are called operational steps. Examples of operational steps include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling, packaging, serving, and selling. The terminology used for operational steps may differ between food service and retail food store operations.

Most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41°F and 135°F:

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

Example flow: Receive – Store – Prepare – Hold – Serve
(other food flows are included in this process, but there is no cook step to destroy pathogens)

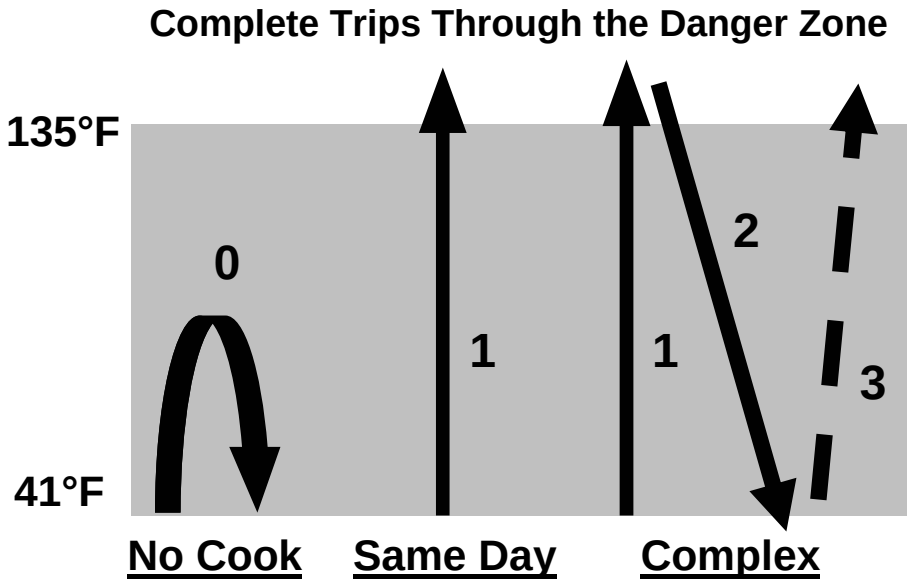
- **Process 2: Preparation for Same Day Service**

Example flow: Receive – Store – Prepare – Cook – Hold – Serve
(other food flows are included in this process, but there is only one trip through the temperature danger zone)

- **Process 3: Complex Food Preparation**

Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve
(other food flows are included in this process, but there are always two or more complete trips through the temperature danger zone)

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



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

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

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

In the process approach to HACCP, conducting a hazard analysis on individual food items is time and labor intensive and is generally unnecessary. Identifying and controlling the hazards in each food preparation process achieves the same control of risk factors as preparing a HACCP plan for each individual product.

Example: An establishment has dozens of food items (including baked chicken and baked meatloaf) in the "Preparation for Same Day Service" category. Each of the food items may have unique hazards, but regardless of the individual hazards, control via proper cooking and holding will generally ensure the safety of <u>all</u> of the foods in this category. An illustration of this concept follows:

- Even though they have unique hazards, baked chicken and meatloaf are items frequently grouped in the "Same Day Service" category (Process 2).

- *Salmonella* spp. and *Campylobacter,* as well as spore-formers, such as *Bacillus cereus* and *Clostridium perfringens*, are significant biological hazards in chicken.

- Significant biological hazards in meatloaf include *Salmonella* spp., *E. coli* O157:H7, *Bacillus cereus,* and *Clostridium perfringens.*

- Despite their different hazards, the control measure used to kill pathogens in both these products is cooking to the proper temperature.

- Additionally, if the products are held after cooking, then proper hot holding or time control is also required to prevent the outgrowth of spore-formers that are not destroyed by cooking.

As with product-specific HACCP, critical limits for cooking remain specific to each food item in the process. In the scenario described above, the cooking step for chicken requires a final internal temperature of 165°F for 15 seconds to control the pathogen load for *Salmonella* spp. Meatloaf, on the other hand, is a ground beef product and requires a final internal temperature of 155°F for 15 seconds to control the pathogen load for both *Salmonella* spp. and *E. coli* O157:H7. Some operational steps such as refrigerated storage or hot holding have critical limits that apply to all foods.

Annex 4, Table 4 further illustrates this concept. Note that the only unique control measure applies to the critical limit of the cooking step for each of the products. Other food safety hazards and control measures may exist that are not depicted here:

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

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

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

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

(F) Facility-wide Considerations

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

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

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

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

Several food flows are represented by this particular process. Many of these food flows are common to both retail food stores and food service facilities, while others only apply to retail operations. Raw, ready-to-eat food like sashimi, raw oysters, and salads are grouped in this category. Components of these foods are received raw and will not be cooked before consumption.

Foods cooked at the processing level but that undergo no further cooking at the retail level before being consumed are also represented in this category. Examples of these kinds of foods are deli meats, cheeses, and other pasteurized dairy products (such as yogurt). In addition, foods that are received and sold raw but are to be cooked by the consumer after purchase, e.g., hamburger meat, chicken, and steaks, are also included in this category.

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

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

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

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

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

(H) Food Preparation Process 2 – Preparation for Same Day Service

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

In this food preparation process, food passes through the danger zone only once in the retail or food service facility before it is served or sold to the consumer. Food is usually cooked and held hot until served, e.g., fried chicken, but can also be cooked and served immediately. In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cooking** to destroy bacteria and parasites

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

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

(I) Food Preparation Process 3 – Complex Food Preparation

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

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

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

- **Cooking** to destroy bacteria and parasites
- **Cooling** to prevent the outgrowth of spore-forming or toxin-forming bacteria
- **Hot and cold holding or using time alone** to control bacterial growth and toxin formation
- **Date marking** of ready-to-eat PHF (TCS food) held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Reheating** for hot holding, if applicable.

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

5. FDA RETAIL HACCP MANUALS

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

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

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

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

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

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

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

6. ADVANTAGES OF USING THE PRINCIPLES OF HACCP

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

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

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

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

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

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

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

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

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

7. SUMMARY

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

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

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

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

8. ACKNOWLEDGEMENTS

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

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

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Fish and Fishery Products Hazards and Controls Guide, Third Edition, June 2001. Food and Drug Administration, Washington, D.C. May be purchased from:

National Technical Information Service
U.S. Department of Commerce
703-487-4650.

The **Fish and Fishery Products Hazards and Controls Guide** is also available electronically at http://www.cfsan.fda.gov/~comm/haccpsea.html.

Single copies may be obtained as long as supplies last from FDA district offices and from:

U.S. Food and Drug Administration
Office of Seafood
5100 Paint Branch Parkway
College Park, MD 20740-3835

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Annex

5 Conducting Risk-based Inspections

1. PURPOSE AND SCOPE
2. RISK-BASED ROUTINE INSPECTIONS
3. WHAT IS NEEDED TO PROPERLY CONDUCT A RISK-BASED INSPECTION?
4. RISK-BASED INSPECTION METHODOLOGY
5. ACHIEVING ON-SITE AND LONG-TERM COMPLIANCE
6. INSPECTION FORM AND SCORING
7. CLOSING CONFERENCE
8. SUMMARY

1. PURPOSE AND SCOPE

This Annex provides regulatory program managers and front-line inspection staff with guidance on planning, scheduling, conducting, and evaluating risk-based inspections. The draft *FDA's Recommended National Retail Food Regulatory Program Standards* (Program Standards) (revised April 2003) (http://www.cfsan.fda.gov/~dms/ret-toc.html) provide additional recommendations to assist regulatory program managers in the planning and development of a risk-based inspection program.

The primary focus of this Annex is to provide inspectors with methods for conducting risk-based inspections. Various strategies that can be used by regulatory professionals to assist operators in achieving active managerial control of foodborne illness risk factors are also included in this Annex.

As presented in Annex 4, the Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne Disease Outbreaks – United States" (http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm) identifies the most frequently reported contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the FDA as "foodborne illness risk factors." These five broad categories are:

- Food from Unsafe Sources
- Inadequate Cooking

- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene.

The FDA manual, *Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems* (FDA's Regulator's Manual) (http://www.cfsan.fda.gov/~dms/hret3toc.html), provides additional information on conducting risk-based inspections. Annex 4 of the Food Code provides additional information on Hazard Analysis and Critical Control Point (HACCP) principles and the process approach to HACCP. It should be reviewed in conjunction with the material found in this Annex to better prepare for performing risk-based inspections.

The "Retail Food Program Resource Guide," a CD-ROM containing pertinent FDA documents referenced in this Annex, is available for use by federal, state, local, and tribal regulatory agencies. It is produced by and available through FDA Regional Retail Food Specialists or the FDA Division of Federal-State Relations (HFC-150); U.S. Food and Drug Administration; 5600 Fishers Lane, Room 12-07; Rockville, Maryland *20857;* PHONE (301) 827-6906; (FAX) (301) 443-2143.

2. RISK-BASED ROUTINE INSPECTIONS

Inspections have been a part of food safety regulatory activities since the earliest days of public health. The term "routine inspection" has been used to describe periodic inspections conducted as part of an on-going regulatory scheme.

Program managers should strive to have adequate staffing and resources to allow all inspectors ample time to thoroughly evaluate establishments and ask as many questions as needed to fully understand establishments' operations. For most jurisdictions, however, inspectors continue to have limited time in which to complete inspections. This does not negate the need to thoroughly identify and assess the control of foodborne illness risk factors during each inspection.

It is a false assumption that inspectors cannot conduct risk-based inspections in a limited timeframe. Even with limited time, inspectors can focus their inspections on assessing the degree of active managerial control an operator has over the foodborne illness risk factors. By focusing inspections on the control of foodborne illness risk factors, inspectors can be assured that they are making a great impact on reducing foodborne illness.

As described in Annex 4, active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their businesses to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

Developing and implementing food safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors is recommended to achieve active managerial control. Regulatory inspections and follow-up activities must be proactive by using an inspection process designed to evaluate the implementation of Food Code interventions and the degree of active managerial control that retail and foodservice operators have over foodborne illness risk factors. The five Food Code interventions below were new interventions introduced with the 1993 Food Code and they are just as important today as they were in 1993. They encompass a wide-range of control measures specifically designed to protect consumer health:

- Demonstration of Knowledge
- Implementation of Employee Health Policies
- Hands as a Vehicle of Contamination
- Time/Temperature Relationships
- Consumer Advisory.

When Food Code interventions are not being implemented or if behaviors, activities, or procedures likely to cause foodborne illness are observed, inspectors should verify that the operator takes immediate corrective action so that consumers do not become sick or injured. Observations made on the day of the inspection, as well as information gained about the behaviors, activities, and procedures that occur at other times, allow inspectors to assess the strengths and weaknesses of the food safety management system that is in place.

An operator should be made aware of the inspectional findings both during, and at the conclusion of, the inspection and strategies for achieving compliance in the future should be discussed. Corrective actions taken during the inspection and repeat violations should be noted on the inspection report. Repeat violations should trigger further compliance and enforcement actions.

The inspection process is also an opportunity to educate the operator on the public health reasons supporting the Code requirements. If operators are afforded the chance to ask questions about general food safety matters, they may clearly understand the public health significance of non-compliance.

Lastly, If the operator demonstrates a history of violations related to foodborne illness risk factors, the inspection process can be used to assist the operator with implementing long-term control systems to prevent those risk factors from occurring in the future.

3. WHAT IS NEEDED TO PROPERLY CONDUCT A RISK-BASED INSPECTION?

A. Schedule Inspections Based on Risk

Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the population served all have a bearing on the occurrence of

foodborne illness risk factors in retail and foodservice establishments. Standard 3 of the Program Standards requires that regulatory jurisdictions develop and use a process that groups food establishments into at least three categories based on potential and inherent food safety risks. In addition, Standard 3 requires that regulatory jurisdictions assign inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk. With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness.

Table 1 of this Annex provides an example of risk categories and assignment of inspection frequency based on risk. In this example, the type of food served, food preparation processes conducted, and history of compliance related to foodborne illness risk factors are used as the basis of categorizing risk. Each jurisdiction is encouraged to develop risk categories tailored to their specific program needs and resources and to reassess the risk categories on an annual basis.

Regardless of the risk category initially assigned to food establishments, regulatory jurisdictions sometimes consider whether the establishment has implemented a voluntary food safety management system like HACCP, to justify a decrease in inspection frequency. Likewise, the following factors are among many that regulatory jurisdictions sometimes use to justify an increase in inspection frequency:

- History of non-compliance with provisions related to foodborne illness risk factors or critical items
- Specialized processes conducted
- Food preparation a day in advance of service
- Large number of people served
- History of foodborne illness and/or complaints
- Highly susceptible population served.

Annex 5, Table 1. Risk Categorization of Food Establishments

RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, nonpotentially hazardous foods (non time/temperature control for safety (TCS) foods). Establishments that prepare only nonpotentially hazardous foods (nonTCS foods). Establishments that heat only commercially processed, potentially hazardous foods (TCS foods) for hot holding. No cooling of potentially hazardous foods (TCS foods). Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.	1
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of potentially hazardous foods (TCS foods) after preparation or cooking. Complex preparation of potentially hazardous foods (TCS foods) requiring cooking, cooling, and reheating for hot holding is limited to only a few potentially hazardous foods (TCS foods). Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.	2
3	An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many potentially hazardous foods (TCS foods). Variety of processes require hot and cold holding of potentially hazardous food (TCS food). Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.	3
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

B. Have the Proper Equipment

In order to conduct risk-based inspections, each inspector must be provided with the proper equipment to assess the control of foodborne illness risk factors within food establishments. See Program Standard 8 at http://www.cfsan.fda.gov/~dms/ret-std8.html for recommendations of equipment needed by inspectors. At a minimum, each inspector should be provided with the following essential equipment:

- Thermocouple with the appropriate probes for the food being tested
- Alcohol swabs or other suitable equipment for sanitizing probe thermometers
- Chemical test kits for different chemical sanitizer types
- Heat-sensitive tape or maximum registering thermometer
- Flashlight
- Head cover, such as baseball cap, hair net, or equivalent.

Other equipment may be provided to inspectors on an "as needed" basis. While it is desirable for each inspector to have the following equipment, depending on the resources available to the agency, this equipment may be shared in a central office as appropriate:

- Pressure gauge for determining in-line pressure of hot water at injection point of warewashing machine (15-25 psi)
- Light meter
- Measuring device for measuring distances
- Time/temperature data logger
- pH meter
- Water activity meter
- Camera
- Computers with or without an electronic inspection system
- Black light
- Foodborne illness investigation kits
- Sample collection kits
- Cell phones.

C. Provide Adequate Training

Standard 2 of the Program Standards explains that regulatory staff shall have the knowledge, skills, and ability to adequately perform their required duties. Inspectors need the proper training before they can be expected to conduct risk-based inspections. Training includes a combination of classroom training, in-field training, standardization, and continuing education. For specific training recommendations refer to Program Standard 2 at http://www.cfsan.fda.gov/~dms/ret-std2.html.

(1) Classroom Training

The first phase of staff training should provide an orientation to the program with a review of program history, structure, and relationships to other food-related programs. Specific emphasis should be on the program's goals and objectives. The basic training curriculum should include the following components:

- Prevailing statutes, regulations, or ordinances
- Public health principles
- Communication skills
- Epidemiology
- Microbiology
- HACCP.

FDA's ORA-U (http://www.fda.gov/ora/training/) provides basic curriculum components free of charge to regulators via the internet. This allows state, local, and tribal health departments to conserve their time and funding resources instead of developing their own training courses. It also allows inspectors to access training as needed. Distance learning allows government agencies and industries to cost-effectively disseminate the most current technical and regulatory information on an as-needed basis.

(2) Field Training and Experience

The second phase of training should move the new inspector into the field with a training officer. On-site training should focus on specific inspection tasks such as interviewing, making observations, measuring conditions such as temperatures and sanitizer strength, assessing the control operators have over the foodborne illness risk factors, ensuring implementation of Food Code interventions, and completing the inspection form. If an electronic database is used by the agency, training in its use should be included in this phase.

The evaluation of food safety management systems based on HACCP principles should be part of the field training experience. The trainee and the trainer should review establishment menus, operations, recipes, and standard operating procedures. Inspectors should be able to demonstrate proficiency in gathering information about the food preparation processes, including accurate charting of the food flows and determination of the Critical Control Points (CCPs) and critical limits in an operation. This part of the training should also include a familiarization with the compliance and enforcement protocol in place in the jurisdiction including recommendation of voluntary strategies to prevent risk factor occurrence.

(3) Standardization

The third part of staff training should include standardization. This process improves uniformity in the application and interpretation of applicable regulations, inspection methodology, and report writing. The Program Standards recommend that staff conducting inspections undergo a standardization process similar to the one described in the *FDA Procedures for Standardization and Certification of Retail Food Inspection/ Training Officers* (http://www.cfsan.fda.gov/~ear/rfi-toc.html). Standardization should be completed after the trainee completes classroom and field training.

(4) Continuing Education

The training process for inspection staff should be continuous. The final phase of training should include a mechanism to ensure that learning is ongoing and staff is kept abreast of food safety issues and the latest science.

D. Ensure Adequate Program Resources

As indicated in Standard 8 of the Program Standards, regulatory agencies should have adequate funding, staff, and equipment necessary to support a risk-based retail food safety program designed to reduce the occurrence of foodborne illness risk factors. Program management should do everything they can to secure funding and resources to support regulatory food programs.

Standard 8 of the Program Standards also states that the program budget should provide the necessary resources to develop and maintain a retail food safety program that has a staffing level of one full-time equivalent (FTE) devoted to food for every 280 - 320 inspections performed. Inspections, for purposes of this calculation, include routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews, and other direct establishment contact time such as on-site training.

4. RISK-BASED INSPECTION METHODOLOGY

A. Focus the Inspection

Conducting a risk-based inspection requires inspectors to focus their efforts on evaluating the degree of active managerial control that operators have over foodborne illness risk factors. In addition, it is essential that the implementation of Food Code interventions also be verified during each inspection. Inspectors need to spend the majority of their time observing the behaviors, practices, and procedures that are likely to lead to out-of-control foodborne illness risk factors and asking management and food employees questions to supplement actual observations.

Retail and food service operators implement “control measures” to ensure food safety. Control measures are actions or activities that are used to prevent, eliminate, or reduce food safety hazards. Inspectors need to determine the control measures that should be implemented to prevent the occurrence of foodborne illness risk factors in each food preparation process. In order to determine the foodborne illness risk factors common to each operation, it is important for inspectors to understand that the food preparation processes and all the associated control measures initiated by a retail or food service operator represent a food safety management system. It will be necessary for inspectors to ask questions in order to gain information about the system already in place. Once the degree of active managerial control is determined, inspectors will be able to assist operators with strengthening their existing food safety management systems.

B. Lead by Example

Nonverbal communication is just as important as verbal communication in relaying important food safety principles to retail and food service operators. By setting the example during inspections, inspectors not only demonstrate competency, but they also relay important food safety information to the person in charge and food employees. The following are ways that inspectors set the example during inspections:

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

C. Conduct Inspections at Variable Times

Inspectors should enter the food establishment during hours of operation or at other reasonable times. Inspectors should show identification and provide the permit holder or person in charge with a verbal or written notice of the purpose of the inspection. Procedures outlined in the Food Code and in the jurisdiction’s procedures should be followed if access to conduct an inspection is denied. Refusal should be documented on the inspection report and an administrative or judicial inspection order obtained.

In planning for inspections, inspectors should consider the importance of timing. Several operational steps at retail such as receiving, preparation, and cooling can be evaluated only during limited time periods. In order to properly evaluate critical

processes that occur outside of the normal 8 a.m. to 5 p.m. working hours, an inspector should be allowed the flexibility to conduct inspections early in the morning, late in the evening, and even on weekends.

D. Establish Inspection Priorities and Use Inspection Time Wisely

With the limited time allotted for inspections, inspectors must develop clear priorities to make the most efficient use of their time in each food establishment. Although basic sanitation issues generally do not change during the course of an inspection, critical behaviors, practices, and procedures leading to foodborne illness risk factors may be only observable during limited time periods of the preparation or cooling process. For this reason, assessment of the active managerial control of foodborne illness risk factors should generally be performed before reviewing basic sanitation issues.

To effectively set priorities, the following four activities should be completed early in the inspection:

(1) Establish an open dialogue with the person in charge
(2) Review previous inspection records
(3) Conduct a menu or food list review
(4) Conduct a quick walk-though.

(1) Establish an Open Dialogue with the Person in Charge

The tone of the inspection is often set during the first few minutes of the inspection. A professional but personable approach is the balance which should be maintained. Genuine interest in the food establishment and the staff translates into good relations which may be helpful in conveying the goal of promoting public health. Having an open dialogue with the person in charge during all phases of the inspection gives inspectors an opportunity to learn important information about the existing food safety management system.

It is important to know both the strengths and weaknesses of the existing food safety management system early in the inspection in order to focus the inspection on weak areas. Questions about practices and procedures related to foodborne illness risk factors and Food Code interventions such as the establishment's employee health policy and consumer advisory notice should be asked during all phases of the inspection. It is important to ask enough questions to fully understand the system being utilized in the food establishment. This is especially true when evaluating whether the employees are adhering to the established no bare hand contact and handwashing policies. Asking the person in charge questions about important activities such as receiving, cooling, and preparation is also important in relaying the importance of out-of-control foodborne illness risk factors.

The person in charge should be encouraged to accompany inspectors during the inspection. This may ultimately save time since violations can be pointed out and

corrected as they are observed. In addition, the importance of violations related to foodborne illness risk factors and Food Code interventions is more apparent if they are pointed out during the inspection rather than waiting until the end. Violations should be marked on the inspection form even if immediate corrective actions are taken. Corrective actions taken should also be recorded on the inspection form. Inspectors can also use this time to share knowledge about critical processes. By communicating the public health rationale behind the regulations, inspectors will leave the person in charge with a clear understanding for why active managerial control of foodborne illness risk factors must be a top priority in the day-to-day operation of the business.

