

**RULES
OF
TENNESSEE DEPARTMENT OF AGRICULTURE
CONSUMER AND INDUSTRY SERVICES**

**CHAPTER 0080-04-09
RETAIL FOOD STORE SANITATION**

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0080-04-09-.01 DEFINITIONS.

- (1) Accredited Program.
 - (a) "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.
 - (b) "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.
 - (c) "Accredited program" does not refer to training functions or educational programs.
- (2) Additive.
 - (a) "Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1).
 - (b) "Color additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).
- (3) "Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.
- (4) "Approved" means acceptable to the commissioner based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.
- (5) Asymptomatic.
 - (a) "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.
 - (b) "Asymptomatic" includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

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- (6) "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.
- (7) "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.
- (8) "Beverage" means a liquid for drinking, including water.
- (9) "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.
- (10) "Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.
- (11) "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.
- (12) "CFR" means Code of Federal Regulations. Citations in this chapter 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.
- (13) CIP.
 - (a) "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.
 - (b) "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.
- (14) "Commingle" means:
 - (a) To combine shellstock harvested on different days or from different growing areas as identified on the tag or label, or
 - (b) To combine shucked shellfish from containers with different container codes or different shucking dates.
- (15) Comminuted.
 - (a) "Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing.
 - (b) "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.
- (16) "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

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transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

- (17) "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.
- (18) "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.
- (19) Core Item.
- (a) "Core item" means a provision in this chapter that is not designated as a priority item or a priority foundation item.
- (b) "Core item" includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (ssops), facilities or structures, equipment design, or general maintenance.
- (20) "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.
- (21) "Counter-mounted equipment" means equipment that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.
- (22) "Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.
- (23) "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.
- (24) "Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.
- (25) "Department" means the Tennessee Department of Agriculture.
- (26) "Dealer" means a person who is authorized by a shellfish control authority for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor of molluscan shellfish according to the provisions of the National Shellfish Sanitation Program.
- (27) "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.
- (28) Drinking Water.
- (a) "Drinking water" means water that meets criteria as specified in 40 CFR 141 National Primary Drinking Water Regulations.

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- (b) "Drinking water" is traditionally known as "potable water."
 - (c) "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.
- (29) "Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not time /temperature control of safety food and dry goods such as single-service items.
- (30) Easily Cleanable.
- (a) "Easily cleanable" means a characteristic of a surface that:
 - 1. Allows effective removal of soil by normal cleaning methods;
 - 2. Is dependent on the material, design, construction, and installation of the surface; and
 - 3. 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.
 - (b) "Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in subparagraph (a) of this definition to different situations in which varying degrees of cleanability are required such as:
 - 1. 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
 - 2. 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.
- (31) "Easily movable" means:
- (a) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and
 - (b) 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.
- (32) Egg.
- (a) "Egg" means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratites or turkey.
 - (b) "Egg" does not include:
 - 1. A balut;
 - 2. The egg of reptile species such as alligator; or
 - 3. An egg product.

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(33) Egg Product.

- (a) "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.
- (b) "Egg Product" does not include food that contains eggs only in a relatively small proportion such as cake mixes.

(34) "Employee" means a person:

- (a) In charge of a food establishment;
- (b) Engaged in the preparation of food or drink;
- (c) Engaged in service of food to the establishment's clientele; or
- (d) Engaged in warewashing.

(35) "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.

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

(37) Equipment.

- (a) "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, or ware washing machine.
- (b) "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.

(38) "Exclude" means to prevent a person from working as an employee in a food establishment or entering a food establishment as an employee.

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

(40) Fish.

- (a) "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.

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

- (41) "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.

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

- (43) "Food-contact surface" means:
 - (a) A surface of equipment or a utensil with which food normally comes into contact; or
 - (b) A surface of equipment or a utensil from which food may drain, drip, or splash:
 - 1. Into a food, or
 - 2. Onto a surface normally in contact with food.