Early in the inspection, inspectors should inquire about activities that are presently occurring. Processes that occur over time like cooling and reheating also need to be assessed over time; thus, inspectors should ask in the beginning of the inspection if any foods are currently being cooled or reheated.

It is important for inspectors to allow the operator a chance to discuss issues related to food safety. One-way communication in which inspectors do all the talking is not conducive to a risk-based philosophy. An effective risk-based inspection is dependent on inspectors' ability to maintain two-way communication in order to properly assess behaviors, processes, and procedures that occur in the food establishment.

(2) Review Previous Inspection Reports

In order to detect trends of out-of-control foodborne illness risk factors, it is important for inspectors to review past inspection reports before conducting an inspection. This can be done in the office or on-site in the food establishment. This activity is especially important in jurisdictions where inspectors rotate from one inspection to the next. If the same foodborne illness risk factor is out-of-control during more than one inspection, it is strongly recommended that the operator develop an intervention strategy to prevent its recurrence. Intervention strategies are discussed later in this Annex.

Knowledge of what has been corrected from the last inspection also gives inspectors an opportunity to provide positive feedback to the operator and allows inspectors to track corrected violations in accordance with their jurisdiction's policies and procedures.

(3) Conduct a Menu/Food List Review

Menus, including all written and verbal lists of foods prepared and offered in a food establishment, can be reviewed in a fairly simple manner. The review can either be done simultaneously with a quick walk-through of the operation or at the beginning of the inspection as a discussion with management. The menu/food list also does not need to be reviewed during every inspection. If a review was done during a recent inspection, inspectors should inquire about new items, seasonal items, substitutions, or changes in preparation since the last menu review was conducted.

A review of the menu/food list allows inspectors to begin to group food items into one of three broad process categories (discussed in Annex 4 of the Food Code and later in this Annex). Mentally grouping products by process assists inspectors in focusing the inspection on the control measures critical to each process. Conducting a review of the menu/food list also allows inspectors to establish inspection priorities by identifying:

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

By identifying high-risk foods or high-risk food preparation processes, inspectors can focus the inspection on those foods or processes that are more likely to cause foodborne illness if uncontrolled. The menu/food list review might be the only time inspectors are made aware of specialized processes such as formulating a food so that it is not potentially hazardous (time/temperature control for safety) food or high-risk seasonal menu items such as "raw oysters on the half shell." Foods such as shellstock and certain fish for raw consumption require documentation that should be reviewed during the inspection. If Caesar salad or hollandaise sauce is served, further inquiry is needed regarding the preparation of these items since they are sometimes prepared with raw or undercooked eggs.

Several operational steps like receiving, preparation, cooking, and cooling may not be inspected as vigorously in retail and food service inspections due, in part, to the hours of the day in which these steps occur. If a food establishment is inspected in the afternoon hours, for example, receiving and food preparation might have already occurred. In order to evaluate the establishment's active managerial control of foodborne illness risk factors, it is imperative that inspectors ask enough questions to obtain information about the operational steps that they cannot directly observe during the current inspection.

(4) Conduct a Quick Walk-through

As inspectors discuss the menu or food list and establishes open communication with the person in charge, it is suggested that they conduct a quick walk-through of the food establishment to observe what is going on at that time. Conducting a quick walk-through is especially important to observe several activities that might otherwise go unnoticed or unobserved until later in the inspection, including:

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

Speaking directly to the food service employees preparing the food is also an excellent way to assess the effectiveness of the establishment's food safety training and standard operating procedures for critical processes such as cooling. Noting that receiving or food preparation is occurring at the beginning of the inspection allows inspectors an opportunity to take advantage of viewing "real-life" production processes and will help inspectors to obtain a clear picture of the establishment's true practices. Receiving and food preparation only occur during limited times, so inspectors may want to stop and observe these operational steps while they are happening.

Early in the inspection, temperatures of potentially hazardous foods (time/temperature control for safety (TCS) foods) should be taken. For example, if inspecting in the morning, inspectors should check the temperatures of last night's stored leftovers. If inspecting in the afternoon, inspectors should check the temperatures of foods prepared that morning that are now cooling. Also, inspectors should ask whether any foods are currently being cooked or reheated.

E. Determine Process Flows

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

As presented in Annex 4 of the Food Code, most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41° F and 135° F. In conducting risk-based inspections, it is necessary for an inspector to be knowledgeable regarding how food is prepared in the operation. Knowing how products are prepared in an establishment allows inspectors to focus their inspections on the critical procedures and steps in the preparation of those products.

F. Determine Foodborne Illness Risk Factors In Process Flows

Annex 4 of the Food Code details the essential control measures specific to each food preparation process, in addition to essential facility-wide control measures. Inspectors should generally focus their inspections on verifying that operators have implemented control measures to control for foodborne illness risk factors common to the processes conducted in each operation. There may be other foodborne illness risk factors unique to specific operations; thus, inspectors should independently evaluate each operation and food preparation process conducted.

G. Assess Active Managerial Control of Foodborne Illness Risk Factors and Implementation of Food Code Interventions

Although some food establishments have formal HACCP plans, many do not. Even without a HACCP system, every food establishment needs to have active managerial control of foodborne illness risk factors. This may be achieved through several means, such as training programs, manager oversight, or standard operating procedures. For example, some food establishments incorporate control measures into individual recipes, production schedules, or employee job descriptions to achieve active managerial control.

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

This section provides a comprehensive discussion of how to assess the active managerial control of each of the foodborne illness risk factors and the implementation of each of the Food Code interventions. Assessment of active managerial control involves more than determining compliance with Food Code provisions. In assessing whether the operator has active managerial control, inspectors should observe whether the operator has established the appropriate control measures and critical limits and whether appropriate monitoring and corrective action procedures are in place and followed. In addition, inspectors should assess whether managers and employees are knowledgeable of food safety principles and critical practices and procedures necessary to prevent foodborne illness. If during the inspection inspectors observes that control measures are not being implemented appropriately to control risk factor occurrence, immediate corrective action must be taken.

(1) Demonstration of Knowledge

It is the responsibility of the person in charge to ensure compliance with the Code. Knowledge and application of Food Code provisions are vital to preventing foodborne illness and injury. Data collected by FDA suggest that having a certified food manager on-site has a positive effect on the occurrence of certain foodborne illness risk factors in the industry.

In order to assess whether the person in charge demonstrates knowledge, inspectors should verify that the person in charge has one or more of the following:

- A valid food protection manager certificate
- No critical violations during the current inspection
- Correct responses to food safety related questions as presented in ¶ 2-102.11(C) of the Food Code.

(2) Assessing Safe Sources and Receiving Temperatures

The time and day of the inspection is important when assessing whether foods are received from safe sources and in sound condition. Foods may be received in the food establishment on set days. Inspectors should ask questions to ascertain the day or days that deliveries are received and also the receiving procedures in place by the food establishment. Inspections can be scheduled at times when it is known that products will be received by the food establishment. If food is being delivered during the inspection, inspectors should:

- Verify internal product temperatures
- Examine package integrity upon delivery
- Look for signs of temperature abuse (e.g., large ice crystals in the packages of frozen products)
- Examine delivery truck and products for potential for cross-contamination
- Observe the food establishment's behaviors and practices as they relate to the establishment's control of contamination and holding and cooling temperatures of received products
- Review receiving logs and other documents, product labels, and food products to ensure that foods are received from regulated food processing plants (no foods prepared at home) and at the proper temperature.

When evaluating approved sources for shellfish, such as clams, oysters, and mussels, inspectors should ask whether shellfish are served at any time during the year. If so, inspectors should review the tags or labels to verify that the supplier of the shellfish is certified and on the most current Interstate Certified Shellfish Shippers List (http://www.cfsan.fda.gov/~ear/shellfis.html). Inspectors should note whether all required information is provided on the tags or label (harvester's certification number, harvest waters and date, type and quantity of shellfish and similar information for each dealer that handles the shellfish after the harvester). Shellstock tags should also be retained for 90 days in chronological order.

With regard to fish, inspectors should verify that fish are commercially caught and harvested and received from reputable vendors. If fish are being delivered during the inspection or if they were received just before inspectors' arrival, temperatures should be taken, especially if there are finfish such as tuna, mahi-mahi, bluefish, mackerel, and snapper. These fish are subject to scombrotoxin formation if time/temperature abused.

Inspectors should verify freshness by conducting an organoleptic inspection of the gills, eyes, and bodies of the fish.

Inspector should verify that fish, except for certain species of tuna, intended for raw or undercooked consumption have been frozen for the required time and temperature parameters to destroy parasites by either reviewing freezing records or verifying that a letter of guarantee from the purveyor is kept on file. If freezing is conducted on-site, inspectors should verify that the freezing records are maintained for at least 90 days beyond the date of sale or service.

With regard to the service of game or wild mushrooms, inspectors should ask if these products are served at any time during the year. If so, inspectors should verify that they are from an approved source by reviewing invoices.

With regard to juice and milk products, inspectors should verify that fluid milk and milk products are pasteurized and received at the proper temperature. For packaged juice, inspectors should verify that the juice was pasteurized or otherwise treated to achieve a 5-log reduction of the most resistant microorganism.

During the inspection, inspectors should inquire as to the source of foods that have been removed from their original containers. If at any time during the inspection there is any doubt as to the source of certain products, inspectors should ask for invoices or receipts to demonstrate their source. Certain products, such as flat breads, waffles, pies, and cakes may require special cooking equipment to prepare. If suitable equipment is not on-site to prepare such products and the products are not stored in original containers, then inspectors should inquire as to the source of these products.

Food from unapproved, unsafe, or otherwise unverifiable sources should be discarded or put on hold or under embargo until appropriate documentation is provided. In addition, inspectors should ensure that management and employees are aware of the risk of serving or selling food from unapproved sources. Fish that are intended to be consumed raw or undercooked and for which no freezing certification or equipment is found on-site, can be used in menu items that will be fully cooked. If cooking is not an option due to the menu items served, the fish should be discarded.

(3) Assessing Contaminated Equipment and Potential for Cross-Contamination

This risk factor involves the proper storage and use of food products and equipment to prevent cross-contamination. The cleaning, sanitization, and storage of food-contact surfaces of equipment and utensils in a manner to prevent transmission of foodborne pathogens or contamination is also included in this risk factor.

As inspectors walk through the food establishment, they should examine food storage areas for proper storage, separation, segregation, and protection from contamination. Inspectors should look to see that raw animal foods and ready-to-eat foods are

separated during receiving, storage, and preparation. For example, cooked shrimp should not be returned to the same container that previously held uncooked product. Cutting boards should be washed, rinsed, and sanitized between trimming uncooked chicken and cooked steak.

In addition, raw animal foods should be separated by cooking temperatures such that foods requiring a higher cooking temperature, like chicken, should be stored below or away from foods requiring a lower temperature, like pork and beef. If potentially hazardous foods (TCS foods) are not being cooled, they should be covered or packaged while in cold storage.

Following the flow of food as it is prepared in the food establishment may alert inspectors to opportunities for cross-contamination. When contamination has occurred between raw and ready-to-eat food, inspectors should assess whether the food can be reconditioned. In some cases, depending on the affected food, it may be possible to reheat the food to eliminate any hazards. If the food cannot be reconditioned, then the food should be discarded.

Inspectors should verify that exposed food such as chips, bread, and dipping sauces are not re-served to the consumer. Consumer self-service operations are addressed in the Code with regard to the types of food offered for consumer self-service, the protection of food on display, and the required monitoring by employees of such operations.

A visual check of the food-contact surfaces of equipment and utensils should be made to verify that the utensils are maintained clean and sanitized using the approved manner and frequency. Utensils that are observed to have debris, grease, or other visible contamination should be rewashed and resanitized.

Observations should be made to determine whether practices are in place to eliminate the potential for contamination of utensils, equipment, and single-service items by environmental contaminants, employees, and consumers. When clean equipment and utensils are stored where they are subject to environmental contamination such as near handwashing sinks or prep sinks, inspectors should have the operator rearrange the equipment in a manner to prevent cross-contamination. Depending on the circumstances, the operator may need to rewash and resanitize the equipment.

Inspectors should observe handwashing operations. If handwashing sinks and fixtures are located where splash may contaminate food contact surfaces or food, then splash guards should be installed or food-contact surfaces should be relocated to prevent cross-contamination.

Inspectors should pay particular attention to prep sinks, especially those that are currently in use at the time of the inspection. Built-up grime is a visible sign that the sink is not being washed, rinsed, and sanitized appropriately before use. If there are designated vegetable or meat sinks, inspectors should verify that the placement of sinks

and food preparation areas do not facilitate opportunities for cross-contamination from one to the other.

With regard to the cleaning and sanitization of food-contact surfaces, inspectors should verify the compliance of any warewashing operations by ensuring that cleaning and sanitizing procedures for all food-contact surfaces conform to the requirements in the Food Code. Questions should be asked to assess how utensils and cookware are washed, rinsed, and sanitized in the food establishment. When assessing the warewashing procedure and equipment, inspectors should pay particular attention to cooking and baking equipment that is too large to fit in the dishmachine or sinks. It is a good idea to have the person responsible for dishwashing demonstrate the procedure that is followed in the food establishment by setting up the sinks and watching the dishwashing procedure.

(4) Assessing Cooking Temperatures

Food cooking temperatures and times should be verified by inspectors during each inspection. Every effort should be made to assess the cooking temperatures of a variety of products served in the food establishment.

To assess cooking, inspections must occur at times when food is being cooked. It is also important to conduct inspections during busy times, such as lunch and dinner, as there may be a tendency for the operator to rush the cooking of foods during these times.

Critical limits for cooking potentially hazardous foods (TCS foods) in the Food Code include specifications that all parts of the food be heated to a certain temperature. For large roasts, temperature measurement should take into account post-cooking heat rise which allows the temperature to reach equilibrium throughout the food. The critical limit of time at the terminal temperature must also be measured during inspections. For example, a roast beef cooked at 54°C (130°F) is required to be held at this temperature for 112 minutes to ensure destruction of pathogens. Cooking times and temperatures should be noted on the inspection report.

The correct temperature measuring device and technique are essential in accurately determining the temperatures of potentially hazardous foods (TCS foods). The geometric center or thickest part of a product are the points of measurement of product temperature particularly when measuring critical limits for cooking.

Inspectors should take internal temperatures of products using a thermocouple or thermistor with a probe suitable for the product thickness. A thin diameter probe should be used for temperature measurements of hamburger patties and fish filets. Alternately, although less desirable, an inspector may use a suitable, calibrated bimetal stem thermometer for checking cooking temperatures of thick foods. Infrared thermometers are inappropriate for measuring internal cooking temperatures.

In order to better assess cooking during all phases of the inspection, inspectors could enlist the help of cooperative food employees to notify them of foods that have finished cooking. This allows inspectors to continue with the inspection in other areas of the operation yet continue to verify that proper cooking temperatures are being met.

Food establishments should routinely monitor cooking temperatures. Inspections should verify that monitoring is occurring by involving the person in charge in these activities during the regulatory inspection. The presence of required thermometers and their proper use should be assessed.

Comparisons should be made between inspectors' calibrated temperature measuring device and those used by the food establishment. Notation of deviations should be made on the inspection report. Inspectors should ask food establishment personnel to demonstrate proper calibration of their temperature measuring devices.

If required cooking temperatures are not met, inspectors should have the operator continue cooking the food until the proper temperature is reached. Additionally, inspectors should explain the public health significance of inadequate cooking to management and food employees.

(5) Assessing Holding Time and Temperatures and Date Marking

Hot and cold holding temperatures, as well as cooling time and temperatures, of potentially hazardous foods (TCS foods) should be thoroughly checked with a thermocouple, thermistor, or other appropriate temperature measuring device during each inspection. This includes the temperature of potentially hazardous food (TCS food) during transport, e.g., hot holding carts being used to transport food to patient rooms in a hospital, satellite kitchens, or off-site catering events. As a rule, every effort should be made to assess every hot and cold holding unit in the food establishment during a risk-based inspection

Use of an infrared thermometer for verifying holding temperatures is not consistent with Food Code requirements since verifying only the surface temperature of the food may not alert inspectors to problems that exist under the food's surface. Such problems could stem from improper cooling, in the case of cold-held foods, or improper reheating, in the case of hot-held foods. In addition, inspectors should not stir a food before taking its temperature since it is important to know the temperature of the food before it is agitated.

The geometric center of a product is usually the point of measurement of product temperature particularly when measuring the critical limit for cold holding.

The hot holding critical limit may need additional measurements taken at points farthest from the heat source, e.g., near the product surface for food held on a steam table. Temperatures monitored between packages of food, such as cartons of milk or packages of meat, may indicate the need for further examination. However, the

temperature of a potentially hazardous food (TCS food) itself, rather than the temperature between packages, is necessary for regulatory citations. In large holding units and on steam tables, it is necessary to take the temperatures of foods in various locations to ensure that the equipment is working properly. If deviations are noted in the product temperatures, it is important to take extra steps to find out whether the problem is the result of equipment failure or whether a breakdown in a process such as cooling or reheating is the reason for the problem.

Corrective actions for foods found in violation should be required based on the jurisdiction's regulatory food code. If foods are to be discarded, forms such as those used for stop sale or embargo may need to be completed and signed by the person in charge in accordance with the jurisdiction's regulatory food code. In order to properly evaluate the degree of time and temperature abuse and the proper disposition of the affected food, several issues must be considered. Answers to these questions, in combination with observations made during the inspection, should provide inspectors with enough information to make the appropriate recommendation for on-site correction:

- Are there any written procedures in place for using time alone as a public health control and, if so, are they being followed properly?
- What are the ingredients of the food and how was it made?
- Is it likely that the food contains *Clostridium perfringens*, *Clostridium botulinum*, or *Bacillus cereus* as hazards?
- Has there been an opportunity for post-cook contamination with raw animal foods or contaminated equipment?
- If there has been an opportunity for post-cook contamination, can the hazards of concern be eliminated by reheating?
- Are the food employees practicing good personal hygiene including frequent and effective handwashing?
- Was the food reheated or cooked to the proper temperature before being allowed out of temperature control?
- What is the current temperature of the food when taken with a probe thermometer?
- How long has the food been out of temperature control (ask both the manager and food employees)? Are the answers of the food employees and the manager consistent with one another?
- Is it likely that food has cooled to its current temperature after being out of temperature control for the alleged time?
- Will the food be saved as leftovers?
- How long before the food will be served?
- Given what is known about the food, the food's temperature, the handling of the food, and the alleged time out of temperature, is it reasonably likely that the food already contains hazards that cannot be destroyed by reheating?

Even if food can be reconditioned by reheating, steps should be taken by the person in charge to ensure compliance in the future. Examples include repairing malfunctioning or inoperative equipment or implementing a risk control plan (RCP) to modify

preparation procedures or to institute a procedure for monitoring holding temperatures of food.

If using time only or time-temperature combinations in lieu of temperature for controlling the growth and toxin-formation of pathogenic bacteria, strict controls must be in place and followed. Inspectors should verify that the written procedures are on-site and followed in accordance with the Food Code.

Date marking is the mechanism by which active managerial control of time-temperature combinations can prevent the growth of *Listeria monocytogenes* in potentially hazardous (TCS), ready-to-eat foods during cold storage. With exceptions, all ready-to-eat, potentially hazardous foods (TCS foods) prepared on-site and held for more than 24 hours should be date marked to indicate the day or date by which the foods need to be served or discarded. Inspectors should ask questions to ascertain whether the system in place to control for *L. monocytogenes* meets the intent of the Food Code. Food that should be date marked and is not should be discarded.

(6) Assessing Reheating for Hot Holding

In order to assess a food establishment's control of reheating for hot holding, the time of day that the inspection occurs is a key factor. Every effort should be made to schedule an inspection during pre-opening preparation. If inspections are conducted during pre-opening preparation or other preparation periods, inspectors should ask questions regarding the history of hot-held foods. Foods in compliance for minimum hot holding temperatures may have in fact been improperly reheated before being placed into hot holding units or steam tables.

If items are found "reheating" on the steam table, further inquiry is needed to assess whether the equipment in question is capable of reheating the food to the proper temperature within the maximum time limit. Corrective action for foods found out of compliance for reheating for hot holding would depend on how long the food had been out of temperature and other factors. In most cases, however, the food may be rapidly reheated and hot held.

(7) Assessing Cooling

Improper cooling remains a major contributor to bacterial foodborne illness. Cooling temperatures and times need to be closely evaluated during every inspection. In order to assess whether a food establishment has control over cooling, the time of day that the inspection occurs is critical. Early morning inspections allow an opportunity to verify that leftovers from the night before were cooled properly or cooled using a proper cooling method. Alternatively, afternoon inspections may allow an inspector to verify cooling of products that may have been prepared that morning. Because many food establishments prepare bulk products only on certain days of the week, it is essential that inspectors become as familiar as possible with each operation and schedule their inspections accordingly.

Due to the time parameters involved in cooling, inspectors should always inquire at the beginning of the inspection whether there are any products currently being cooled. This allows inspectors an opportunity to take initial temperatures of the products and still have time to re-check temperatures later in the inspection in order to verify that critical limits are being met.

Problems with cooling can often be discovered through inquiry alone. Even when no cooling is taking place, inspectors should ask the food employees and managers questions about the cooling procedures in place.

When examining cold holding units, bulk containers and buckets, tightly packed pans, shrouded rolling racks, or closed rolling cabinets should warrant further temperature and time investigation. Bulk containers and buckets should be opened since they are commonly reused for food storage and cooling.

The geometric center of a product is often chosen as the point of measurement of product temperature particularly when measuring the critical limits for cooling. For foods that are being cooled, temperature profiles throughout the product may show proper temperatures at outer edges and hot spots at the core of the product. Inspectors can verify cooling by first taking a temperature measurement in the geometric center of the product, then at various points around the perimeter of the product. Warmer temperatures in the center of the product, in combination with cooler temperatures around the perimeter, indicate that a product is cooling. Additional questions should be asked to ascertain the cooling time parameters of the food in question. Information gained from food employees and management, in combination with temperature measurements taken, should form the basis for assessing compliance of cooling during an inspection.

The following guidance may be used for determining the appropriate corrective action for improper cooling. Cooked hot food may be reheated to 165 ºF for 15 seconds and the cooling process started again using a different cooling method if the food is:

- Above 70 ºF and two hours or less into the cooling process; and
- Above 41 ºF and six hours or less into the cooling process.

Cooked hot food should be discarded immediately if the food is:

- Above 70 ºF and more than two hours into the cooling process; or
- Above 41 ºF and more than six hours into the cooling process.

A different, more accelerated, cooling method may be used for prepared ready-to-eat foods if the food is above 41 ºF and less than four hours into the cooling process; however, such foods should be discarded if the food is above 41 ºF and more than four hours into the cooling process.

(8) Assessing Personal Hygiene, Hands As a Vehicle of Contamination, and Proper Implementation of Employee Health Policies

Special attention should be given to the potential for hands as a vehicle of contamination. An effective management system for prevention of hand contamination involves three elements:

- Employee health policy
- Proper handwashing
- No bare hand contact with ready-to-eat foods.

There are a wide range of communicable diseases and infections that can be transmitted by an infected food employee. Proper management of the risks associated with ill food employees begins with employing healthy people and implementing a policy that excludes or restricts ill employees as specified in Chapter 2 of the Food Code. Employees must be aware of the symptoms, illnesses, or conditions that must be reported to the person in charge. In addition, the person in charge must be knowledgeable regarding the appropriate action to take should certain symptoms, illnesses, or conditions be reported.

With regard to the employee health policy, inspectors should ask a series of open-ended questions to ascertain whether the employee health policy in place complies with the Food Code. The following are example questions that may be asked:

- What kind of policy do you have in place for handling sick employees?
- Is there a written policy? (Note: a written policy is not required in the Food Code, but having a written policy may give an indication of the formality of the policy being discussed.)
- Describe how managers and food employees are made knowledgeable about their duties and responsibilities under the employee health policy.
- Are food employees asked if they are experiencing certain symptoms or illnesses upon conditional offer of employment? If so, what symptoms or illnesses are food employees asked about? Is there a written record of this inquiry?
- What are food employees instructed to do when they are sick?
- What conditions or symptoms are reported?
- What may some indicators be of someone who is working while ill?
- When are employees restricted from working with exposed food or food-contact surfaces? When are they excluded from working in the food establishment?
- For employees that are sick and cannot come to work, what policy is in place for allowing them to return and for notifying the regulatory authority?

Special attention should be given to the potential for hands as a vehicle of contamination. Ensuring that hands are washed using the proper procedure and at the appropriate times must be a top priority during every inspection. Data show that viruses

can be tenacious even in the presence of good handwashing. Inspectors should observe employee use of utensils and gloves during the preparation and service of ready-to-eat foods and ingredients, such as salads and sandwiches.

If ready-to-eat food is touched with bare hands, inspectors will need to address several questions in order to make the appropriate on-site correction recommendation. The answers to the following questions should provide enough information to determine the likelihood of occurrence of hazards transmitted by bare hands and should be the basis for making a recommendation for on-site correction:

- Does the facility have an employee health policy to identify, restrict, and exclude ill employees?

- Did the employees working with the food in question effectively wash their hands and are handwashing facilities adequate?

- Is there an approved, alternate procedure to no bare hand contact in place and was it followed before the bare hand contact?

- Has there been an opportunity for the employee's hands to become contaminated?

Inspectors should examine the location of handwashing sinks in relation to where food is being prepared. Many jurisdictions use a basic distance measurement as a guideline when considering the location and number of handwashing sinks required in a food establishment during the plan review process. While this information can be used to assist with the review process, it should not be used as the sole basis for determining whether there are an adequate number of handwashing sinks or whether the handwashing sinks are conveniently located.

Special emphasis should be placed on spacing in and around fixed equipment, the expected staffing, and the flow of food throughout a food establishment. For instance, a kitchen may be 30 feet in length and 12 feet wide. Although the size of the kitchen may dictate only one handwashing sink using a basic distance measurement, if a prep table the length of the line is placed between the line and the handwashing sink, the handwashing sink may not be conveniently located. Likewise, one handwashing sink located at the end of cook line is useless to employees working at the other end if there is limited space for employees to go around one another during busy periods.

(9) Assessing Compliance with Approved Procedures

When conducting certain specialized processes, variances and HACCP plans are required by the Code. This is because such processes carry a considerable risk if not conducted under strict controls. For food establishments conducting specialized processes, each inspection should involve a review of the written variance, if applicable,

and the implementation of the HACCP plan to ensure that food safety hazards are being consistently controlled.

(10) Assessing Special Requirements Related to Highly Susceptible Populations (HSP)

Food establishments that serve highly susceptible populations (HSP) must adhere to additional requirements as specified under Part 3-8 of the Code. Every effort should be made to inspect such facilities during preparation, service, or other applicable times to assess these additional requirements as well as those in other sections of the Food Code.

Because those persons who are very young, elderly, or who live in a facility that provides custodial care are extremely vulnerable to foodborne illness because of age or health status, it is important that risk factors be controlled on-site in a timely manner. Inspections of HSP facilities should be conducted by inspectors knowledgeable in the control of foodborne illness risk factors who take extra care to assure that the most vulnerable segment of the population are not at risk.

(11) Assessing Labeling, Storage, and Use of Poisonous and Toxic Chemicals

During each inspection, the proper labeling, storage, and use of poisonous and toxic chemicals should be verified. Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label. Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies should be clearly and individually identified with the common name of the material. Only chemicals that are necessary to 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, should be in the food establishment. Medicines necessary for the health of employees may be allowed in a food establishment, but they should be labeled and stored to prevent contamination of food and food-contact surfaces.

Inspectors should verify that solutions containing poisonous and toxic chemicals, like mop water, are discarded in an appropriate service sink to prevent contamination of food and food-contact surfaces. In addition, inspectors should check delivery trucks to verify that food is protected from chemical contamination during shipment. Any food that has been cross-contaminated with poisonous or toxic chemicals should be discarded or rejected immediately.

(12) Assessing Compliance with Consumer Advisory

Inspectors should ascertain whether animal foods such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish are served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient

in another ready-to-eat food. Inspectors should review the menu or food list to verify that a consumer advisory with a disclosure and reminder is present as specified under § 3-603.11 of the Food Code.

In addition to reviewing the menu or food list, inspectors should ask whether raw or undercooked foods are served or sold routinely or seasonally. It is useful to know foods that are often served in this manner such as oysters-on-the half shell, hollandaise sauce, béarnaise sauce, eggnog, salad dressings, hamburgers to order, or sunny-side-up eggs.

H. Evaluating Basic Sanitation and Facilities (Good Retail Practices)

An important part of a risk-based, routine inspection is to review how the food establishment actively monitors the active managerial control of foodborne illness risk factors and interventions; however, overall sanitation should not be overlooked. Systems to control basic operational and sanitation conditions within a food establishment, referred to as Good Retail Practices (GRPs), are the foundation of a successful food safety management system. GRPs found to be out-of-compliance may give rise to conditions that may lead to foodborne illness, e.g., sewage backing up in the kitchen. Just as monitoring is required by the food establishment to ensure that foodborne illness risk factors are controlled and interventions are in place, monitoring of basic sanitation conditions in the food establishment allows the operator an excellent opportunity to detect weaknesses and initiate actions for improvement. Basic operational and sanitation programs must be in place to:

- Protect products from contamination by biological, chemical, and physical food safety hazards
- Control bacterial growth that can result from temperature abuse during storage
- Maintain equipment, especially equipment used to maintain product temperatures.

Examples of concerns addressed by the basic operation and sanitation programs mentioned above include the following:

- Pest control
- Food protection (non-critical)
- Equipment maintenance
- Water
- Plumbing
- Toilet facilities
- Sewage
- Garbage and refuse disposal
- Physical facilities.

5. ACHIEVING ON-SITE AND LONG-TERM COMPLIANCE

A. Developing an Effective Compliance and Enforcement Protocol

Compliance and enforcement are essential elements of a regulatory program and encompass all voluntary and regulatory enforcement actions taken to achieve compliance with regulations. Standards 3 and 6 of the Program Standards explain the need of regulatory jurisdictions to establish a compliance and enforcement protocol that results in credible follow-up for each violation noted during an inspection, especially violations related to foodborne illness risk factors and Food Code interventions. Lack of follow-up on the part of the regulatory agency signals to the operator that the critical violations noted were not important.

The resolution of out-of-compliance foodborne illness risk factors and Food Code interventions must be documented in each food establishment record. The desired outcome of Standard 6 is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Compliance and enforcement options may vary depending on state and local law. It is essential that regulatory jurisdictions develop a written compliance and enforcement protocol that details the order in which both voluntary corrections may be taken on the part of the operator and involuntary enforcement actions are to be taken on the part of the regulatory authority. Involuntary enforcement actions include, but are not limited to, such activities as warning letters, re-inspections, citations, administrative fines, permit suspensions, and hearings.

Food establishment with a history of noncompliance at a level predetermined by the jurisdiction or with the number of foodborne illness risk factors and interventions violated warranting a regulatory action, signals the need either a strong regulatory response or an alternate approach to compliance to protect public health, e.g., active managerial control, behavioral change.

Voluntary corrections taken on the part of the operator include, but are not limited to, such activities as on-site corrections at the time of inspection, voluntary destruction, risk control plans, and remedial training. Obtaining voluntary corrections by the operator can be very effective in achieving long-term compliance. Voluntary corrections by the operator are referred to in FDA's Regulator's Manual as "intervention strategies." Intervention strategies can be divided into two groups:

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

Successful intervention strategies for out-of-control foodborne illness risk factors can be tailored to each operation's resources and needs. This will require inspectors to work

with the operator to identify weaknesses in the existing food safety management system and consulting with the operator to strengthen any weak areas noted.

B. On-site Correction

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

It is essential to consumer protection and to regulatory credibility for on-site correction to be obtained for any out-of-control foodborne illness risk factors before completing the inspection and leaving the food establishment. Obtaining on-site correction conveys the seriousness of the violation to management. Failure to require on-site correction when an out-of-control risk factor has been identified implies that the risk factor has little importance to food safety.

When recommending on-site correction, effective communication regarding out-of-control foodborne illness risk factors is essential and can be accomplished best by:

- Discussing food safety concerns in words that can be easily understood by the person in charge and employees

- Conveying the seriousness of the out-of-control foodborne illness risk factors in terms of increased risk of illness or injury.

During the discussion of inspection findings with the person in charge, inspectors should keep the discussion focused on correction of violations that present an immediate danger to the consumer. Discussion of less serious code violations should be deferred until out-of-control foodborne illness risk factors are discussed and on-site correction is obtained.

In most cases, selecting the most appropriate on-site correction when out-of-control foodborne illness risk factors are observed will be straightforward; however, in instances such as improper cooling, the appropriate corrective action may be more complicated. Since determining on-site correction depends on a number of factors, an inspector may need to conduct a hazard analysis of the food in order to determine the appropriate course of action to take.

C. Intervention Strategies for Achieving Long-term Compliance

While on-site correction of out-of-control foodborne illness risk factors is essential to consumer protection, achieving long-term compliance and behavior change is equally important. Overcoming several misconceptions about long-term compliance will help in achieving a desirable change of behavior. For example, in jurisdictions using a 44-item inspection report in which only observed violations are marked, it is often taken for

granted that if there are no violations marked, the foodborne illness risk factors are being controlled. This is not necessarily true since the observation of code violations is subject to many variables such as the time of day, day of the week, or duration of the inspection. An inspection system that records only observed violations rather than the actual status of all foodborne illness risk factors, such as whether the risk factor was in compliance, not observed, or not applicable to the operation, may be unable to detect some foodborne illness risk factors that are continually or cyclically out of control.

Another misconception is that training alone will result in foodborne illness risk factors being controlled. While training may help, there is no guarantee that knowledge acquired will equate to knowledge applied in the workplace. In order for knowledge to translate into changed behavior, it must be reinforced and the behavior must be repeated for a period of time sufficient for the behavior to become an ingrained pattern. Another assumption is that regulatory enforcement actions such as citations or administrative hearings or on-site corrections alone will automatically result in future management control. Unfortunately, there is no assurance that any of these actions will result in the long-term control of foodborne illness risk factors.

Long-term compliance may best be achieved through voluntary actions by the operator. If an operator supports the concept that a food safety management system is needed, there is a better chance that long-term compliance will be achieved. The following are ways operators can better ensure long-term active managerial control of foodborne illness risk factors.

(1) Change Equipment and Layout

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

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

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

(2) Establish Buyer Specifications

Written specifications for the goods and services purchased by a food establishment prevent many problems. For example:

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

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

(3) Develop and Implement Recipe/Process Instructions

Simple control measures integrated into recipes and processes can improve management control over foodborne illness risk factors. For example:

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

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

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

- Pasta is chilled in an ice bath immediately after cooking and before apportioning into single servings. This is specified in the procedures for cooking spaghetti.

(4) Establish First-In-First-Out (FIFO) Procedures

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

(5) Develop and Implement Standard Operating Procedures (SOPs)

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

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

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

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

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

(6) Develop and Implement Risk Control Plans (RCPs)

An RCP is a concisely written management plan developed by the retail or food service operator with input from inspectors that describes a management system for controlling specific out-of-control foodborne illness risk factors. An RCP is intended to be a voluntary strategy that inspectors and the person in charge jointly develop to promote long-term compliance for *specific* out-of-control foodborne illness risk factors. For example, if food is improperly cooled in the establishment, a system of monitoring and record keeping outlined in an RCP can ensure that new procedures are established to adequately cool the food in the future. An RCP should require that the basic control systems in the plan be implemented for a designated period of time (e.g., 60 – 90 days) and allow inspector oversight. The longer the plan is implemented, the more likely it is that the new controls will become "habits" that continue to be used in the food establishment after inspector oversight ends.

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

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

- How are the results of the RCP communicated to inspectors?

By implementing an RCP, the retail or food service operator will have the opportunity to determine the appropriate corrective action for the identified problem and design an implementation strategy to best suit the establishment and operation. Since the RCP is tailored to meet the needs of the food establishment, the operator takes complete ownership of the plan and is ultimately responsible for its development and implementation. The role of inspectors are to consult with the operator by suggesting ways that the risk factor(s) might be controlled.

By creating an RCP, the operator realizes that a problem exists in the established food safety management system and commits to a specific correction plan rather than merely acknowledging a single violation. Follow up by telephone or in person indicates to the operator that inspectors are interested in seeing the plan succeed. This also gives nspectors an opportunity to answer any questions and offer feedback to the operator to make the RCP more useful. An example of an RCP, along with a blank template that can be used by regulatory jurisdictions, is found in FDA's Regulator's Manual: http://www.cfsan.fda.gov/~dms/hret3toc.html.

(7) Develop and Implement Comprehensive Voluntary Food Safety Management Systems based on HACCP Principles

The *Food Code* only requires HACCP plans for a few specialized processes; however, the development of voluntary HACCP plans is always encouraged. FDA Operator's Manual, *"Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments"* is written to aid food establishment managers in the development of food safety management systems based on HACCP principles. A retail or food service operator, in consultation with an appropriate regulatory authority or other food safety professional, can use this document to establish an effective food safety management system to control for all foodborne illness risk factors. This document is available from FDA through the following website: http://www.cfsan.fda.gov/~dms/hret2toc.html.

6. INSPECTION FORM AND SCORING

A. The Inspection Form

The inspection form is the official document utilized by a regulatory agency for documentation of compliance of the food establishment with regulatory requirements. The goal of the inspection form is to clearly, concisely, and fairly present the compliance status of the food establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection.

The inspection report should be kept in the food establishment's files for subsequent compliance actions and review before the next inspection. Individual inspection reports

are to be made available for public review in accordance with Freedom of Information criteria.

Annex 7 of the Food Code provides an inspection form that may be completed for routine, follow-up, and compliance inspections. This inspection form meets requirements established in Standards 3 and 6 of the Program Standards.

B. Debiting Methodology

If a violation exists during an inspection, it should always be marked on the inspection report, even if corrected on site. Violations existing at the time of the inspection probably would have persisted if it were not for the inspection. Slight violations, such as one dirty utensil among hundreds of clean utensils, does not indicate that the food establishment is significantly deviating from the Code requirements; therefore, discretion in marking is required.

It is very important to investigate the root causes of violations and mark them appropriately. Without taking this extra step, inspectors will merely point out violations and will not identify weaknesses in the management system in place. If long-term control of the behaviors or practices leading to the violations is expected, inspectors must identify the causes.

C. Scoring

Regulatory agencies may use scoring methods to rate food establishments. Depending on the system used, establishment scoring may provide an indication of how well a food establishment is complying with the food safety rules of the regulatory agency.

Some agencies use a system of compliance tools as provided in Chapter 8 and Annex 1 of the Food Code to protect public health. The inspection score may serve as the basis for triggering follow-up inspections or other forms of regulatory sanctions when they fall too far from the accepted levels. In addition, scoring may provide a mechanism for consumers to make informed choices regarding where they want to eat.

Use of scoring systems also has negative consequences. For example, it is possible for a food establishment to receive a high numerical or letter score while exhibiting some very serious deficiencies. In recognition of this drawback, some jurisdictions forego scoring systems in favor of demerits or debit systems without assigning a final score. This focuses attention on the items needing correction. Compliance and enforcement decisions can still be based on the increasing levels of identified deficiencies. Whatever method or system of establishment rating is used, policies regarding follow-up and enforcement actions should be established in writing, linked to the rating system, and administered consistently.

7. CLOSING CONFERENCE

The closing conference should include a detailed discussion of the food establishment's plans for correcting violations found during the inspection. The evidence collected or observed during the inspection and the alternatives available for compliance should be emphasized. On-site corrections made during the inspection should be acknowledged on the inspection report and in the closing conference.

The compliance plan should address changes in procedures that will prevent the recurrence of noted violations. The food establishment's compliance plans should be formally documented on the inspection report form. Follow-up letters may be necessary to elicit fulfillment of these agreements. It is important to stress to the operator that long-term correction of violations related to foodborne illness risk factors and Food Code interventions is far more important than corrections of non-critical items.

8. SUMMARY

Although a retail and food service operator has the responsibility for establishing a food safety management system for controlling foodborne illness risk factors, inspectors have a vital, multi-faceted role in consumer protection. It is essential that inspectors are provided with the proper training, equipment, time, and resources to adequately perform their jobs.

The primary role of inspectors is to ensure that the operator has effective control of foodborne illness risk factors. Once inspectors have established a dialogue with the person in charge and employees, conducted a menu/food list review, and established a dialogue with the person in charge, inspectors will have enough information to mentally place menu items into one of the three process flows. The inspection can then focus on assessing the operator’s active managerial control of foodborne illness risk factors associated with each process.

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

Annex

6 Food Processing Criteria

1. INTRODUCTION
2. REDUCED OXYGEN PACKAGING
3. SMOKING AND CURING

1. INTRODUCTION

From its inception, the retail segment of the food industry has prepared foods in consumer-sized portions, using commercially available equipment for cutting, grinding, slicing, cooking, and refrigeration, and applying herbs and spices readily available to consumers at their local grocery.

Over the past score of years, retail segment operators have expanded into food manufacturing/processing-type operations, often using sophisticated new technologies and equipment that are sometimes microprocessor-controlled. Many now desire to alter the atmospheres within food packages, or apply federally regulated chemical food additives as a method of food preservation. Food processing operations now being conducted or proposed include cook-chill; vacuum packaging; sous vide; smoking and curing; brewing, processing, and bottling alcoholic beverages, carbonated beverages, or drinking water; and custom processing of animals.

The Food Code specifies that a HACCP plan acceptable to the regulatory authority be the basis for approving food manufacturing/processing operations at retail. The HACCP plans are to be provided and accepted in two ways as follows.

(A) Reduced Oxygen Packaging

Section 3-502.12 of the Food Code provides the criteria that are to be met in the HACCP plans of those operators who are conducting reduced oxygen packaging (ROP) operations. Unless prior approval of the HACCP plan is required by the regulatory authority, the HACCP plan covering this operation along with the related records documenting monitoring and corrective actions need only be available and acceptable to the regulatory authority at the time of inspection.

(B) Other Food Manufacturing/Processing Operations

Except for ROP as discussed in (A) above, the Food Code specifies under §§ 3-502.11, 8-103.10, 8-103.11, and 8-201.13 that the food establishment operator must obtain a variance from the regulatory authority for all food manufacturing/processing operations based on the prior approval of a HACCP plan.

The purpose of this Annex is to provide processing criteria for different types of food manufacturing/processing operations for use by those preparing and reviewing HACCP plans and proposals. Criteria for additional processes will be provided as they are developed, reviewed, and accepted.

2. REDUCED OXYGEN PACKAGING

(A) Introduction

ROP which provides an environment that contains little or no oxygen, offers unique advantages and opportunities for the food industry but also raises many microbiological concerns. Products packaged using ROP may be produced safely if proper controls are in effect. Producing and distributing these products with a HACCP approach offer an effective, rational, and systematic method for the assurance of food safety. The purpose of this Annex is to provide guidelines for effective food safety controls for retail food establishments covering the receipt, processing, packaging, holding, displaying, and labeling of food in reduced oxygen packages.