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

- (45) Food Establishment.
 - (a) "Food establishments" means retail food stores, and food service establishments located within retail food stores;
 - (b) The term "food establishments" is to be used throughout this chapter when a provision is applicable to both retail food stores and food service establishments located within retail food stores;

- (46) "Food Service Establishment" means:
 - (a) Any establishment, place or location, whether permanent, temporary, seasonal or itinerant, where food is prepared and the public is offered to be served, or is served, food, including, but not limited to, foods, vegetables, or beverages not in an original package or container, food and beverages dispensed at soda fountains and delicatessens, sliced watermelon, ice balls, or water mixtures.
 - (b) "Food service establishment" includes any such places regardless of whether there is a charge for the food.
 - (c) "Food service establishment" does not include private homes where food is prepared or served and not offered for sale, retail food store operations other than delicatessens, the location of vending machines, and supply vehicles.
 - (d) "Food service establishment" does not include churches, temples, synagogues or other religious institutions, civic, fraternal, or veteran's organizations where food is prepared, served, transported, or stored by volunteer personnel only on non-consecutive days; provided, however, that the storage of unopened, commercially canned food, packaged bulk food that is not time/temperature control for safety food as defined by department rules and regulations, and dry goods shall not apply for these purposes;
 - (e) "Food service establishment" does not include grocery stores that may, incidentally, make infrequent casual sales of uncooked foods for consumption on the premises, or any establishment whose primary business is other than food service, that may,

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incidentally, make infrequent casual sales of coffee or prepackaged foods, or both, for consumption on the premises. For the purposes of this subparagraph, infrequent casual sales means sales not in excess of one hundred fifty dollars (\$150) per day on any particular day;

- (f) "Food service establishment" does not include a location from which casual, occasional food sales are conducted solely in connection with youth-related amateur athletic or recreational activities or primary or secondary school-related clubs by volunteer personnel and that are in operation for twenty-four (24) consecutive hours or less;
 - (g) "Food service establishment" does not include a catering business that employs no regular, full-time employees, the food preparation for such business is solely performed within the confines of the principal residence of the proprietor, and the catering business makes only "occasional sales" during any thirty-day period; and
 - (h) "Food service establishment" does not include a house or other residential structure where seriously ill or injured children and their families are provided temporary accommodations in proximity to their treatment hospitals and where food is prepared, served, transported or stored by volunteer personnel; provided, that the house or structure is supported by a § 501(c)(3) organization, as defined in 26 U.S.C. § 501(c)(3), that has as a component of its mission the support of programs that directly improve the health and well-being of children.
- (47) Food Manufacturing Plant.
- (a) "Food manufacturing 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.
 - (b) "Food manufacturing plant" does not include a food establishment.
- (48) Game Animal.
- (a) "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.
 - (b) "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.
 - (c) "Game animal" does not include ratites.
- (49) "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 restricted use.
- (50) "Good repair" means equipment and utensils shall be maintained in a state of repair and condition that meets the requirements specified under 0080-04-09-.04.
- (51) "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.

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- (52) "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.
- (53) Handwashing Sink.
- (a) "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.
- (b) "Handwashing sink" includes an automatic handwashing facility.
- (54) "Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.
- (55) "Health practitioner" means a physician licensed to practice medicine, or if allowed by law, a nurse practitioner, or physician assistant.
- (56) "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.
- (57) "Highly susceptible population" means persons who are more likely than other people in the general population to experience foodborne disease because they are:
- (a) Immunocompromised; preschool age children, or older adults; and
- (b) 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.
- (58) "Imminent health hazard" means any condition, deficiency, or practice that, if not corrected, is very likely to result in illness, injury, or loss of life to any person.
- (59) "Injected" means manipulating meat to which a solution has been introduced into its interior by processes that are referred to as "injecting," "pump marinating," or "stitch pumping."
- (60) Juice.
- (a) "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.
- (b) "Juice" does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.
- (61) "Kitchenware" means food preparation and storage utensils.
- (62) "Law" means applicable local, state, and federal statutes, regulations, and ordinances.
- (63) "Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.
- (64) Major Food Allergen.
- (a) "Major food allergen" means:

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1. 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
 2. A food ingredient that contains protein derived from a food, as specified in part (a)1 of this definition.
- (b) "Major food allergen" does not include:
1. Any highly refined oil derived from a food specified in part (a)1 of this definition and any ingredient derived from such highly refined oil; or
 2. 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).
- (65) "Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goat, other edible animals except fish, poultry, and wild game animals as specified under 0080-04-09-.03 (2)(a)7(i)(III), (IV).
- (66) Mechanically Tenderized.
- (a) "Mechanically tenderized" means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using blades, pins, needles or any mechanical device.
- (b) "Mechanically tenderized" does not include processes by which solutions are injected into meat.
- (67) "mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).
- (68) "Mobile food unit" means a food establishment designed to be readily moved and vend food.
- (69) "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.
- (70) Non-Continuous Cooking.
- (a) "Non-continuous cooking" means the cooking of food in a food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service.
- (b) "Non-continuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.
- (71) Packaged.
- (a) "Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether packaged in a food establishment or a food processing plant.
- (b) "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.