(B) Definitions

The term ROP is defined as any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include other packaging options such as:

(1) *Cook-chill* is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a plastic or metal crimp.

(2) *Controlled Atmosphere Packaging (CAP)* is an active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. CAP is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.

(3) *Modified Atmosphere Packaging (MAP)* is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. MAP is defined as packaging of a product in an

atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, 0.03% carbon dioxide.

(4) *Sous Vide* is a specialized process of ROP for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization step that reduces bacterial load but is not sufficient to make the food shelf-stable. The process involves the following steps:

(a) Preparation of the raw materials (this step may include partial cooking of some or all ingredients);

(b) Packaging of the product, application of vacuum, and sealing of the package;

(c) Pasteurization of the product for a specified and monitored time/temperature;

(d) Rapid and monitored cooling of the product at or below 3°C(38°F) or frozen; and

(e) Reheating of the packages to a specified temperature before opening and service.

(5) *Vacuum Packaging* reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.

(C) Benefits of ROP

ROP can create a significantly anaerobic environment that prevents the growth of aerobic spoilage organisms, which generally are Gram-negative bacteria such as pseudomonads or aerobic yeast and molds. These organisms are responsible for off-odors, slime, and texture changes, which are signs of spoilage.

ROP can be used to prevent degradation or oxidative processes in food products. Reducing the oxygen in and around a food retards the amount of oxidative rancidity in fats and oils. ROP also prevents color deterioration in raw meats caused by oxygen. An additional effect of sealing food in ROP is the reduction of product shrinkage by preventing water loss.

These benefits of ROP allow an extended shelf life for foods in the distribution chain, providing additional time to reach new geographic markets or longer display at retail. Providing an extended shelf life for ready-to-eat convenience foods and advertising foods as "Fresh – Never Frozen" are examples of economic and quality advantages.

(D) Safety Concerns

Use of ROP with some foods can markedly increase safety concerns. Unless potentially hazardous foods (time/temperature control for safety foods) are protected inherently, simply placing them in ROP without regard to microbial growth will increase the risk of foodborne illnesses. ROP processors and regulators must assume that during distribution of foods or while foods are held by retailers or consumers, refrigerated temperatures may not be consistently maintained. In fact, a serious concern is that the increased use of vacuum packaging at retail supermarket deli-type operations may be followed by temperature abuse in the establishment or by the consumer. Consequently, at least one barrier or multiple hurdles resulting in a barrier need to be incorporated into the production process for products packaged using ROP. The incorporation of several sub-inhibitory barriers, none of which could individually inhibit microbial growth but which in combination provide a full barrier to growth, is necessary to ensure food safety.

Some products in ROP contain no preservatives and frequently do not possess any intrinsic inhibitory barriers (such as, pH, a_w, or salt concentrations) that either alone or in combination will inhibit microbial growth. Thus, product safety is not provided by natural or formulated characteristics.

An anaerobic environment, usually created by ROP, provides the potential for growth of several important pathogens. Some of these are psychrotrophic and grow slowly at temperatures near the freezing point of foods. Additionally, the inhibition of the spoilage bacteria is significant because without these competing organisms, tell-tale signs signaling that the product is no longer fit for consumption will not occur.

The use of one form of ROP, vacuum packaging, is not new. Many food products have a long and safe history of being vacuum packaged in ROP. However, the early use of vacuum packaging for smoked fish had disastrous results, causing a long-standing moratorium on certain uses of this technology.

(1) *Refrigerated Holding Requirements for Foods in ROP*

Safe use of ROP technology demands that adequate refrigeration be maintained during the entire shelf-life of potentially hazardous foods (time/temperature control for safety foods) to ensure product safety.

Bacteria, with the exception of those that can form spores, are eliminated by pasteurization. However, pathogens may survive in the final product if pasteurization is inadequate, poor quality raw materials or poor handling practices are used, or post-

processing contamination occurs. Even if foods that are in ROP receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and repackage them. This operation presents the potential for post-processing contamination by pathogens.

If products in ROP are subjected to mild temperature abuse, i.e., 5°-12°C (41°-53°F), at any stage during storage or distribution, foodborne pathogens, including ***Bacillus cereus***, ***Salmonella*** spp., ***Staphylococcus aureus***, and ***Vibrio parahaemolyticus***, can grow slowly. Marginal refrigeration that does not facilitate growth may still allow ***Salmonella*** spp., ***Campylobacter*** spp., and ***Brucella*** spp. to survive for long periods of time.

Published surveys indicate that refrigeration practices at retail need improvement. Some refrigerated products offered in convenience stores were found at or above 7.2°C (45°F) 50% of the time; in several cases temperatures as high as 10°C (50°F) were observed. Delicatessen display cases have been shown to demonstrate poor temperature control. Foods have been observed above 10°C (50°F) and above 12.8°C (55°F) in several instances. Supermarket fresh meat cases appear to have a relatively good record of temperature control. However, even these foods can occasionally be found above 10°C (50°F).

Temperature abuse is common throughout distribution and retail markets. Strict adherence to temperature control and shelf-life must be observed and documented by the establishment using ROP. Information on temperature control should also be provided to the consumer. Currently these controls are not extensively used. Additionally, some commercial equipment is incapable of maintaining foods below 7.2°C (45°F) because of refrigeration capacity, insufficient refrigerating medium, or poor maintenance.

Most warehouses and transport vehicles in U.S. distribution chains maintain temperatures in the 0°-3.3°C (32°-38°F) range. It must be assumed, however, for purposes of assessing risk, that occasionally temperatures of 10°C (50°F) or higher may occur for extended periods. At retail, further temperature abuse must also be assumed. For instance, retail display cases can be as high as 13.3°C (56°F) for short periods and some refrigerated foods are provided no refrigeration for short periods of time. These realities point to the need for establishments to implement controls, such as buyer specifications, over refrigerated distribution systems so that better temperature control can be ensured.

(2) *Control of **Clostridium botulinum** and **Listeria monocytogenes** in Reduced Oxygen Packaged Foods*

There has been an increased interest in vacuum packaging or MAP at retail using conventional refrigeration for holding. Refrigerated foods packaged at retail may be chilled either after they are physically prepared and repackaged, or packaged after a cooking step. In either case but primarily the latter, germination of ***Clostridium***

botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. Sanitary safeguards must be employed to prevent reintroduction of pathogens. Chief among these is ***Listeria monocytogenes***.

Clostridium botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. The organism is an anaerobic spore-forming bacteria that produces a potent neurotoxin. The spores are ubiquitous in nature, relatively heat-resistant, and can survive most minimal heat treatments that destroy vegetative cells. Certain strains of ***C. botulinum*** (type E and non-proteolytic types B and F), which have been primarily associated with fish, are psychrotrophic and can grow and produce toxin at temperatures as low as 3.3^{o}C (38°F). Other strains of ***C. botulinum*** (type A and proteolytic types B and F) can grow and produce toxin at temperatures slightly above 10°C (50°F). If present, ***C. botulinum*** could potentially grow and render toxigenic a food packaged and held in ROP because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable. This is particularly true of psychrotrophic strains of ***C. botulinum*** that do not produce tell-tale proteolytic enzymes. Because botulism is potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.

The potential for botulism toxin to develop also exists when ROP is used after heat treatments such as pasteurization, or sous vide, processing of foods which will not destroy the spores of ***C. botulinum***. Mild heat treatments in combination with ROP may actually select for ***C. botulinum*** by killing off its competitors. If the applied heat treatment does not produce commercial sterility, the food requires refrigeration to prevent spoilage and ensure product safety. For this reason, sous vide products are frequently flash frozen in liquid nitrogen and held in frozen storage until use.

There is a further microbial concern with ROP at retail. Processed products such as meats and cheeses which have undergone an adequate cooking step to kill ***L. monocytogenes*** can be contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place.

Processors of products using ROP should be cautious if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls and monitored refrigeration equipment. If extended shelf life is sought, a temperature of 3.3^{o}C (38°F) or lower must be maintained at all times to prevent outgrowth of ***C. botulinum*** and the subsequent production of toxin. ***Listeria monocytogenes*** can grow at even lower temperatures; consequently, appropriate use-by dates must be established and readily apparent to the consumer. Since refrigeration alone does not guarantee safety from pathogenic microorganisms, additional growth barriers must be provided. Growth barriers are provided by hurdles such as low pH, a_w, or short shelf life, and constant monitoring of the temperature. Any

one hurdle, or a combination of several, may be used with refrigeration to control pathogenic outgrowth.

(3) *Design of Heat Processes for Foods in Reduced Oxygen Packages*

Heat processes for sous vide or cook-chill operations should be designed so that, at a minimum, all vegetative pathogens are destroyed by a pasteurization process. Special labeling of these products is necessary to ensure adequate warning to consumers that these foods must be refrigerated at 5°C (41°F) and consumed by the date required by the Code for that particular product.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), chartered by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), commented on the microbial safety of refrigerated foods containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf life and are ready-to-eat or prepared with little or no additional heat treatment. The NACMCF recommended guidelines for evaluating the ability of thermal processes to inactivate ***L. monocytogenes*** in extended shelf life refrigerated foods. Specifically, it recommended a proposed requirement for demonstrating that an ROP process provides a heat treatment sufficient to achieve a 4 decimal log reduction (4D) of ***L. monocytogenes***.

Other scientific reports recommend more extensive thermal processing. Thermal processes for sous vide practiced in Europe are designed to achieve a 12-13 log reduction (12-13D) of the target organism ***Streptococcus faecalis***. It is reasoned that thermal inactivation of this organism would ensure destruction of all other vegetative pathogens.

Food manufacturers with adequate in-house research and development programs may have the ability to design their own thermal processes. However, small retailers and supermarkets may not be able to perform the microbiological challenge studies necessary to provide the same level of food safety. If a retail establishment wishes to use an ROP process, microbiological studies should be performed by, or in conjunction with, an appropriate process authority or person knowledgeable in food microbiology who is acceptable to the regulatory authority.

Finally, if foods are held long enough, even under proper refrigeration, extended shelf life may be a problem. A study on fresh vegetables inoculated with ***L. monocytogenes***, conducted to determine the effect of CAP on shelf life, found that CAP lengthened the time that all vegetables were considered acceptable, but that populations of ***L. monocytogenes*** increased during that extended storage.

(4) *Consumer Handling Practices and In-Home Refrigerator Temperatures*

Extended shelf life provided by ROP is cause for concern because of the potential for abuse by the consumer. Consumers often cannot, or do not, maintain adequate refrigeration of potentially hazardous foods (time/temperature control for safety foods) at home. Foods in ROP that are taken home might not be eaten until enough time/temperature abuse has occurred to allow any pathogens present to increase to levels which can increase the chance of illness. Under the best of circumstances, home refrigerators can be expected to range between 5° and 10°C (41°-50°F). One study reported that home refrigerator temperatures in 21% of the households surveyed were 10°C (50°F). Another study reported more than 1 of 4 home refrigerators are above 7.2^{o}C (45°F) and almost 1 of 10 are above 10°C (50°F). Thus, refrigeration alone cannot be relied on for ensuring microbiological safety after foods in ROP leave the establishment.

Consumers have come to expect that certain packages of foods would be safe without refrigeration. Low-acid canned foods have been thermally processed, which renders the food shelf-stable. Retort heating ensures the destruction of ***C. botulinum*** spores as well as all other foodborne pathogens. Yet consumers may not understand that most products that are packaged in ROP are not commercially sterile or shelf-stable and must be refrigerated. A clear label statement to keep the product refrigerated must be provided to consumers.

The use of ROP has been extensively studied by regulators and the food industry over the past several years. Recommendations have been adapted from the Association of Food and Drug Officials "Retail Guidelines - Refrigerated Foods in Reduced Oxygen Packages" and New York State Department of Agriculture and Markets "Proposed Reduced Oxygen Packaging Regulations." As provided in the Food Code, some ROP operations may be conducted under provision 3-502.12 Reduced Oxygen Packaging, Criteria. Food that is packaged by an ROP method under these provisions is considered safe while it is under the control of the establishment and, if the labeling instructions are followed, while under the control of the consumer.

(E) Safety Barrier Verification

The safety barriers for all processed foods held in ROP at retail must be verified in writing. This can be accomplished through written certification from the product manufacturer. Independent laboratory analysis using methodology approved by the regulatory authority can also be used to verify incoming product and should be used to verify the barriers in a product that is packaged within the establishment by an ROP method. It should be noted that the Association of Food and Drug Officials (AFDO) guidelines recommend that laboratory analysis be conducted by official methods of the AOAC International (AOAC).

The multiple barrier or hurdle efficacy should be validated by inoculated pack or challenge studies. A product should be tested under abuse temperatures to demonstrate product safety during the food's shelf life.

Any changes in product formulation or processing procedures are cause for notification of the regulatory authority and a required approval of the revised ROP process. A record of all safety barrier verifications should be updated every 12 months. This record must be available to the regulatory authority for review at the time of inspection.

(F) USDA Process Exemption

Meat and poultry products cured at a food processing plant regulated by the U.S. Department of Agriculture using substances specified in 9 CFR 424, Preparation and Processing Operations, are exempt from the safety barrier verification requirements. Other ROP operations may be developed that do not meet the provisions of section 3-502.12 of the Code and that will require a variance and prior approval by the regulatory authority under section 3-502.11.

(G) Recommendations for ROP Without Multiple Barriers

(1) *Employee Training*

If ROP is used, employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines in this Annex and the potential hazards associated with these foods. At the discretion of the regulatory authority, a description of the training and course content provided to the employees must either be available for review or have prior approval by the regulatory authority.

(2) *Refrigeration Requirements*

Foods in ROP that have only one barrier, i.e., refrigeration, to ***C. botulinum***, must be refrigerated to 5°C (41°F) or below and marked with a use-by date within either the manufacturer's labeled use-by date or 14 days after preparation at retail, whichever comes first. Alternatively, foods packaged by ROP may be kept frozen if freezing is used as the declared primary safety barrier. Any extension of shelf life past 14 days will require a further variance that considers lower refrigeration temperatures. Foods that are intended for refrigerated storage beyond 14 days must be maintained at or below 3°C (38°F).

(3) *Labeling - Refrigeration Statements*

All foods in ROP which rely on refrigeration as a barrier to microbial growth must bear the statement "Important - Must be kept refrigerated at 5°C (41°F)" or "Important - Must be kept frozen," in the case of foods which rely on freezing as a primary safety barrier. The statement must appear on the principal display panel in bold type on a contrasting background. Foods held under ROP which have lower refrigeration requirements as a condition of safe shelf life must be monitored for temperature history and must not be offered for retail sale if the temperature and time specified in the variance are exceeded.

(4) *Labeling - "Use-by date"*

Each container of food in ROP must bear a "use-by" date. This date cannot exceed 14 days from retail packaging or repackaging without a further variance granted by the regulatory authority. The date assigned by a repacker cannot extend beyond the manufacturer's recommended "pull date" for the food. The "use-by" date must be listed on the principal display panel in bold type on a contrasting background. Any label must contain a combination of a "sell-by" date and use-by instructions which makes it clear that the product must be consumed within 14 days of retail packaging or repackaging, as an acceptable alternative to a 14 day "use-by" date, i.e., for product packaged on November 1, 1999 - "Sell by November 10, 1999" - use within 4 days of sell-by date. Foods that are frozen before or immediately after packaging and remain frozen until use should bear a "Keep frozen, use within 4 days after thawing" statement.

(H) Foods Which Require a Variance Under Code Section 3-502.11 if Packaged in Reduced Oxygen Atmosphere

(1) Processed fish and smoked fish may not be packed by ROP unless establishments are approved for the activity and inspected by the regulatory authority. Establishments packaging such fish products, and smoking and packing establishments, must be licensed in accordance with applicable law. Caviar may be packed on the premises by ROP if the establishment is approved by the regulatory authority and has an approved scheduled process established by a processing authority acceptable to the regulatory authority.

(2) Soft cheeses such as ricotta, cottage cheese, cheese spreads, and combinations of cheese and other ingredients such as vegetables, meat, or fish at retail must be approved for ROP and inspected by the regulatory authority.

(3) Meat or poultry products which are smoked or cured at retail, except that raw food of animal origin which is cured in a USDA-regulated processing plant, or establishment approved by the regulatory authority to cure these foods may be smoked in accordance with approved time/temperature requirements and packaged in ROP at retail if approved by the regulatory authority.

(I) Hazard Analysis and Critical Control Point (HACCP) Operation

All food establishments packaging food in a reduced oxygen atmosphere must develop a HACCP plan and maintain the plan at the processing site for review by the regulatory authority. For ROP operations the plan must include:

(1) A complete description of the processing, packaging, and storage procedures designated as critical control points, with attendant critical limits, corrective action plans, monitoring and verification schemes, and records required;

(2) A list of equipment and food-contact packaging supplies used, including

compliance standards required by the regulatory authority, i.e., USDA or a recognized third party equipment by the evaluation organization such as NSF International;

(3) A description of the lot identification system acceptable to the regulatory authority;

(4) A description of the employee training program acceptable to the regulatory authority;

(5) A listing and proportion of food-grade gasses used; and

(6) A standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

(J) Precautions Against Contamination at Retail

Only unopened packages of food products obtained from sources that comply with the applicable laws relating to food safety can be used to package at retail in a reduced oxygen atmosphere. If it is necessary to stop packaging for a period in excess of one-half hour, the remainder of that product must be diverted for another use in the retail establishment.

(K) Disposition of Expired Product at Retail

Processed reduced oxygen foods that exceed the "use-by" date or manufacturer's "pull date" cannot be sold in any form and must be disposed of in a proper manner.

(L) Dedicated Area/Restricted Access

All aspects of reduced oxygen packaging shall be conducted in an area specifically designated for this purpose. There shall be an effective separation to prevent cross contamination between raw and cooked foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in food packaged by an ROP method. Some ROP procedures such as sous vide may require a "sanitary zone" or dedicated room with restricted access to prevent contamination.

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3. SMOKING AND CURING

(A) Introduction

Meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices. These

are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat. The process may include dry curing, immersion curing, direct addition, or injection of the curing ingredients. Curing mixtures are typically composed of salt (sodium chloride), sodium nitrite, and seasonings. The preparation of curing mixtures must be carefully controlled. A number of proprietary mixtures which are uniform in composition are available. The maximum residual sodium nitrite in the finished product is limited to 200 ppm by the USDA Food Safety and Inspection Service (FSIS). A sodium nitrite concentration of 120 ppm is usually sufficient for most purposes. Specific requirements for added nitrite may be found in USDA regulations, 9 CFR 424. It is important to use curing methods which achieve uniform distribution of the curing mixture in the meat or poultry product.

(B) Definitions

Cured meat and poultry can be divided into three basic categories: (1) uncomminuted smoked products; (2) sausages; and (3) uncomminuted unsmoked processed meats.

(1) *Uncomminuted smoked products* - include bacon, beef jerky, hams, pork shoulders, turkey breasts, turkey drumsticks.

(2) *Sausages* - include both finely ground and coarse ground products. Finely ground sausages include bologna, frankfurters, luncheon meats and loaves, sandwich spreads, and viennas. Coarse ground sausages include chorizos, kielbasa, pepperoni, salami, and summer sausages.

(3) *Cured sausages* - may be categorized as: (1) raw, cured; (2) cooked, smoked; (3) cooked, unsmoked; and (4) dry, semidry, or fermented.

(4) *Uncomminuted, unsmoked processed products* - include corned beef, pastrami, pig's feet, corned tongues. This category of products may be sold as either raw ready-to-cook or ready-to-eat.

(C) Incorporation of Cure Ingredients

Regardless of preparation method, cure ingredients must be distributed throughout the product. Cure ingredients may be introduced into sausage products during mixing or comminuting. Proper and thorough mixing is necessary whether the cure is added to the formulation in dry or solution form. Muscle cuts may be cured by immersion into a curing (pickle) solution. These methods depend on slow diffusion of the curing agents through the product. Products must be properly refrigerated during immersion curing.

Several methods may be used to shorten curing times. These include hot immersion curing greater than 49°C (>120°F), injection by arterial pumping (e.g., hams), and stitch pumping by a series of hollow needles. If the injection method is used, injection needles must be frequently monitored during processing to ensure that they are not fouled or plugged.

Tumbling or massaging may also be used as an aid to hasten curing. Proper sanitation must be observed to prevent contamination during this operation.

The dry curing method, a similar process, may also be used. In this case, curing ingredients are rubbed over cuts and surfaces of meat held under refrigeration. Precautions must include wearing sanitary gloves when meat is handled. Product temperature maintenance is critical.

(D) Smoking

Smoking is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking. Smoke may be produced by burning wood chips or using an approved liquid smoke preparation. Liquid smoke preparations may also be substituted for smoke by addition directly onto the product during formulation in lieu of using a smokehouse or another type of smoking vessel. As with curing operations, a standard operating procedure must be established to prevent contamination during the smoking process.

(E) Fermentation and Dehydration

Meat may be fermented or dehydrated for preservation. The purpose of fermentation is to reduce the pH to below 4.6 and inhibit bacteria harmful to health as well as bacteria which can cause spoilage. Meat products may also be cured and then dehydrated to prevent germination and growth of bacterial spores. Many fermented and dehydrated meats are made without a cooking step. Sanitary practices in the production of these products are extremely important because ***Staphylococcus aureus*** can be introduced. ***Staphylococcus aureus*** produces an enterotoxin that is heat stable and thus will not be inactivated by subsequent cooking.

Processed pork products require treatment to destroy ***Trichinella spiralis***. At retail, products which contain raw pork and which are not subsequently cooked must be produced from certified trichina-free pork or treated to destroy trichinae. USDA regulations, 9 CFR 318.10(c)(3), establish various requirements for destroying trichina in pork by heating, freezing, drying, or smoking.

Some fermented and dry cured products are processed without cooking. The labeling for these products should include instructions to the consumer to cook thoroughly before consumption.

(F) Recommendations for Safe Curing of Meat and Poultry

(1) *Posting of Acceptable Products*

A list of products approved by the regulatory authority, or by an approved knowledgeable authority on curing acceptable to the regulatory authority, must be posted in the processing area of the establishment.

(2) *Employee Training*

Employees assigned to cure meat or poultry must demonstrate familiarity with these guidelines and the potential hazards associated with curing foods. A description of the training and course content provided to the employees must be available for review by the regulatory authority.

(3) *HACCP*

A HACCP plan is needed for all curing operations. The following recommendations must be met to cure meat and poultry products in the establishment. References are available from local USDA extension offices, public libraries, and college or university food or meat science departments to develop HACCP plans for curing meat and poultry.

(a) *Critical Control Points*

The following are critical control points to be addressed:

(i) Purchase of prepared cure mixes; or

(ii) If cure mixes are blended on the premises instead of acquired pre-mixed, mixing must be carefully controlled by using calibrated weighing devices.

(iii) Cure ingredients must be stored in a dry location. Cure must be discarded if the package is wet or appears to have been wetted.

(b) *Raw Material Handling*

(i) Thawing must be monitored and controlled to ensure thoroughness and to prevent temperature abuse. Improperly thawed meat could cause insufficient cure penetration. Temperature abuse can cause spoilage or growth of pathogens.

(ii) Meat must be fresh. Curing may not be used to salvage meat that has excessive bacterial growth or spoilage.

(c) Formulating, Preparation and Curing

(i) A formulation and preparation procedure must be documented.

(ii) All equipment and utensils must be cleaned and sanitized.

(iii) Pieces must be prepared to uniform sizes to ensure uniform cure penetration. This is extremely critical for dry and immersion curing.

(iv) Calibrated scales must be used to weigh ingredients.

(v) A schedule or recipe must be established for determining the exact amount of curing formulation to be used for a specified weight of meat or meat mixture.

(vi) Methods and procedures must be strictly controlled to ensure uniform cure.

(vii) Mixing of curing formulation with comminuted ingredients must be controlled and monitored.

(viii) All surfaces of meat must be rotated and rubbed at intervals of sufficient frequency to ensure cure penetration when a dry curing method is used.

(ix) Immersion curing requires periodic mixing of the batch to facilitate uniform curing.

(x) The application of salt during dry curing of muscle cuts requires that the temperature of the product be strictly controlled between 1.7°C (35°F) and 7.2°C (45°F). The lower temperature is set to limit microbial growth and the upper temperature is set for the purpose of ensuring cure penetration. Refer to USDA regulations 9 CFR 318.10(c)(3)(iv) for specific details on dry curing.

(xi) Curing solutions must be discarded daily unless they remain with the same batch of product during its entire curing process.

(xii) Injection needles must be inspected for plugging when stitch pumping or artery pumping of muscle cuts is performed.

(xiii) Sanitary casings must be provided for sausage, chub or loaf forming.

(xiv) Casings may not be stripped for reuse in forming additional chubs or sausages from batch to batch.

(xv) Hot curing of bacon bellies, hams, or any other products must be performed at >49°C (120°F) as specified in 9 CFR 318.

(d) *Cooking and/or Smoking*

(i) When smokehouses are initially installed or structurally modified, calibration of product heating characteristics must be ascertained by competent food technologists. Tests should be run with full range of anticipated product loading. Verification of even airflow and moisture should be recorded in operational records of the smokehouse for these various loads.

(ii) Procedures for delivering the appropriate thermal treatment of cooked meats in conformance with the *Food Code* must be developed and used. (Also see 9 CFR 318.17 and 318.23 for USDA requirements for meat products.) A minimum of 73.9°C (165°F) should be used for cured poultry products.

(iii) Cooking equipment that provides even temperature control of the heating medium must be used.

(iv) Products must be adequately separated to prevent overlap in the cooking media whether immersed in hot water, sprayed with hot water, steamed, or oven heated.

(v) Calibrated temperature measuring devices must be used for determining internal product temperatures.

(vi) Temperature measuring device probes must be sanitized to prevent contaminating products when internal temperatures are measured.

(vii) Calibrated temperature measuring devices must be used for measuring temperatures of the heating medium.

(viii) Raw products must be separated from cooked products.

(ix) Time/temperature parameters of the cooking process must be monitored and recorded. In some processes, the heating medium temperature should also monitored.

(e) *Cooling*

(i) Cooling must be done in accordance with recommendations in the *Food Code* or under a variance. The USDA Cooling Guideline, FSIS Directive 7110.3 for special procedures for cured products, provides specific guidance.

(ii) Written cooling procedures must be established.

(iii) Chill water used in water sprays or immersion chilling which is in direct contact with products in casings or products cooked in an impervious package must be properly chlorinated.

(iv) Chill water temperature must be monitored and controlled.

(v) Chill water may not be reused until properly chlorinated. Reclaimed chill water must be discarded daily.

(vi) Product must be placed in a manner that allows chilled water or air to uniformly contact the product for assurance of uniform cooling.

(vii) Internal temperatures must be monitored during cooling by using calibrated temperature measuring devices.

(viii) Adequate cooling medium circulation must be maintained and monitored.

(ix) Temperatures of the cooling medium must be monitored and recorded in accordance with a written procedure.

(x) Handling of product must be minimized during cooling, peeling of casing, and packaging. Sanitary gloves must be used in these procedures.

(f) *Fermentation and Drying*

(i) Temperature and time must be controlled and logs must be maintained that record the monitoring of this process.

(ii) Humidity must be controlled by use of a humidistat. Monitoring of the process must be recorded in a written log.

(iii) Product must be kept separated to allow adequate air circulation during the process.

(iv) Use of an active and pure culture must be ensured to effect a rapid pH drop of the product. Use of commercially produced culture is necessary and the culture must be used according to the manufacturer's instructions.

(v) Determination of the pH of fermented sausages at the end of the fermentation cycle must be recorded.

(vi) Handling of products must be minimized and only done with sanitary gloves or sanitized utensils.

(vii) Dry (unfermented) products may not be hot smoked until the curing and drying procedures are completed.

(viii) Semi-dry fermented sausage must be heated after fermentation to a time/temperature sufficient to control growth of pathogenic and spoilage organisms of concern.

(4) *Dedicated Area/Restricted Access*

All aspects of curing operations must be conducted in an area specifically designated for this purpose. There must be an effective separation to prevent cross contamination between raw and cooked foods or cured and uncured foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in curing foods.

(5) *Equipment Cleaning and Sanitizing*

The procedures for cleaning and sanitization must be accomplished according to parts 4-6 and 4-7 of the Food Code.

(G) References

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Annex

7 *Model Forms, Guides, and Other Aids*

1) **Employee health information and Application form for bare hand contact Procedure**

   a) **Form 1-A** CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE INTERVIEW
   b) **Form 1-B** CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE REPORTING AGREEMENT
   c) **Form 1-C** CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE MEDICAL REFERRAL
   d) **Form 1-D** APPLICATION FOR BARE HAND CONTACT PROCEDURE

2) **Adoption information**

   a) **Form 2-A** ADOPTION BY REFERENCE
   b) **Form 2-B** ADOPTION BY SECTION-BY-SECTION REFERENCE

3) **Inspection information**

   a) **Form 3-A** FOOD ESTABLISHMENT INSPECTION REPORT
   b) **Guide 3-B** CODE REFERENCE SHEET FOR THE FOOD INSPECTION REPORT
   c) **Guide 3-C** INSTRUCTIONS FOR MARKING THE FOOD ESTABLISHMENT INSPECTION REPORT

4) **Summary information**

   a) **Chart 4-A** SUMMARY CHART FOR MINIMUM COOKING FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3
   b) **Chart 4-B** SUMMARY CHART FOR MINIMUM FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3 FOR REHEATING FOODS FOR HOT HOLDING
   c) **Chart 4-C** SUMMARY CHART – READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE, CONTROL FOR SAFETY FOOD) DATE MARKING § 3-501.17(A) – (E) AND DISPOSITION § 3-501.18
   d) **Chart 4-D** FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX
   e) **Summary of Changes**

The documents provided in this Annex are intended to facilitate adoption of the Food Code and the application of its provisions as they relate to conditional employees' and food employees' health and to food establishment inspections.

Forms 1-A through 1-C are designed to assist those responsible for managing employees in order to prevent foodborne disease. The Food Code specifies that the **permit holder is responsible** for requiring conditional employees or food employees to report certain symptoms, diagnoses, and past illnesses, as they relate to diseases transmitted through food by infected workers. The **conditional employee or food employee is personally responsible** for reporting this information to the person in charge.

Form 1-D is a user-aid for a regulatory agency when considering a request to allow bare hand contact with ready-to-eat food.

Forms 2-A and 2-B can be used for the Code adoption process and Form 3-A is provided for use in recording HACCP information and inspectional observations. Guide 3-B is a compressed outline of the Code to use as a tool in locating and citing Code provisions. Guide 3-C is intended to be used during inspections to ensure that observations of the provisions of the Code are accurately recorded on the Food Code Establishment Inspection Report form.

FORM 1-A

Conditional Employee and Food Employee Interview

Preventing Transmission of Diseases through Food by Infected Food Employees or Conditional Employees with Emphasis on illness due to Norovirus, ***Salmonella* Typhi, *Shigella*** spp., Enterohemorrhagic (EHEC) or Shiga toxin-producing ***Escherichia coli*** (STEC), or hepatitis A Virus

The purpose of this interview is to inform conditional employees and food employees to advise the person in charge of past and current conditions described so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

Conditional employee name (print) _____
Food employee name (print) _____
Address _____
Telephone *Daytime:*_____ *Evening:* _____
Date _____

Are you suffering from any of the following symptoms? (Circle one)

		If YES, Date <u>of Onset</u>
Diarrhea?	**YES / NO**	_____
Vomiting?	**YES / NO**	_____
Jaundice?	**YES / NO**	_____
Sore throat with fever?	**YES / NO**	_____

Or

Infected cut or wound that is open and draining, or lesions containing pus on the hand, wrist, an exposed body part, or other body part and the cut, wound, or lesion not properly covered? **YES / NO**
(Examples: *boils and infected wounds, however small)*

<u>In the Past</u>:

Have you ever been diagnosed as being ill with typhoid fever (*Salmonella* Typhi) **YES / NO**
If you have, what was the date of the diagnosis? _____
If within the past 3 months, did you take antibiotics for *S. Typhi?* **YES / NO**
If so, how many days did you take the antibiotics? _____
If you took antibiotics, did you finish the prescription? _____ **YES / NO**

<u>History of Exposure</u>:

1. Have you been suspected of causing or have you been exposed to a confirmed foodborne disease outbreak recently? **YES / NO**
If YES, date of outbreak: _____

a. If YES, what was the cause of the illness and did it meet the following criteria?
Cause: _____

i.	**Norovirus (last exposure within the past 48 hours)**	**Date of illness outbreak** _____
ii.	***E. coli* O157:H7 infection (last exposure within the past 3 days)**	**Date of illness outbreak** _____
iii.	**Hepatitis A virus (last exposure within the past 30 days)**	**Date of illness outbreak** _____
iv.	**Typhoid fever (last exposure within the past 14 days)**	**Date of illness outbreak** _____
v.	**Shigellosis (last exposure within the past 3 days)**	**Date of illness outbreak** _____

FORM 1-A (continued)

b. If YES, did you:
- **i. Consume food implicated in the outbreak?** _____
- **ii. Work in a food establishment that was the source of the outbreak?** _____
- **iii. Consume food at an event that was prepared by person who is ill?** _____

2. Did you attend an event or work in a setting, recently where there was a confirmed disease outbreak? **YES / NO**

If so, what was the cause of the confirmed disease outbreak? _____

If the cause was one of the following five pathogens, did exposure to the pathogen meet the following criteria?

a.	**Norovirus (last exposure within the past 48 hours)**	**YES / NO**
b.	***E. coli* O157:H7 (or other** EHEC/STEC **(last exposure within the past 3 days)**	**YES / NO**
c.	***Shigella* spp. (last exposure within the past 3 days)**	**YES / NO**
d.	***S.* Typhi (last exposure within the past 14 days)**	**YES / NO**
e.	**hepatitis A virus (last exposure within the past 30 days)**	**YES / NO**

Do you live in the same household as a person diagnosed with Norovirus, Shigellosis, typhoid fever, hepatitis A, or illness due to *E. coli* O157:H7 or other EHEC/STEC**?**
YES / NO Date of onset of illness _____

3. Do you have a household member attending or working in a setting where there is a confirmed disease outbreak of Norovirus, typhoid fever, Shigellosis, EHEC/STEC **infection, or hepatitis A?**
YES / NO Date of onset of illness _____

Name, Address, and Telephone Number of your Health Practitioner or doctor:
Name _____
Address _____
Telephone – *Daytime:* _____ *Evening:* _____

Signature of Conditional Employee _____ **Date** _____

Signature of Food Employee _____ **Date** _____

Signature of Permit Holder or Representative _____ **Date** _____

FORM 1-B

Conditional Employee or Food Employee Reporting Agreement

Preventing Transmission of Diseases through Food by Infected Conditional Employees or Food Employees with Emphasis on illness due to Norovirus, ***Salmonella* Typhi, *Shigella*** spp.***,*** Enterohemorrhagic (EHEC) or Shiga toxin-producing ***Escherichia coli*** (STEC), or hepatitis A Virus

The purpose of this agreement is to inform conditional employees or food employees of their responsibility to notify the person in charge when they experience any of the conditions listed so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

I AGREE TO REPORT TO THE PERSON IN CHARGE:

Any Onset of the Following Symptoms, Either While at Work or Outside of Work, Including the Date of Onset:

1. Diarrhea
2. Vomiting
3. Jaundice
4. Sore throat with fever
5. Infected cuts or wounds, or lesions containing pus on the hand, wrist , an exposed body part, or other body part and the cuts, wounds, or lesions are not properly covered (*such as boils and infected wounds, however small)*

Future Medical Diagnosis:

Whenever diagnosed as being ill with Norovirus, typhoid fever (***Salmonella* Typhi**), **shigellosis** (***Shigella*** spp. infection), ***Escherichia* coli O157:H7 or other EHEC/STEC infection, or hepatitis A (hepatitis A virus infection)**

Future Exposure to Foodborne Pathogens:

1. Exposure to or suspicion of causing any confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, *E.* coli O157:H7 or other EHEC/STEC **infection, or hepatitis A.**
2. A household member diagnosed with Norovirus, typhoid fever, shigellosis, illness due to EHEC/STEC, **or hepatitis A.**
3. A household member attending or working in a setting experiencing a confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, *E.* coli O157:H7 or other EHEC/STEC **infection, or hepatitis A.**

I have read (or had explained to me) and understand the requirements concerning my responsibilities under the **Food Code** and this agreement to comply with:

1. Reporting requirements specified above involving symptoms, diagnoses, and exposure specified;
2. Work restrictions or exclusions that are imposed upon me; and
3. Good hygienic practices.

I understand that failure to comply with the terms of this agreement could lead to action by the food establishment or the food regulatory authority that may jeopardize my employment and may involve legal action against me.

Conditional Employee Name (please print) _____

Signature of Conditional Employee _____ **Date** _____

Food Employee Name (please print) _____

Signature of Food Employee _____ **Date** _____

Signature of Permit Holder or Representative _____ **Date** _____

FORM 1-C

Conditional Employee or Food Employee Medical Referral

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on Illness due to Norovirus, Typhoid fever (***Salmonella* Typhi**), **Shigellosis (*Shigella* spp.), *Escherichia coli* O157:H7** or other Enterohemorrhagic (EHEC) or Shiga toxin-producing ***Escherichia* coli** (STEC), and hepatitis A Virus

The **Food Code** specifies, under ***Part 2-2 Employee Health Subpart 2-201 Disease or Medical Condition,*** that Conditional Employees and Food Employees obtain medical clearance from a health practitioner licensed to practice medicine, unless the Food Employees have complied with the provisions specified as an alternative to providing medical documentation, whenever the individual:

1. Is chronically suffering from a symptom such as **diarrhea;** *or*
2. Has a **current illness** involving Norovirus, typhoid fever **(*Salmonella* Typhi)**, shigellosis **(*Shigella* spp.) *E. coli* O157:H7** infection (or other EHEC/STEC), or hepatitis A virus (hepatitis A), *or*
3. Reports ***past illness*** involving typhoid fever **(*S.* Typhi)** within the past three months (while salmonellosis is fairly common in U.S., typhoid fever, caused by infection with ***S.* Typhi**, is rare).

Conditional employee being referred: (Name, please print) _____

Food Employee being referred: (Name, please print) _____

4. Is the employee assigned to a food establishment that serves a population that meets the Food Code definition of a **highly susceptible population** such as a day care center with preschool age children, a hospital kitchen with immunocompromised persons, or an assisted living facility or nursing home with older adults?
YES ☐ **NO** ☐

Reason for Medical Referral: The reason for this referral is checked below:

☐ Is chronically suffering from vomiting or diarrhea; or (specify) _____
☐ Diagnosed or suspected Norovirus, typhoid fever, shigellosis, ***E. coli*** O157:H7 (or other EHEC/STEC) infection, or hepatitis A. (Specify) _____
☐ Reported past illness from typhoid fever within the past 3 months. (Date of illness) _____
☐ Other medical condition of concern per the following description: _____

Health Practitioner's Conclusion: (Circle the appropriate one; refer to reverse side of form)

☐ Food employee is free of **Norovirus** infection, typhoid fever **(*S.* Typhi** infection**), *Shigella*** spp. infection, ***E. coli*** O157:H7 (or other **EHEC/STEC** infection), or **hepatitis A** virus infection, and may work as a food employee without restrictions.
☐ Food employee is an asymptomatic shedder of ***E.*** coli O157:H7 (or other **EHEC/STEC**), ***Shigella*** spp., or Norovirus, and is restricted from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles in food establishments that do not serve highly susceptible populations.
☐ Food employee is not ill but continues as an asymptomatic shedder of ***E. coli*** O157:H7 (or other **EHEC/STEC**), ***Shigella*** spp. and should be excluded from food establishments that serve highly susceptible populations such as those who are preschool age, immunocompromised, or older adults and in a facility that provides preschool custodial care, health care, or assisted living.
☐ Food employee is an asymptomatic shedder of **hepatitis A** virus and should be excluded from working in a food establishment until medically cleared.
☐ Food employee is an asymptomatic shedder of **Norovirus** and should be excluded from working in a food establishment until medically cleared, or for at least 24 hours from the date of the diagnosis.
☐ Food employee is suffering from Norovirus, typhoid fever, shigellosis, ***E. coli*** O157:H7 (or other **EHEC/STEC** infection), or **hepatitis A** and should be excluded from working in a food establishment.

FORM 1-C (continued)

COMMENTS: (In accordance with Title I of the Americans with Disabilities Act (ADA) and to provide only the information necessary to assist the food establishment operator in preventing foodborne disease transmission, please confine comments to explaining your conclusion and estimating when the employee may be reinstated.)

_____

_____

_____

_____

_____

_____

_____

_____

Signature of Health Practitioner _____ **Date** _____

Paraphrased from the FDA Food Code for Health Practitioner's Reference

From Subparagraph 2-201.11(A)(2) <u>Organisms of Concern</u>:

Any foodborne pathogen, with special emphasis on these 5 organisms:

1. **Norovirus** 2. ***S.* Typhi** 3. ***Shigella*** spp. 4. ***E. coli*** O157:H7 (or other EHEC/STEC) 5. **Hepatitis A** virus

From Subparagraph 2-201.11(A)(1) <u>Symptoms</u>:

Have any of the following symptoms:

Diarrhea **Vomiting** **Jaundice** **Sore throat with fever**

From Subparagraph 2-201.11(A)(4)-(5) <u>Conditions of Exposure of Concern</u>:

(1) Suspected of causing a foodborne outbreak or being exposed to an outbreak caused by 1 of the 5 organisms above, at an event such as a family meal, church supper, or festival because the person:
Prepared or consumed an implicated food; or
Consumed food prepared by a person who is infected or ill with the organism that caused the outbreak or who is suspected of being a carrier;

(2) Lives with, and has knowledge about, a person who is diagnosed with illness caused by 1 of the 5 organisms; or

(3) Lives with, and has knowledge about, a person who works where there is an outbreak caused by 1 of the 5 organisms.

From Subparagraph 2-201.12 <u>Exclusion and Restriction</u>:

Decisions to exclude or restrict a food employee are made considering the available evidence about the person's role in actual or potential foodborne illness transmission. Evidence includes:

Symptoms **Diagnosis** **Past illnesses** **Stool/blood tests**

In facilities serving highly susceptible populations such as day care centers and health care facilities, a person for whom there is evidence of foodborne illness is almost always <u>excluded</u> from the food establishment.

In other establishments such as restaurants and retail food stored, that offer food to typically healthy consumers, a person might only be <u>restricted</u> from certain duties, based on the evidence of foodborne illness.

Exclusion from any food establishment is required when the person is:

- Exhibiting or reporting diarrhea or vomiting;
- Diagnosed with illness caused by *S.* Typhi; or
- Jaundiced within the last 7 days.

For ***Shigella*** spp. or ***Escherichia coli*** O157:H7 or other EHEC/STEC infections, the person's stools must be negative for 2 consecutive cultures taken no earlier than 48 hours after antibiotics are discontinued, and at least 24 hours apart or the infected individual must have resolution of symptoms for more than 7 days or at least 7 days have passed since the employee was diagnosed.