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- (72) "Permit" means the document issued by the department that authorizes a person to operate a food establishment.
- (73) "Permit holder" means the entity that:
- (a) Is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person; and
 - (b) Possesses a valid permit to operate a food establishment.
- (74) "Person" means any individual, partnership, firm, corporation, agency, municipality, state or political subdivision, or the federal government and its agencies and departments.
- (75) "Person in charge" means an individual present at a food establishment who is responsible for the operation at the time of inspection. A person in charge shall be present at the establishment during food preparation and handling, and may put instructions in place for cleaning and preparing the establishment prior to the preparation of any food or beverage.
- (76) Personal Care Items.
- (a) "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.
 - (b) "Personal care items" include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.
- (77) "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.
- (78) "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.
- (79) "Plumbing fixture" means a receptacle or device that:
- (a) Is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or
 - (b) Discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.
- (80) "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.
- (81) "Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four categories:
- (a) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

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- (b) Pesticides, except sanitizers, which include substances such as insecticides and rodenticides;
 - (c) 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
 - (d) 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.
- (82) "Poultry" means:
- (a) 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
 - (b) 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.
- (83) "Premises" means:
- (a) The physical facility, its contents, and the contiguous land or property under the control of the permit holder; or
 - (b) The physical facility, its contents, and the land or property not described in subparagraph (a) of this definition if its facilities and contents are under the control of the permit holder and may impact food establishment personnel, facilities, or operations, and a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.
- (84) "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.
- (85) Priority Item.
- (a) "Priority item" means a provision in this chapter whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.
 - (b) "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
 - (c) "Priority item" is an item that is denoted in this chapter with (P).
- (86) Priority Foundation Item.
- (a) "Priority foundation item" means a provision in this chapter whose application supports, facilitates or enables one or more priority items.
 - (b) "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training,

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infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and

- (c) "Priority foundation item" is an item that is denoted in this chapter with (Pf).
- (87) "Public water system" has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.
- (88) "Ratite" means a flightless bird such as an emu, ostrich, or rhea.
- (89) "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 0080-04-09-.03(4)(a)1(i) or (ii), 0080-04-09-.03(4)(a)2, or 0080-04-09-.03(4)(b)1 or as specified in 0080-04-09-.03(4)(a)1(iii); or
 - (b) Is a raw or partially cooked animal food and the consumer is advised as specified in 0080-04-09-.03(4)(a)1(iv)(I) and (III); or
 - (c) Is prepared in accordance with a variance that is granted as specified in 0080-04-09-.03(4)(a)1(iv)(IV); and
 - (d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.
 - (e) "Ready-to-eat food" includes:
 - 1. Raw animal food that is cooked as specified under 0080-04-09-.03(4)(a), or frozen as specified under 0080-04-09-.03(4)(b);
 - 2. Raw fruits and vegetables that are washed as specified under 0080-04-09-.03(3)(b)5;
 - 3. Fruits and vegetables that are cooked for hot holding, as specified under 0080-04-09-.03(4)(a)3;
 - 4. All time/temperature control for safety food that is cooked to the temperature and time required for the specific food under 0080-04-09-.03(4) and cooled as specified under 0080-04-09-.03(5)(a)4;
 - 5. 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;
 - 6. Substances derived from plants such as spices, seasonings, and sugar;
 - 7. A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;
 - 8. 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

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

(90) Reduced Oxygen Packaging.

(a) "Reduced oxygen packaging" means:

1. 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
2. A process as specified in part (a)(1) of this definition that involves a food for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form.

(b) "Reduced oxygen packaging" includes:

1. Vacuum packing, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;
2. 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;
3. 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;
4. Cook chill packaging, in which cooked food is hot filled into impermeable bags that 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 psychrotrophic pathogens; or
5. 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 psychrotrophic pathogens.

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

(92) "Reminder" means a written statement concerning the health risk of consuming animal food raw, undercooked, or without otherwise being processed to eliminate pathogens.

(93) "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.

(94) "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.