FORM 1-D

Application for Bare Hand Contact Procedure
(As specified in Food Code ¶ 3-301.11(D))

Please type or print legibly using black or blue ink

1. **Establishment Name:** _____

2. **Establishment Address:** _____

3. **Responsible Person:** _____ **Phone:** _____
Legal Representative Business

4. **List Procedure and Specific Ready-To-Eat-Foods** to be considered for use of bare hand contact with ready-to-eat foods:
_____
_____
_____

5. **Handwashing Facilities**:

(a) There is a handwashing sink located immediately adjacent to the posted bare hand contact procedure and the hand sink is maintained in accordance with provisions of the Code. (§ 5-205.11, § 6-301.11, § 6-301.12, § 6-301.14) ☐ YES ☐ NO (Include diagram, photo or other information)

(b) All toilet rooms have one or more handwashing sinks in, or immediately adjacent to them, and the sinks are equipped and maintained in accordance with provisions of the Code. (§ 5-205.11, § 6-301.11, § 6-301.12, § 6-301.14) ☐ YES ☐ NO

6**. Employee Health Policy:** The written **e**mployee health policy must be attached to this form along with documentation that food employees and conditional employees acknowledge their responsibilities. (§ 2-201.11, § 2-201.12, § 2-201.13)

7**. Employee Training**: Provide documentation that food employees have received training in:

- The risks of contacting the specific ready-to-eat foods with bare hands
- Personal health and activities as they relate to diseases that are transmissible through food.
- Proper handwashing procedures to include how, when, where to wash, & fingernail maintenance. (§ 2-301.12, § 2-301.14, § 2-301.15, § 2-302.11)
- Prohibition of jewelry. (§ 2-303.11)
- Good hygienic practices. (§ 2-401.11, § 2-401.12)

8. Documentation of Handwashing Practices: Provide documentation that food employees are following proper handwashing procedures prior to food preparation and other procedures as necessary to prevent cross-contamination during all hours of operation when the specific ready-to-eat foods are prepared or touched with bare hands.

9. Documentation of Additional Control Measures: Provide documentation to demonstrate that food employees are utilizing two or more of the following control measures when contacting ready-to-eat foods with bare hands:

- Vaccination against hepatitis A for food employees including initial booster shots or documented medical evidence that a food employee has had a previous illness from hepatitis A virus;
- Double handwashing;
- Use of nailbrushes;
- Use of hand antiseptic after handwashing;
- Incentive programs such as paid leave encouraging food employees not to work when they are ill; or
- Other control measures approved by the regulatory authority.

Statement of Compliance:

I certify all of the following: All food employees are individually trained in the risks of contacting ready-to-eat foods with bare hands, personal health and activities as they relate to diseases that are transmissible through food, proper handwashing procedures, prohibition of jewelry, and good hygienic practices. A record of this training is kept on site. I understand that bare hand contact with ready-to-eat food is prohibited except for those items listed in section four (4) above. A handwashing sink is located immediately adjacent to the posted bare hand contact procedure. All handwashing sinks are maintained with hot water, soap, and drying devices. I understand that documentation is needed for handwashing practices and additional control measures. I understand that records to document handwashing are kept current and kept on site.

SIGNATURE:_____ DATE _____
(Signature of legal representative of the facility listed above)

Regulatory Authority (RA) Use Only:
Permit Number: _____
File Review Conducted on History of Handwashing Compliance: ☐ Yes ☐ No
Site Visit Conducted ☐ Yes ☐ No Comments: _____
☐ Approved: Effective Date: _____ RA name _____
☐ Not Approved: Reason for Denial:
_____

FORM 2-A	Adoption by Reference

This "short form" may be used by governmental bodies adopting the Food Code where authorized by law. Use of the adoption by reference form may substantially reduce the cost of publishing and printing.

The description of the Food Code, below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(statute/regulation/ordinance) Number

ADOPTING THE 2005 EDITION OF THE "FOOD CODE" REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD), FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING, AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The **(governing body)** of the **(jurisdiction)** does ordain as follows:

SECTION 1. ADOPTION OF FOOD CODE

That a certain document, three copies of which are on file in the office of the **(jurisdiction's keeper of records)** of the **(type of jurisdiction)** of **(name of jurisdiction)** being marked and designated as the *Food Code, 2005 Recommendations of the United States Public Health Service/Food and Drug Administration* as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration be, and is hereby adopted as, the Food Code of **(type of jurisdiction)** of **(name of jurisdiction)** in the State of **(state name)**; for regulating the design, construction, management, and operation of food establishments, and providing for plans submission and approval and the issuance of permits and collection of fees therefore.

SECTION 2. INSERTIONS AND CHANGES

That the following provisions are hereby revised as follows:

Paragraph 8-811.10(B)(1) and (2) Insert **(Dollar Amount)**
Paragraph 8-813.10(B) Insert **(Dollar Amounts)**
Subparagraph 8-811.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That **(statute/regulation/ordinance)** number **(present code number)** of the **(jurisdiction)** titled, **(complete title of the food code[s] in effect at the present time so they will be repealed by definite mention)** and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the **(jurisdiction's keeper of records)** shall certify the adoption of this **(statute/regulation/ordinance** and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect **(time period)** from and after the date of its final passage and approval.

PASSED AND APPROVED BY **(name of adopting authority)** on this **(day)** of **(month, year)**.

BY:

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

A. For Wholesale Food Violations:

Criminal fines and sentence for violations of up to **$1,000** and up to **one** year imprisonment if there is shown an intent to defraud or mislead, and

Civil penalties of up to **$1,000** per day for certain violations.

B. For Retail Food Violations:

Criminal fines and sentence for violations of not less than twenty-five dollars ($25) or more than one thousand dollars ($1000) for each offense, or by imprisonment in the county jail for a term not exceeding six months, or by both such fine and imprisonment.

Maryland law provides:

Criminal fines and sentence for certain misdemeanors of up to **$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **$25,000** and **three** years imprisonment; and

Civil penalties of up to **$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **$1,250** through **$10,000.** Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Though rarely used with retail food establishments, **Federal** law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **$250,000** for individuals and **$500,000** for corporations.

FORM 2-B	Adoption by Section-by-Section Reference

This "long form" may be used by governmental bodies adopting the Food Code section-by-section.

The description of the "Food Code," below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(statute/regulation/ordinance) Number

ADOPTING A CODE REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD), FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The **_(governing body)_** of the **_(jurisdiction)_** does ordain as follows:

(REPRINT THE *FOOD CODE, ___(date)___ RECOMMENDATIONS OF THE UNITED STATES PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION,* SECTION-BY-SECTION)

SECTION 2. INSERTIONS AND CHANGES

That the following provisions may need to be completed as follows:

Paragraph 8-811.10(B)(1) and (2) Insert (**Dollar Amount**)
Paragraph 8-813.10(B) Insert **(Dollar Amounts)**
Subparagraph 8-811.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That **_(statute/regulation/ordinance)_** number **_(present code number)_** of the **_(jurisdiction)_** titled, **(complete title of the food code[s] in effect at the present time so they will be repealed by definite mention)** and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the **(jurisdiction's keeper of records)** shall certify the adoption of this **(statute/regulation/ordinance)** and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect **(time period)** from and after the date of its final passage and approval.

PASSED AND APPROVED BY **(name of adopting authority)** on this **(day)** of **(month, year)**.

BY:

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

A. For Wholesale Food Violations:

Criminal fines and sentence for violations of up to **$1,000** and up to **one** year imprisonment if there is shown an intent to defraud or mislead, and

Civil penalties of up to **$1,000** per day for certain violations.

B. For Retail Food Violations:

Criminal fines and sentence for violations of not less than twenty-five dollars ($25) or more than one thousand dollars ($1000) for each offense, or by imprisonment in the county jail for a term not exceeding six months, or by both such fine and imprisonment.

Maryland law provides:

Criminal fines and sentence for certain misdemeanors of up to **$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **$25,000** and **three** years imprisonment; and

Civil penalties of up to **$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **$1,250** through **$10,000.** Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Though rarely used with retail food establishments, **Federal** law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **$250,000** for individuals and **$500,000** for corporations.

FORM 3-A	Food Establishment Inspection Report

The food establishment inspection report is the official regulatory authority document regarding compliance of the establishment with agency requirements. The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection. The Food Establishment Inspection Report form is provided as a model for use during routine, follow-up, and investigative inspections.

Refer to Annex 5 for further information.

FORM 3-A

Food Establishment Inspection Report

Page _____ of _____

As Governed by State Code Section	No. of Risk Factor/Intervention Violations		Date _____
	No. of Repeat Risk Factor/Intervention Violations		Time In _____
	Score *(optional)*		Time Out _____

Establishment	Address	City/State	Zip Code	Telephone

License/Permit #	Permit Holder	Purpose of Inspection	Est. Type	Risk Category

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

Circle designated compliance status (IN, OUT, N/O, N/A) for each numbered item — Mark "X" in appropriate box for COS and R

IN=in compliance **OUT**=not in compliance **N/O**=not observed **N/A**=not applicable **COS**=corrected on-site during inspection **R**=repeat violation

	Compliance Status		COS	R
	Supervision			
1	IN OUT	Person in charge present, demonstrates knowledge, and performs duties		
	Employee Health			
2	IN OUT	Management awareness; policy present		
3	IN OUT	Proper use of reporting, restriction & exclusion		
	Good Hygienic Practices			
4	IN OUT N/O	Proper eating, tasting, drinking, or tobacco use		
5	IN OUT N/O	No discharge from eyes, nose, and mouth		
	Preventing Contamination by Hands			
6	IN OUT N/O	Hands clean and properly washed		
7	IN OUT N/A N/O	No bare hand contact with ready-to-eat foods or approved alternate method properly followed		
8	IN OUT	Adequate handwashing facilities supplied & accessible		
	Approved Source			
9	IN OUT	Food obtained from approved source		
10	IN OUT N/A N/O	Food received at proper temperature		
11	IN OUT	Food in good condition, safe, and unadulterated		
12	IN OUT N/A N/O	Required records available: shellstock tags, parasite destruction		
	Protection from Contamination			
13	IN OUT N/A	Food separated and protected		
14	IN OUT N/A	Food-contact surfaces: cleaned & sanitized		
15	IN OUT	Proper disposition of returned, previously served, reconditioned, and unsafe food		

	Compliance Status		COS	R
	Potentially Hazardous Food (TCS food)			
16	IN OUT N/A N/O	Proper cooking time and temperatures		
17	IN OUT N/A N/O	Proper reheating procedures for hot holding		
18	IN OUT N/A N/O	Proper cooling time and temperatures		
19	IN OUT N/A N/O	Proper hot holding temperatures		
20	IN OUT N/A	Proper cold holding temperatures		
21	IN OUT N/A N/O	Proper date marking and disposition		
22	IN OUT N/A N/O	Time as a public health control: procedures & records		
	Consumer Advisory			
23	IN OUT N/A	Consumer advisory provided for raw or undercooked foods		
	Highly Susceptible Populations			
24	IN OUT N/A	Pasteurized foods used; prohibited foods not offered		
	Chemical			
25	IN OUT N/A	Food additives: approved and properly used		
26	IN OUT	Toxic substances properly identified, stored, used		
	Conformance with Approved Procedures			
27	IN OUT N/A	Compliance with variance, specialized process, and HACCP plan		

Risk factors are food preparation practices and employees behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors in foodborne illness outbreaks. **Public health interventions** are control measures to prevent foodborne illness or injury.

GOOD RETAIL PRACTICES

Good Retail Practices are preventative measures to control the introduction of pathogens, chemicals, and physical objects into foods.

Mark "X" in box if numbered item is **not** in compliance — Mark "X" in appropriate box for COS and/or R — **COS**=corrected on-site during inspection **R**=repeat violation

			COS	R
		Safe Food and Water		
28		Pasteurized eggs used where required		
29		Water and ice from approved source		
30		Variance obtained for specialized processing methods		
		Food Temperature Control		
31		Proper cooling methods used; adequate equipment for temperature control		
32		Plant food properly cooked for hot holding		
33		Approved thawing methods used		
34		Thermometers provided and accurate		
		Food Identification		
35		Food properly labeled; original container		
		Prevention of Food Contamination		
36		Insects, rodents, and animals not present		
37		Contamination prevented during food preparation, storage & display		
38		Personal cleanliness		
39		Wiping cloths: properly used and stored		
40		Washing fruits and vegetables		

			COS	R
		Proper Use of Utensils		
41		In-use utensils: properly stored		
42		Utensils, equipment and linens: properly stored, dried, handled		
43		Single-use/single-service articles: properly stored, used		
44		Gloves used properly		
		Utensils, Equipment and Vending		
45		Food and nonfood-contact surfaces cleanable, properly designed, constructed, and used		
46		Warewashing facilities: installed, maintained, used; test strips		
47		Nonfood-contact surfaces clean		
		Physical Facilities		
48		Hot and cold water available; adequate pressure		
49		Plumbing installed; proper backflow devices		
50		Sewage and waste water properly disposed		
51		Toilet facilities: properly constructed, supplied, cleaned		
52		Garbage/refuse properly disposed; facilities maintained		
53		Physical facilities installed, maintained, and clean		
54		Adequate ventilation and lighting; designated areas use		

Person in Charge (Signature) **Date:**

Inspector (Signature) **Follow-up:** **YES** **NO** **(Circle one)** **Follow-up Date:**

GUIDE 3-B

Food Code References for Risk Factors/Interventions and Good Retail Practices Specified on the Food Establishment Inspection Report Form

The major headings from the Food Establishment Inspection Report form have been extracted and condensed in Guide 3-B to key word phrases to assist the person conducting inspections in locating the Food Code citation that corresponds to a given violation and recording inspectional observations.

Guide 3-B

Food Code References for Risk Factors/Interventions and Good Retail Practices Specified on the Food Establishment Inspection Report

Part 1. Risk Factors and Interventions

Supervision

1.	2-101.11	Assignment *
	2-102.11	Demonstration *
	2-103.11	Person-In-Charge (PIC) Duties

Employee Health

2.	2-201.11	Responsibility of PIC, Conditional & Food Employees *
3.	2-201.12	Exclusions & Restrictions *
	2-201.13	Removal of Exclusions & Restrictions

Good Hygienic Practices

4.	2-401.11	Eating, Drinking, or Using Tobacco *
	3-301.12	Preventing Contamination when Tasting *
5.	2-401.12	Discharges from the Eyes, Nose, and Mouth *

Control of Hands as a Vehicle of Contamination

6.	2-301.11	Clean condition *
	2-301.12	Cleaning Procedure *
	2-301.14	When to Wash *
	2-301.15	Where to Wash
	2-301.16	Hand Antiseptics
7.	3-301.11	Preventing Contamination from Hands *
8.	5-203.11	Handwashing Sinks (nos./capacities) *
	5-204.11	Handwashing Sinks (loc./placement) *
	5-205.11	Using a Handwashing Sink
	6-301.11	Handwashing Cleanser, Availability
	6-301.12	Hand Drying Provision
	6-301.13	Handwashing Aids & Devices, Use Restrictions
	6-301.14	Handwashing Signage
	6-501.18	Maintaining & Using Handwashing Sinks

Approved Source

9.	3-201.11	Compliance with Food Law *
	3-201.12	Food in Hermetically Sealed Container *
	3-201.13	Fluid Milk & Milk Products *
	3-201.14	Fish *
	3-201.15	Molluscan Shellfish *
	3-201.16	Wild Mushrooms *
	3-301.17	Game Animals *
	3-202.13	Eggs *
	3-202.14	Eggs & Milk Products, Pasteurized *
	3-202.110	Prepackaged Juice-Treated
	5-101.13	Bottled Drinking Water *
10.	3-202.11	Temperature *
11.	3-101.11	Safe, Unadulterated & Honestly Presented *
	3-202.15	Package Integrity *
12.	3-202.18	Shellstock Identification *
	3-203.12	Shellstock, Maintaining Identification *
	3-402.11	Parasite Destruction *
	3-402.12	Records, Creation, & Retention

Protection from Contamination

13.	3-302.11	Separation, Packaging, & Segregation *
	3-304.11	Food Contact with Equipment & Utensils *
	3-306.13(A)	Consumer Self Service Operations *

Protection from Contamination

14.	4-501.111	Manual Warewashing, Hot Water Sanitization *
	4-501.112	Mechanical Warewashing, Hot Water Sanitization
	4-501.113	Mechanical Warewashing, Sanitization Pressure
	4-501.114	Chemical Sanitization-Temp, pH, Concentration, Hardness *
	4-501.115	Manual Warewashing Eqip. Detergent Sanitizers
	4-601.11(A)	Food Contact Surface Clean to Sight & Touch *
	4-602.11	Food Contact Surface-Cleaning Frequency *
	4-602.12	Cooking & Baking Equipment
	4-702.11	Before Use After Cleaning *
	4-703.11	Hot Water and Chemical *
15.	3-306.14	Returned Food & Re-service of Food *
	3-801.11	Discarding/Reconditioning Adulterated Food *

Potentially Hazardous Food (Time/Temperature Control for Safety Food)

16.	3-401.11	Cooking Raw Animal Foods *
	3-401.12	Microwave Cooking *
17.	3-403.11	Reheating for Hot Holding *
18.	3-501.14	Cooling *
19.	3-501.16	Hot Holding *
20.	3-501.16	Cold Holding *
21.	3-501.17	RTE PHF (TCS Food), Date Marking[1]
	3-501.18	RTE PHF (TCS Food), Disposition *
22.	3-501.19	Time as a Public Health Control *

Consumer Advisory

23.	3-603.11	Consumer Advisory for Raw/ Undercooked Food*

Highly Susceptible Populations

24.	3-801.11	Pasteurized Foods & Prohibited Food *

Chemical

25.	3-202.12	Approved Additives *
	3-302.14	Protection from Unapproved Additives *
26.	7-101.11	Identifying Information*
	7-102.11	Common Name, Working Containers *
	7-201.11	Separation, Storage *
	7.202.11	Restriction *
	7-202.12	Conditions of use *
	7-203.11	Poisonous or Toxic Material Containers *
	7-204.11	Sanitizers, Criteria *
	7-204.12	Chemicals for Washing Fruits & Vegetables *
	7-204.13	Boiler Water Additives *
	7-204.14	Drying Agents *
	7-205.11	Incidental Food Contact, Criteria*
	7-206.11	Restricted Use Pesticides *
	7-206.12	Rodent Bait Stations *
	7-206.13	Tracking Powders, Pest Control & Monitoring*
	7-207.11	Restriction & Storage; Medicines *
	7-207.12	Refrigerated Medicines, Storage *
	7-208.11	Storage-First Aid Supplies *
	7-209.11	Storage-Personal Care Items
	7-301.11	Separation-for Retail Sale*

Conformance with Approved Procedures

27.	3-502.11	Variance Requirement *
	3-502.12	Reduced Oxygen Packaging, Criteria *
	3-404.11	Treating Juice
	8-103.12	Compliance with Variance and HACCP Plan *

Internal Cooking Temperature Specifications

145°F for 15 seconds	Raw eggs cooked for immediate service Fish, except as listed below	Meat, except as listed in the next 2 rows Commercially raised game animals, rabbits
155°F for 15 seconds:	Ratites (Ostrich, Rhea and Emu) Injected meats	Comminuted meat, fish, or commercially raised game animals
165°F for 15 seconds:	Wild game animals Poultry Raw eggs not for immediate service	Stuffed fish, meat, pork, pasta, ratites & poultry Stuffing containing fish, meat, ratites & poultry
Whole Meat Roasts	Refer to cooking charts in the *Food Code* ¶ 3-401.11(B)	

Asterisk (*) items are listed as critical items in the Food Code. September 2005

[1]RTE PHF (TCS food) means ready-to-eat potentially hazardous food (time/temperature control for safety food).

Annex 7, Guide 3-B (continued)
Part 2. Good Retail Practices

Safe Food & Water

28. Pasteurized eggs used where required
    - 3-302.13 Pasteurized eggs substituted for raw eggs in uncooked, egg-based recipes

29. Water & ice from approved source
    - 3-202.16 Ice used as a food/cooling medium made from potable water*
    - 5-101.11 Drinking water from an approved source*
    - 5-102.11 Standards of quality for public drinking water met*
    - 5-102.12 Nondrinking water used only for non-food purposes*
    - 5-102.13 Sampling report for non-public water tested as required
    - 5-102.14 Recent report available
    - 5-104.12 Alternative water supply delivered through approved means

30. Variance obtained for specialized processing methods
    - 8-103.11 Documentation & justification for variance on file with regulatory authority

Food Temperature Control

31. Proper cooling methods used; adequate equipment for temperature control
    - 3-501.11 Frozen food stored frozen
    - 3-501.15 Proper cooling methods used for PHF (TCS Foods)
    - 4-301.11 Cooling, heating, & holding equipment sufficient in number, capacity & in

32. Plant food properly cooked for hot holding
    - 3-401.13 Plant food (vegetables/fruit) cooked to 135°F or above for hot holding

33. Approved thawing methods used
    - 3-501.12 Frozen PHF (TCS Foods) slacked properly;
    - 3-501.13 Proper thawing methods used for PHF (TCS Foods)

34. Thermometers provided & accurate
    - 4-203.11 Food thermometers accurate in the intended range of use
    - 4-203.12 Ambient air & water thermometers accurate in the intended range of use
    - 4-204.112 Thermometers located in refrigerators/hot holding units to measure ambient air in warmest/coolest areas of units
    - 4-302.12 Food thermometers provided & accessible; Appropriate thermometer for measuring thin foods provided

Food Identification

35. Food properly labeled; original container
    - 3-202.17 Proper identification & sell-by date on packages of shucked shellfish
    - 3-203.11 Molluscan shellfish stored in original container until sold/prepped
    - 3-302.12 Food storage containers identified with common name of food
    - 3-305.13 Vended PHF (TCS Foods) dispensed in original container
    - 3-601.11 Standards of identity met for packaged foods
    - 3-601.12 Foods honestly presented, do not misinform consumers
    - 3-602.11 Food packaged in the food establishment labeled as specified in law
    - 3-602.12 Consumer warnings as required by law on labels

Prevention of Food Contamination

36. Insects, rodents, & animals not present
    - 2-403.11 Food employees not handling animals*
    - 6-202.13 Insect control devices properly designed & installed
    - 6-202.15 Openings to outside protected against entry of pest;
    - 6-202.16 Protective barriers provided for exterior
    - 6-501.111 Effective pest control measures in place*
    - 6-501.112 Dead or trapped pest removed traps at adequate frequency
    - 6-501.115 Prohibited live animals not on premises*

37. Contamination prevented during food preparation, storage, & display
    - 3-202.19 Shellstock free of mud, dead shellfish & shellfish with broken shells
    - 3-303.11 Ice as a coolant not used as food
    - 3-303.12 Packaged food not stored in direct contact with water/ice during display
    - 3-304.13 Linens & napkins not used in contact with food unless as a liner & replaced each time
    - 3-305.11 Food stored 6" off the floor in clean, dry location
    - 3-305.12 Food not stored in prohibited areas
    - 3-305.14 Unpackaged food protected from environmental contamination during preparation
    - 3-306.11 Food on display protected by food guards/packaging
    - 3-306.12 Condiments protected in dispensers/individual packets
    - 3-306.13(B) Consumer self-service operations provided with suitable utensils[N]
    - 3-306.13(C) Consumer self-service operations monitored[N]
    - 3-307.11 Food not contaminated by any other source
    - 6-404.11 Distressed food segregated & properly located away from food, utensils, or equipment

38. Personal cleanliness
    - 2-302.11 Fingernails neat & trimmed; Gloves worn over polished nails & artificial nails
    - 2-303.11 No jewelry worn during food handling except plain wedding band
    - 2-304.11 Outer clothing clean
    - 2-402.11 Hair restraints & clothes that cover body hair worn by food employees

39. Wiping cloths properly used & stored
    - 3-304.14 Cloths for spills used for only one purpose; wet wiping cloths stored in sanitizer; wet & dry cloths stored clean
    - 4-101.16 Sponges not used on sanitized food contact surfaces
    - 4-901.12 Wiping cloths laundered in establishment, air dried if no clothes dryer present

40. Washing fruits & vegetables
    - 3-302.15 Raw fruits & vegetables thoroughly washed before use

Proper Use of Utensils

41. In-use utensils properly stored
    - 3-304.12 In-use utensils properly stored between uses

Annex 7, Guide 3-B (continued)
Part 2. Good Retail Practices

42. Utensils, equipment, & linens properly stored, dried, & handled
    - 4-801.11 Clean linens free of food residues & soil
    - 4-802.11 Based on use, linens laundered at adequate frequency
    - 4-803.11 Soiled linens properly stored
    - 4-803.12 Linens mechanically washed unless only wiping cloths are laundered on site
    - 4-901.11 Equipment/utensils air dried after washing, rinsing, & sanitizing
    - 4-903.11 Equipment/utensils/linens stored 6" off floor in clean, dry location
    - 4-903.12 Equipment/utensils/linens not stored in prohibited areas
    - 4-904.11 Kitchenware/tableware handled to protect food-/lip-contact surfaces
    - 4-904.12 Soiled tableware removed from eating areas
    - 4-904.13 Preset tableware wrapped/covered; unused settings removed from table
43. Single-service & single-use articles properly stored & used
    - 4-502.12 Single-service items available if no warewashing facilities present *
    - 4-502.13 Single-service/-use items not reused
    - 4-502.14 Molluscan/crustacean shells used only once as serving container
    - 4-903.11 Single-service/use items stored 6" off the floor in a clean, dry location
    - 4-903.12 Single-service/-use items not stored in specified places
    - 4-904.11 Single-service/-use items properly handled to protect food-/lip-contact surfaces
44. Gloves used properly
    - 3-304.15 Single-use gloves only used for one task; Appropriate gloves used for task being performed

Utensils, Equipment, and Vending

45. Food- & nonfood-contact surfaces cleanable, properly designed, constructed, & used
    - 3-304.16 Clean tableware for seconds provided to
    - 3-304.17 Returnables not refilled at food establishment
    - 4-101.11 Utensils/food-contact surfaces made of safe, durable, smooth materials*
    - 4-101.12 Cast iron not used for food-contact surfaces, unless it meets exemptions
    - 4-101.13 Lead, pewter, & solder exceeding limits for lead, not used for food-contact surfaces
    - 4-101.14 Copper not used for food-contact surfaces*
    - 4-101.15 Galvanized metal not used for food-contact surfaces*
    - 4-101.17 Wood used for food-contact surfaces constructed of hard wood
    - 4-101.18 Nonscratching utensil used with nonstick coatings
    - 4-101.19 Nonfood-contact surfaces made of durable, smooth materials
    - 4-102.11 Single-service/-use items made of safe & clean materials*
    - 4-201.11 Equipment and Utensil Durability and Strength
    - 4-201.12 Food Temperature Measuring Devices*
    - 4-202.11-.12 Food-contact surfaces smooth & easily accessible for cleaning;* CIP equipment easily cleanable
    - 4-202.13 "V" threads only used for hot oil equipment
    - 4-202.14 Hot Oil Filtering Equipment

45. Food- & nonfood-contact surfaces cleanable, properly designed, constructed, & used (continued)
    - 4-202.15 Cutting parts of can opener readily removable for cleaning/replacement
    - 4-202.16 Nonfood-contact surfaces
    - 4-202.17 Kick plates removable for cleaning
    - 4-204.12 Covers/lids for equipment openings overlap the opening & sloped to drain
    - 4-204.15 Equipment requiring lubricants designed so that lubricants do not drip into food
    - 4-204.16 Beverage tubing not in contact with stored ice
    - 4-204.17 Liquid waste drains do not pass through ice storage bins
    - 4-204.18 Condenser unit separated from food storage space
    - 4-204.19 Can openers on vending machines protected from contamination
    - 4-204.110 Molluscan shellfish tanks marked for display only or operated under a HACCP plan
    - 4-204.13 Dispensing equipment designed to protect unpackaged product
    - 4-204.14 Vending machine equipped with self-closing door or cover
    - 4-204.111 Vending machines for PHF (TCS Foods) equipped with auto shutoff *
    - 4-204.121 Vending machines for liquids equipped with drains, internal waste receptacle, & automatic shutoff
    - 4-204.122 Case lot handling equipment movable by hand, hand trucks, or forklifts
    - 4-204.123 Vending machine doors/openings tight-fitting
    - 4-302.11 Dispensing utensils provided for each container of consumer self-service unit
    - 4-401.11 Equipment, washers/dryers, linen, & storage cabinets properly located
    - 4-402.11 Fixed or counter-mounted equipment properly spaced or sealed
    - 4-402.12 Fixed or counter-mounted equipment properly elevated or sealed
    - 4-501.11 Equipment in good repair & adjusted per manufacturer's specs
    - 4-501.12 Scratched cutting boards resurfaced or discarded
    - 4-501.13 Microwave ovens meeting safety standards specified in CFR
    - 4-502.11 Utensils maintained in good repair; thermometers calibrated per manufacturer's specs
    - 4-603.11 Dry cleaning methods used with non PHF (non TCS Foods) only
    - 4-603.17 Cleaning/refilling of returnables only for non PHF (non TCS Foods) or conducted at a regulated facility*
    - 4-902.11 Food-contact surfaces not contaminated during lubricating of equipment
    - 4-902.12 Food-contact surfaces not contaminated during reassembly of equipment

Annex 7, Guide 3-B (continued)
Part 2. Good Retail Practices

46. Warewashing facilities installed, maintained, & used; test strips
    - 4-203.13 Hot water pressure devices accurate to ± 2 pounds per square inch
    - 4-204.113 - .116 Data plate/baffles/thermometers on warewashing machines; heater/basket present for manual heat sanitization
    - 4-204.117 Warewashing machine equipped with means to verify dispensing of detergents & sanitizers
    - 4-204.118 - .120 Pressure device on machines with hot water sanitizing rinse; sinks, drainboards, compartments self-draining
    - 4-301.12 3 compartment sink large enough to immerse largest utensil
    - 4-301.13 Adequate drainboards provided
    - 4-302.13 -.14 Thermometer for testing sanitizing water temperature &/or test kit for measuring sanitizer concentration provided
    - 4-501.14 Warewashing equipment cleaned before use & every 24 hours
    - 4-501.15 Warewashing machine operated per data plate
    - 4-501.16 Warewashing sinks cleaned & sanitized before & after use for washing food or wiping cloths
    - 4-501.17 Cleaning agents used for washing utensils in accordance with manufacturer's instructions
    - 4-501.18 Wash, rinse & sanitize solutions maintained clean
    - 4-501.19 Manual wash temperature maintained ≥110°F
    - 4-501.110 Wash temperature requirement met for warewashing machine based on machine type
    - 4-501.116 Concentration of sanitizer solution determined by use of test kit
    - 4-603.12 Equipment/utensils precleaned before washing
    - 4-603.13 Soiled items properly loaded into warewashing machines
    - 4-603.14 Equipment food-contact surfaces & utensils effectively washed
    - 4-603.15 Fixed equipment & equipment too large for warewashing sink/machine washed by approved alternative method
    - 4-603.16 Utensils & equipment rinsed after washing
47. Nonfood-contact surfaces clean
    - 4-601.11(B) - (C) Equipment maintained free of encrusted grease/soil deposits
    - 4-602.13 Nonfood-contact surfaces cleaned at frequency to prevent buildup of residue

Physical Facilities

48. Hot & cold water available; adequate pressure
    - 5-103.11 - .12 Capacity* & pressure adequate to meet facility demands
    - 5-104.11 Water provided by public water main or approved system

49. Plumbing installed; proper backflow devices
    - 5-101.12 Drinking water system flushed & disinfected after repair or emergency*
    - 5-201.11 Plumbing system constructed of approved materials*
    - 5-202.11 Plumbing system designed, constructed & installed according to law*
    - 5-202.13 Air gap provided between water supply inlet & flood level rim of plumbing fixture*
    - 5-202.14 Backflow prevention device designed per approved standards
    - 5-202.15 Water filter/screen/water conditioning device installed to allow ease of cleaning
    - 5-203.13 Service sink available for cleaning of mops & disposal of liquid waste
    - 5-203.14 Backflow prevention device or air gap provided on plumbing fixtures as required*
    - 5-203.15 Backflow prevention device on carbonator with no air gap*
    - 5-204.12 -.13 Backflow prevention devices/conditioning devices located to allow service/maintenance
    - 5-205.12 No cross connection between drinking & non-drinking water*
    - 5-205.13 Water treatment device inspected & serviced
    - 5-205.14 Water reservoir of fogging devices maintained & cleaned*
    - 5-205.15 Plumbing system maintained in good repair*
    - 5-301.11 Mobile water tank constructed of safe, durable, finished materials
    - 5-302.11 -.16 Mobile water tank sloped to drain & designed to allow inspection & cleaning
    - 5-303.11 -.13 Mobile water tank designed with cover for water inlet/outlet & dedicated hose connection
50. Sewage & waste water properly disposed
    - 5-304.11 -.14 Water tank/pump/hoses properly disinfected & handled * Backflow prevention in place; waste water properly disposed
    - 5-401.11 Mobile holding tank adequately sized for capacity & sloped to drain
    - 5-402.11 Backflow prevention – no direct connection between sewage system & food equipment*
    - 5-402.12 -.13 Grease trap located to allow ease of cleaning; Sewage conveyed through approved sanitary sewage system*
    - 5-402.14 -.15 Mobile establishment waste removed through approved removal procedure; waste retention tank flushed in a sanitary manner
    - 5-403.11 -.12 Approved sewage disposal system used for waste disposal* Other liquid wastes drained to disposal per law
51. Toilet facilities properly constructed, supplied, & cleaned
    - 5-203.12 At least one toilet available or number specified by law *
    - 5-501.17 Covered receptacle in women's toilet room
    - 6-202.14 Toilet rooms completely enclosed
    - 6-302.11 Toilet tissue supplied at each toilet
    - 6-402.11 Toilet rooms convenient & accessible during all business hours
    - 6-501.12 Toilet rooms & fixtures cleaned as often as necessary
    - 6-501.19 Toilet room doors kept closed except during cleaning/maintenance

Annex 7, Guide 3-B (continued)
Part 2. Good Retail Practices

52. Garbage, refuse, recylables, returnables properly disposed; facilities maintained
    - 5-501.11 Outdoor storage surface constructed of nonabsorbent material & sloped to drain
    - 5-501.12 Outdoor enclosure for refuse constructed of durable, cleanable materials
    - 5-501.13 Receptacles durable, cleanable, insect-/rodent-resistant & leakproof
    - 5-501.14 Receptacles not within vending machines
    - 5-501.15 Outside receptacles designed with tight-fitting lids/doors/covers & properly installed
    - 5-501.16 Sufficient storage capacity – & area/ receptacles provided to hold refuse
    - 5-501.18 Cleaning implements/supplies provided for effective cleaning of receptacles
    - 5-501.19 Refuse storage areas located separate from food/utensils/equipment & not creating a nuisance
    - 5-501.110 Receptacles for refuse, recyclables, returnables inaccessible to insects/rodents
    - 5-501.111 Storage areas/receptacles in good repair
    - 5-501.112 Receptacles, such as plastic bags accessible to rodents, not stored outside
    - 5-501.113 Inside receptacles covered if not continually used; Outside receptacles equipped with tight fitting lids
    - 5-501.114 Drain plugs provided in receptacles with drains
    - 5-501.115 Refuse areas & enclosures maintained clean
    - 5-501.116 Cleaning of receptacles done in way not to contaminate food/utensils/equipment
    - 5-502.11 -.12 Refuse, recyclables, returnables removed in approved manner & at roper frequency to minimize attracting pests & developing odors
    - 5-503.11 Refuse disposed of in an approved public or private facility
    - 6-202.110 Outdoor refuse areas curbed & graded to drain
53. Physical facilities installed, maintained, & clean
    - 4-301.15 Clothes washer & dryer provided for laundering conducted on premises
    - 4-401.11(C) Washer & dryer properly located away from food/utensils/equipment
    - 4-803.13 Laundry facilities used only for items used in the facility
    - 6-101.11 Materials for floors/walls/ceilings smooth, durable, & easily cleanable under normal use
    - 6-102.11 Outdoor areas surfaced with concrete/asphalt; Exterior surfaces weather-resistant
    - 6-201.11 -.12 Floors/walls/ceilings smooth & easily cleanable; Utility lines not unnecessarily exposed
    - 6-201.13 Floor to wall junctures coved; Water-flushed floors provided with drains & graded to drain
    - 6-201.14 -.15 Carpeting not in areas subject to moisture; Mats/ duckboards removable & easily cleanable
    - 6-201.16 -.18 Wall & ceiling coatings/attachments easily cleanable; Studs unexposed in areas subject to moisture
    - 6-202.17 -.19 Overhead protection at outdoor vending & servicing areas; Outdoor walking/driving surfaces graded to drain
    - 6-202.111 -.112 Living/sleeping quarters not used for food establishment operations; living/sleeping quarters on the premises separated from food operation
    - 6-501.11 -.12 Physical facilities maintained in good repair & cleaned as often as necessary to keep them clean
    - 6-501.13 Floors cleaned by dustless methods
    - 6-501.15 Mop water/maintenance tools not put in prep, handwashing, or warewashing sinks *
    - 6-501.16 Mops allowed to air dry after use
    - 6-501.17 Sawdust/wood shavings/granular salt/clay not used on floors
    - 6-501.113 -.114 Maintenance tools properly stored; premises free of unnecessary items/litter
54. Adequate ventilation & lighting; designated areas provided/used
    - 4-202.18 Ventilation filters designed for ease of cleaning & maintenance
    - 4-204.11 Ventilation hood designed to prevent condensate from dripping onto food/equipment
    - 4-301.14 Ventilation hood adequate to prevent grease & condensation build-up
    - 6-202.12 Heating/ventilation/air conditioning units properly designed to prevent contamination
    - 6-304.11 Mechanical ventilation of adequate capacity to remove steam, heat, vapors, odors, smoke, fumes
    - 6-501.14 Ventilation system cleaned in way not to cause contamination or create a public health hazard
    - 6-202.11 Protective shielding on light bulbs over exposed food/utensils/equipment
    - 6-303.11 Lighting intensity adequate in food prep, storage, & service areas
    - 6-305.11 Dressing rooms designated if employees change on-site; Lockers provided for employees
    - 6-403.11 Designated areas for employees for eating/ drinking/smoking
    - 6-501.110 Designated dressing rooms/lockers used by employees

GUIDE 3-C

Instructions for Marking the Food Establishment Inspection Report

Guide 3-C is intended to be used during inspections to ensure that observations of the provisions of the Code are not overlooked during the inspection, and accurately recorded on the Food Code Establishment Inspection Report form.

GUIDE 3-C Instructions for Marking the Food Establishment Inspection Report

All references and code sections in these marking instructions are based on the 2005 Food Code.

A. GENERAL MARKING INSTRUCTIONS

HEADER Information

Establishment	Complete this section using the "usual/common name" or "Doing Business As" name of the business. This information should be the same as the license/permit application completed at the initiation of the business.
Address	Street address of the actual business location
Zip Code	Actual business location
Telephone	Contact phone number for the establishment
License/Permit #	License number or tracking identification
Permit Holder	Name of Owner or Operator as shown on application
Purpose	The reason for the inspection – routine, reinspection, complaint, or follow-up, etc.
Est. Type	Description or code for describing the type of facility (e.g. restaurant, market, vehicle, temporary food facility)
Risk Category	Designation of risk/priority level for determining frequency of inspection
Number of Risk Factor/ Intervention Violations	The number of boxes marked OUT in items 1-27 should be counted and the total number placed here
Number of Repeat Risk Factor/Intervention Violations	The number of boxes marked R (repeat) in items 1-27 should be counted and the total number placed here
Score (optional)	A score is optional for this form. If a jurisdiction has a scoring system, it should be incorporated into the inspection form and the score of an inspection placed here.
Date	The date of the inspection including month, day, and year
Time In	The actual time the inspection begins
Time Out	The actual time the inspection ends

B. RISK FACTORS AND INTERVENTIONS

Risk factors are food preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks. Risk factors include: Food from Unsafe Sources, Improper Holding Temperatures, Inadequate Cooking, Contaminated Equipment, and Poor Personal Hygiene. These items are prominent on the Food Establishment Inspection Report because maintaining these items in compliance is vital to preventing foodborne illness. Additionally, five key public health interventions were introduced in the 1993 Food Code that supplemented the other interventions long-established by the Food and Drug Administration (FDA) model codes and guidances to protect consumer health. The five key interventions are: Demonstration of Knowledge, Employee Health Controls, Controlling Hands as a Vehicle of Contamination, Time and Temperature Parameters for Controlling Pathogens, and the Consumer Advisory.

For each item on the inspection report form in the Foodborne Illness Risk Factors and Public Health Interventions section, the inspector should indicate one of the following for **COMPLIANCE STATUS: "IN"** which

means that the item is in compliance; **"OUT"** which means that the item is not in compliance; "**N.O."** which means that the item was not observed during the inspection; or **"N.A."** which means that the item is not applicable for the facility. If N.A. or N.O. is not listed as an option for a particular item, this means that this item must be evaluated during the inspection and a compliance status must be determined. **If the item is marked "OUT", document details of each violation for the item number in the "Observations and Corrective Actions" section on the second page of the inspection report.** Compliance status should be determined as a result of observations that establish a pattern of non-compliance. Consideration should be given to the seriousness of the observation with regard to prevention of foodborne illness.

For items marked **"OUT,"** further indicate the status of the violation by marking an **"X"** in the corresponding box for Corrected On-Site (**COS)** during the inspection and/or Repeat violation **(R)**. Marking **COS** indicates that all violations cited under that particular item number have been corrected and verified before completing the inspection. The actual corrective action taken for each violation should be documented in the "Observations and Corrective Actions" section of the inspection report. For example, Item #7 *Handwashing sink* is marked out of compliance because the establishment does not have soap and paper towels at the handwashing sink. The person in charge partially corrects the problem by putting soap at the sink, but does replace the paper towels or provide any other effective means for drying hands. The corrective action taken for the soap is documented in the narrative on the form, but **COS** is **not** marked for Item #7 because all violations under that item were not corrected. Marking **R** indicates that the same violation under a particular item number was cited on the last inspection report. Using the same scenario, on the subsequent inspection if the provision of soap and paper towels is not in violation, but employees are not washing hands in the correct sink (which is also cited under Item #7 *Handwashing sink*), **R** would **not** be marked because this is a new violation which was not cited on the previous inspection report.

C. MARKING INSTRUCTIONS FOR EACH RISK FACTOR AND INTERVENTION ON THE INSPECTION REPORT

Supervision

1. PIC present, demonstrates knowledge, and performs duties

IN/OUT This item should be marked IN or OUT of compliance. The person in charge (PIC) has three assigned responsibilities – Presence; Demonstration of Knowledge; and Duties. This item is marked OUT of compliance if any **one** of the responsibilities is not met.

A. Person in charge is present. This item is marked OUT of compliance when there is no PIC.

B. Demonstration of Knowledge. The PIC has three options for demonstrating knowledge. This item is marked OUT of compliance if the PIC fails to meet at least **one** of the options. The three options for demonstration of knowledge allowed by the Food Code are:
   1. Certification by an ACCREDITED PROGRAM;
   2. Complying with this Code by having no violations of critical items during the current inspection; or
   3. Correct responses to the inspector's questions regarding public health practices and principles applicable to the operation. The inspector should assess this item by asking open-ended questions that would evaluate the PIC's knowledge in each of the areas enumerated in ¶ 2-102.11(C). Questions can be asked during the initial interview, menu review, or throughout the inspection as appropriate. The Inspector should ask a sufficient number of questions to enable the inspector to make an informed decision concerning the PIC's knowledge of the Code requirements and public health principles as they apply to the operation. The dialogue should be extensive enough to reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

C. Duties of the PIC. This item should be marked OUT of compliance when there is a pattern of non-compliance and obvious failure by the PIC to ensure employees are complying with the duties listed in § 2-103.11. Since marking this item out of compliance requires judgment, it is important that this item not be marked for an isolated incident, but rather for an overall evaluation of the PIC's ability to ensure compliance with the duties described in § 2-103.11.

N.A. **Do Not Mark** this item N.A.
N.O. **Do Not Mark** this item N.O.

Employee Health

2. Management awareness, policy present

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance when all of the following criteria are met:

1. The PIC is aware of the Food Code provision that conditional or food employees are required to report certain symptoms or diagnosed illnesses to the person in charge, and
2. The PIC can convey knowledge of an employee health policy **or** have access to an employee health policy (the Code does not require a written policy except for use of bare hand contact with ready-to-eat food) identifying what actions are necessary following a report that an employee has a certain symptom or diagnosed illness.

The policy must reflect the current Food Code provisions. Verbal communication of the employee health policy must be specific to the types of illnesses and symptoms that require reporting. Nonspecific statements such as, "sick or ill employees are not allowed to work," are not acceptable as meeting this requirement.

N.A. **Do Not Mark** this item N.A.
N.O. **Do Not Mark** this item N.O.

3. Managing Ill Employees - reporting, excluding, and restricting

IN/OUT This item must be marked IN or OUT of compliance. To be marked IN there must be no ill employees, employees experiencing symptoms requiring reporting, or reason for the PIC to exclude or restrict an employee observed at the time of the inspection.

N.A. **Do Not Mark** this item N.A.
N.O. **Do Not Mark** this item N.O.

Good Hygienic Practices

4. Proper eating, tasting, drinking, or tobacco use

IN/OUT **This item should be marked IN or OUT of compliance.**
N.A. **Do Not Mark** this item N.A.
N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection.

5. No discharge from eyes, nose, and mouth

IN/OUT This item should be marked IN or OUT of compliance.
N.A. **Do Not Mark** this item N.A.
N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection.

Preventing Contamination by Hands

6. Hands clean and properly washed

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance only when employees are observed using proper handwashing techniques at appropriate times and places.

N.A. **Do Not Mark** this item N.A.

N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection. (If there are no food workers present, but the PIC accompanies the inspector on the inspection and touches food, clean equipment, or utensils without washing his/her hands, this item is marked OUT.)

7. No bare hand contact with ready-to-eat foods or approved alternate method followed

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance only when employees are observed using suitable utensils or gloves to prevent bare hand (or arm) contact with ready-to-eat foods or are observed following a pre-approved alternative procedure to no bare hand contact.

N.A.

N.O. This item may be marked N.O. for establishments that prepare ready-to-eat foods only, but no food preparation is performed at the time of inspection.

8. Adequate handwashing sinks, properly supplied and accessible

IN/OUT This item should be marked IN or OUT of compliance.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Approved Source

9. Food obtained from approved source

IN/OUT This item should be marked IN or OUT of compliance.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

10. Food received at proper temperature

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. for retail operations when the establishment receives only foods that are not PHF (TCS) food and that are not frozen.

N.O. This item may be marked N.O. if food is not received during the inspection.

11. Food in good condition, safe and unadulterated

IN/OUT This item should be marked IN or OUT of compliance.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

12.Required records available: shellstock tags, parasite destruction

***NOTE**: Fish that are sold with the intent that the consumer will cook it are not required to be frozen for parasite destruction.*

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. when shellstock are not used in the establishment and the only fish sold as raw, raw-marinated or undercooked is the tuna species or aquacultured fish listed as exempted from freezing in the Food Code.

N.O. This item may be marked N.O. when shellstock or raw, raw-marinated and undercooked fish are sold periodically in the establishment, but are not being sold at the time of inspection and prior compliance through tags, invoices, or purchase records cannot be verified.

Protection from Contamination

13. Food separated and protected

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. when there are no raw animal foods used in the facility and only prepackaged foods are sold.

N.O. Do not mark this item N.O.

14. Food-contact surfaces: cleaned and sanitized

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. only when there is no requirement to clean equipment and utensils such as when only prepackaged foods are sold.

N.O. **Do Not Mark** this item N.O.

15. Proper disposition of returned, previously served, reconditioned, and unsafe food

IN/OUT This item should be marked IN or OUT of compliance. This item is marked OUT of compliance if food is found unsafe, adulterated, from an unapproved source, or ready-to-eat food is contaminated by employees and is not discarded or reconditioned according to an approved procedure, or if previously served unwrapped, unprotected food is observed being re-served.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Potentially Hazardous Food (PHF) (Time Temperature Control for Safety Food) (TCS Food)

16. Proper cooking time and temperatures

***NOTE**:* *The cooking temperatures of foods must be measured to determine compliance or noncompliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or noncompliance. The temperature of raw animal foods in each species cooked during the inspection should be taken. For instance, if the facility fries chicken, scrambles eggs, bakes fish, grills hamburgers, and slow-roasts prime rib during the inspection – the cook temperatures of all of the products should be measured and recorded. Temperatures, both IN compliance and OUT of compliance, should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Actions" section on the second page of the inspection report. If a food is cooked below the required temperature but the facility has an approved Consumer Advisory or an approved variance with HACCP plan for that food item, mark the item IN compliance, record the temperature and document the reason it is in compliance. The time of inspections should be varied so that cooking can be observed.*

IN/OUT This item should be marked IN or OUT of compliance. This item should be marked OUT of compliance if the items checked do not meet the temperature requirements for cooking and the employee doing the cooking attempts to serve the product without returning the product to the cooking process.

N.A. This item may be marked N.A. when no raw animal foods are cooked in the establishment.

N.O. This item may be marked N.O. when no raw animal foods are cooked during the time of inspection.

The cooking temperature / time requirements for each raw animal species are as follows:

- *Raw eggs broken on request and prepared for immediate service cooked to 63°C (145°F) for 15 seconds; Raw eggs broken, but not prepared for immediate service, cooked to 68°C (155°F) for 15 seconds*
- *Comminuted fish, meat, game animals cooked to 68°C (155°F) for 15 seconds*

- *Roasts, including formed roasts, are cooked to 54.4°C (130°F) for 112 minutes or as chart specified and according to oven parameters per chart*
- *Ratites and injected meats cooked to 68°C (155°F) for 15 seconds*
- *Poultry, stuffed fish/meat/pasta/poultry/ratites, or stuffing containing fish, meat, poultry or ratites cooked to 74°C (165°F) for 15 seconds*
- *Wild game animals cooked to 74°C (165°F) for 15 seconds*
- *Whole-muscle, intact beef steaks cooked to surface temperature of 63°C (145°F) on top and bottom; meat surfaces have a cooked color change*
- *Raw animal foods rotated, stirred, covered, and heated to 74°C (165°F) in microwave; food stands covered for 2 minutes after cooking*
- *All other raw animal foods cooked to 63°C (145°F) for 15 seconds*

17. Proper reheating procedures for hot holding

***NOTE**: The reheating temperatures of foods must be taken to determine compliance or noncompliance. Do not rely solely upon discussions with managers or cooks to determine compliance or noncompliance. Temperatures IN and OUT of compliance should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Actions" section of the inspection report. This item should be marked OUT of compliance if the items checked are not reheated to the required temperatures.*

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. when foods are not held over for a second service and/or reheating for hot holding is not performed in the establishment.

N.O. This item may be marked N.O. such as when foods are held over for a second service, but no foods are reheated during the time of inspection.

The reheating for hot holding temperature / time requirements are as follows:

- *PHF (TCS) rapidly reheated to 74°C (165°F) for 15 seconds within 2 hours*
- *Food reheated in a microwave to 74°C (165°F) or higher*
- *Commercially processed ready-to-eat PHF (TCS) reheated to 57°C (135°F) or above within 2 hours*
- *Remaining unsliced portions of roasts reheated for hot holding using minimum oven parameters*

18. Proper cooling time and temperatures

***NOTE:** The requirement for cooling cooked PHF (TCS) food, is that the food must be cooled from 135°F to 41°F or less (or to 45°F or less based on the jurisdictions cold holding temperature requirement), in 6 hrs provided that the food is cooled from 135°F to 70°F within the first 2 hours. For example, if a facility cools chili from 135°F to 70°F in 1.5 hours; they then have 4.5 hours to get it from 70°F to 41°F or less (or 45°F or less). There are two critical limits that must be met with cooling. If the food is not cooled from 135°F to 70°F within 2 hours, this item is marked OUT. If the food is not cooled from 70°F to 41°F or less (or 45°F or less) within 6 hours minus the time it took the food to cool from 135°F to 70°F, the item is marked OUT. Discussions with the person in charge along with observations should be used to determine compliance. For instance, during discussion the person in charge says that a food product was cooled overnight in the walk-in cooler. The product is checked and the temperature is 50°F. Eight hours have elapsed from closing to opening. This item should be marked out because the product did not cool from 135°F to 70°F within two hours and from 70°F to 41°F or less (or 45°F or less) within 6 hours. Temperatures IN compliance and OUT of compliance should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Actions" section of the inspection report.*

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. when the establishment does **not** receive raw eggs, shellstock, or milk, prepares **no** PHF (TCS) food from ambient temperature ingredients that require cooling, and does **not** cool cooked PHF (TCS) food.

N.O. This item may be marked N.O. when the establishment does cool PHF (TCS) food, but proper cooling per the prescribed temperature and time parameters cannot be determined during the length of the inspection.

The cooling categories and their temperature / time requirements are as follows:

- *Cooked PHF (TCS) food cooled from 57°C (135°F) to 5°C (41°F) or less, or to 7°C (45°F) or less in 6 hrs, provided that the food is cooled from 57°C (135°F) to 21°C (70°F) within the first 2 hours*
- *PHF (TCS) food from ambient temperature ingredients cooled to 7°C/5°C (45°F/41°F) or below within 4 hours*
- *Foods (shellstock, milk) received at a temperature according to law cooled to 7°C/5°C (45°F/ 41°F) within 4 hours*
- *Raw eggs received at an ambient temperature of 7°C (45°F) immediately placed in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F)*

19. Proper hot holding temperatures

NOTE: *Temperatures IN compliance and OUT of compliance should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Action" section of the inspection report.*

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. when the establishment does not hot hold food.

N.O. This item may be marked N.O. when the establishment does hot hold foods, but no foods are being held hot during the time of inspection.

20. Proper cold holding temperatures

NOTE: *Temperatures IN compliance and OUT of compliance should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Action" section of the inspection report.*

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. when the establishment does **not** cold hold food.

N.O. **Do not mark** this item N.O.

21. Proper date marking and disposition

IN/OUT This item should be marked IN or OUT of compliance. For disposition, mark IN when foods are all within date marked time limits or food is observed being discarded within date marked time limits or OUT of compliance, such as when date marked food exceeds the time limit or date-marking is not done,

N.A. This item may be marked N.A. when there is no ready-to-eat, PHF (TCS) food prepared and held, or commercial containers of ready-to-eat, PHF (TCS) food opened and held, over 24 hours in the establishment.

N.O. This item may be marked N.O. when the establishment does handle foods requiring date marking, but there are no foods requiring date marking in the facility at the time of inspection. For disposition, mark N.O. when RTE, PHF (TCS) food is prepared-on-premises, or opened commercial container is held beyond the 7-day or 4-day time limits and you are unable to determine compliance.

22. Time as a Public Health Control: procedures and records

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. when the establishment does not use time only as the public health control.

N.O. This item may be marked N.O. when the establishment uses time only as the public health control, but is not using this practice at the time of inspection.

Consumer Advisory

23. Consumer advisory provided for raw or undercooked food

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance if the establishment provides an advisory that meets disclosure and reminder.

N.A. This item may be marked N.A. when the establishment does not serve raw or undercooked animal foods.

N.O. **Do Not Mark** this item N.O.

Highly Susceptible Population

24. Pasteurized foods used; prohibited foods not offered

NOTE: Discussions with the person in charge and employees regarding whether or not certain foods are served or certain practices occur in the establishment, along with observations should be used to determine compliance

IN/OUT This item should be marked IN or OUT of compliance.

N.A This item may be marked N.A. if a highly susceptible population is not served.

N.O. **Do Not Mark** this item N.O.

Food/Color Additives and Toxic Substances

25. Food additives: approved and properly used

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance if approved food and color additives are on site and used properly or if sulfites are on the premises, and they are not applied to fresh fruits/vegetables for raw consumption. This item is marked OUT of compliance if unapproved additives are found on the premises or approved additives are improperly used, such as sulfites being applied to fresh fruits or vegetables.

N.A. This item may be marked N.A. if the food establishment does **not** use any additives or sulfites on the premises.

N.O. **Do Not Mark** this item N.O.

26. Toxic substances properly identified, stored, and used

IN/OUT This item should be marked IN or OUT of compliance.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Conformance with Approved Procedures

27. Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan

IN/OUT This item should be marked IN or OUT of compliance.

N.A. This item may be marked N.A. if the establishment is not required by the regulatory authority to have a variance or HACCP plan, juice is not packaged or reduced oxygen packaging is not done on the premises.

N.O. **Do Not Mark** this item N.O.

D. MARKING INSTRUCTIONS FOR EACH GOOD RETAIL PRACTICE (GRP) ON THE INSPECTION REPORT

Good Retail Practices (**GRPs**) are preventive measures that include practices and procedures which effectively control the introduction of pathogens, chemicals, and physical objects into food. If GRPs are not controlled, they could be contributing factors to foodborne illness. However, the intention of this inspection form is to focus the inspector's attention on those factors that have been shown to be most often linked with causing foodborne illness. Since the major emphasis of an inspection should be on the Risk Factors that cause foodborne illness

and the Public Health interventions that have the greatest impact on preventing foodborne illness, the GRPs have been given less importance on the inspection form and a differentiation between IN, OUT, N.A. and N.O. is not made in this area. For marking the GRPs section, place an "X" in the box to the left of the numbered item if a code provision under that item is **OUT** of compliance. Document each violation of the code provision for the item number in the "Observations and Corrective Actions" section on the second page of the inspection report. For items marked out of compliance, further indicate the **VIOLATION STATUS** by marking an **"X"** in the corresponding box**: COS** = Corrected on site during inspection and **R =** Repeat violation per the same instructions as given in the Risk Factor section. References to the appropriate Food Code provisions that can be debited under each numbered GRP item are listed in Guide 3-B.

E. TEMPERATURE OBSERVATIONS

Item/location	Record the common name of the food as well as the condition, process, and location of the food at the time of monitoring e.g. hot holding, refrigerator, prep-table. Temperatures in compliance and out of compliance should be documented. If there is insufficient space for the number of temperatures taken, record the additional temperatures in the "Observations and Corrective Actions" section of the inspection report.
Food Temperature	Record the temperature indicated on the inspector's thermometer. Specify the measurement in °F or °C. *(Note: Food temperature measuring devices that are scaled only in Fahrenheit should be accurate to ±2°F in the intended range of use. Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit should be accurate to ± 1°C in the intended range of use.)*

F. OBSERVATIONS AND CORRECTIVE ACTIONS

Include here specific descriptions of violations observed and recorded in the Risk Factors and Interventions section and Good Retail Practices check boxes. Also include corrective actions for the noted violations and temperatures if there is insufficient space in the allotted section for temperature recordings.

G. SIGNATURE BLOCK

Person in Charge	The PIC is the individual present at a food establishment who is responsible for the operation at the time of the inspection.
Inspector	The Inspector is the individual conducting the inspection.
Date	The date the inspection is completed.
Follow-up	The determination of whether to conduct a reinspection or other enforcement action.
Follow-up Date	The date the follow-up inspection will be conducted.

Chart 4-A

Summary Chart for Minimum Cooking Food Temperatures and Holding Times Required by Chapter 3

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature
Raw Eggs prepared for immediate service **Commercially Raised Game Animals and Exotic Species of Game Animals** **Fish, Pork, and Meat** Not Otherwise Specified in this Chart or in ¶ 3-401.11(B)	**63°C (145°F)**	**15 seconds**
Raw Eggs not prepared for immediate service **Comminuted Commercially Raised Game Animals and Exotic Species of Game Animals** **Comminuted Fish and Meats** **Injected Meats**	70°C (158°F) **68°C (155°F)** 66°C (150°F) 63°C (145°F)	< 1 second **15 seconds** 1 minute 3 minutes
Poultry **Baluts** **Stuffed Fish; Stuffed Meat; Stuffed Pasta;** **Stuffed Poultry; Stuffed Ratites** **Stuffing Containing Fish, Meat, Poultry, or Ratites** **Wild Game Animals**	**74°C (165°F)**	**15 seconds**
Food Cooked in A Microwave Oven	**74°C (165°F)**	**and hold for 2 minutes after removing from microwave oven**

Chart 4-B

Summary Chart for Minimum Food Temperatures and Holding Times Required by Chapter 3 for Reheating Foods for Hot Holding

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature	Maximum Time to Reach Minimum Temperature
¶ 3-403.11(A) and (D) Food that is cooked, cooled, and reheated	74°C (165°F)	15 seconds	2 hours
¶ 3-403.11(B) and (D) Food that is reheated in a microwave oven	74°C (165°F)	and hold for 2 minutes after reheating	2 hours
¶ 3-403.11(C) and (D) Food that is taken from a commercially processed, hermetically sealed container or intact package	57°C (135°F)	No time specified	2 hours
¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)		Not applicable
	OR		
	Minimum and maximum time and temperature conditions listed in this chart for ¶ 3-403.11(A), and (D).		

Chart 4-C **Summary Chart**

Ready-to-Eat, Potentially Hazardous Food (Time/temperature, Control for Safety Food)

Date Marking § 3-501.17(A) – (E) and Disposition § 3-501.18

"IF" → **"THEN"**

(A) or (B) On site preparation and held > 24 hours, or Commercial container is opened →

(1) @ ≤ 41°F for ≤ 7 days

or

(2) @ > 41 - ≤ 45°F for ≤ 4 days

(A) or (B) Remove from freezer →

(a) @ ≤ 41°F 7 days minus*

or

(b) @ > 41 - ≤ 45°F 4 days minus*

*Time from preparation, or opening commercial container, to freezing.

Example: The morning of October 1, a chicken was cooked, then cooled, refrigerated for 2 days at 41°F and then frozen. If the chicken is thawed October 10, the food must be consumed or discarded no later than midnight of October 14.

Date	Shelf Life Day	Action
Oct. 1	1	cook/cool
Oct. 2	2	cold hold at 41°F
Oct. 3		freeze
Oct. 10	3	thaw to 41°F
Oct. 11	4	cold hold
Oct. 12	5	cold hold
Oct. 13	6	cold hold
Oct. 14	7	consume or discard

Chart 4-D

FDA Food Code Mobile Food Establishment Matrix

This table is a plan review and inspectional guide for mobile food establishments based on the mobile unit's menu and operation. Mobile units range in type from push carts to food preparation catering vehicles.

To use the table, read down the columns based on the menu and operation in use. For example, if only prepackaged potentially hazardous food (time/temperature control for safety food) is served, then requirements listed in the **Potentially Hazardous (TCS) Menu - *Prepackaged*** column apply. Likewise, if only food that is not potentially hazardous (time/temperature control for safety food) is prepared on board, then requirements listed in the **Not Potentially Hazardous Menu (TCS) - *Food Preparation*** column apply. Note that if a mobile food establishment has available for sale to the consumer both prepackaged potentially hazardous food (time/temperature control for safety food) and potentially hazardous food (time/temperature control for safety food) prepared on board, then the more stringent requirements of the **Potentially Hazardous (TCS) Menu - *Food Preparation*** column apply.

It is important to remember that mobile units may also be subject to all Food Code provisions that apply to food establishments. Consult the local regulatory authority for specific local requirements.

The local regulatory authority's decision to require auxiliary support services such as a commissary or servicing area should be based on the menu, type of operation, and availability of on-board or on-site equipment.

NOTE: The Food Code definition of "Food Establishment" does not include an establishment that offers only prepackaged foods that are not potentially hazardous (time/temperature control for safety foods).

FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX			
Food Code	***Potentially Hazardous Food (TCS food) Menu***		***Not Potentially Hazardous Food (TCS Food) Menu***
Areas/Chapter	*Food Preparation*	*Prepackaged*	*Food Preparation*
Personnel	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)
Food	3-101.11 3-201.11-.16 3-202.16; Applicable Sections of Part 3-3; 3-501.16 3-501.18(A)	3-101.11 3-201.11-.16 3-303.12(A) 3-501.16 3-305.11; 3-305.12 (Applicable to Service Area or Commissary)	3-101.11; 3-201.11 3-202.16; Applicable Sections of Part 3-3
Temperature Requirements	3-202.11; Applicable Sections of Parts 3-4 & 3-5	3-202.11 3-501.16	NONE
Equipment Requirements	Applicable Sections of Parts 4-1- 4-9 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-6 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-5 - 4-6 and 5-5
Water & Sewage	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13-.15	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13 -.15	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13-.15
Physical Facility	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111	6-101.11 6-102.11(A) & (B) 6-202.15 6-501.111	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111
Toxic Materials	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7
Servicing	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code
Compliance and Enforcement	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1