(Rule 0080-04-09-.01, continued)

- (95) "Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.
- (96) "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.
- (97) Retail food store.
- (a) "Retail food store" means any establishment or a section of an establishment where food and food products are offered to the consumer and intended for off-premise consumption;
- (b) "Retail food store" does not include:
- (i) Establishments that handle only prepackaged, non-time/temperature control for safety food, as defined by department rules and regulations;
 - (ii) Roadside markets that offer only fresh fruits and fresh vegetables;
 - (iii) Food and beverage vending machines;
 - (iv) Food service establishments not located within a retail food store; or
 - (v) A person who makes infrequent casual sales of honey or who packs or sells less than one hundred fifty gallons (150 gals.) of honey per year.
- (98) "Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.
- (99) "Safe material" means:
- (a) 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;
 - (b) An additive that is used as specified in § 409 of the Federal Food, Drug, and Cosmetic Act; or
 - (c) Other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.
- (100) "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.
- (101) "Sealed" means free of cracks or other openings that allow the entry or passage of moisture.
- (102) "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.
- (103) "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.

(Rule 0080-04-09-.01, continued)

- (104) "Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.
- (105) "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.
- (106) "Shellstock" means raw, in-shell molluscan shellfish.
- (107) "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.
- (108) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.
- (109) "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.
- (110) Single-Use Articles.
- (a) "Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded.
- (b) "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 0080-04-09-.04-(1)(a), (2)(a), (b) for multiuse utensils.
- (111) "Stacking" 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.
- (112) "Smooth" means:
- (a) 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;
- (b) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and
- (c) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.
- (113) "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.
- (114) "Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

(Rule 0080-04-09-.01, continued)

(115) "Temporary food establishment" means a food establishment that operates at a fixed location in conjunction with an organized temporary event for more than one (1) day and not more than fourteen (14) consecutive days.

(116) Time/Temperature Control for Safety Food.

(a) "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.

(b) "Time/temperature control for safety food" includes:

1. An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and
2. Except as specified in subpart 3(iv) 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-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - .95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

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

(Rule 0080-04-09-.01, continued)

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-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

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

3. "Time/temperature control for safety food" does not include:

- (i) 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;
- (ii) 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;
- (iii) A food that because of its pH or A_w value, or interaction of A_w and pH values, is designated as a non-TCS food in Table A or B of this definition;
- (iv) 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

(Rule 0080-04-09-.01, continued)

- (III) A combination of intrinsic and extrinsic factors; or
 - (v) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subparts 3(i) – 3(iv) 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.
- (117) “USDA” means the U.S. Department of Agriculture.
- (118) “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.
- (119) “Variance” means a written document issued by the commissioner that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the commissioner, a health hazard or nuisance will not result from the modification or waiver.
- (120) “Warewashing” means the cleaning and sanitizing of utensils sanitizing of utensils and food-contact surfaces of equipment.
- (121) “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.

Authority: T.C.A. § 53-8-204. **Administrative History:** Original rule filed September 30, 1986; effective November 14, 1986. Amendment filed February 20, 2002; effective June 28, 2002. Amendment filed June 27, 2008; effective October 28, 2008. Repeal and new rule filed March 27, 2015; effective June 25, 2015.

0080-04-09-.02 MANAGEMENT AND PERSONNEL.

- (1) Supervision.
 - (a) Responsibility 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. (Pf)
 - (b) Knowledge Demonstration. Based on the risks inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the commissioner knowledge of foodborne disease prevention, application of the Hazard Analysis and Critical Control Point principles, and the requirements of these rules. The person in charge shall demonstrate this knowledge by:
 1. Complying with these rules by having no violations of priority items during the current inspection; (Pf)
 2. Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; (Pf) or
 3. Responding correctly to the inspector’s questions as they relate to the specific food operation. The areas of knowledge include:
 - (i) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee; (Pf)

(Rule 0080-04-09-.02, continued)

- (ii) 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; (Pf)
- (iii) Describing the symptoms associated with the diseases that are transmissible through food; (Pf)
- (iv) Explaining the significance of the relationship between maintaining the time and temperature of time/temperature control for safety food and the prevention of foodborne illness; (Pf)
- (v) Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish; (Pf)
- (vi) Stating the required food temperatures and times for safe cooking of time/temperature control for safety food including meat, poultry, eggs, and fish; (Pf)
- (vii) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of time/temperature control for safety food; (Pf)
- (viii) Describing the relationship between the prevention of foodborne illness and the management and control of the following:
 - (I) Cross contamination, (Pf)
 - (II) Hand contact with ready-to-eat foods, (Pf)
 - (III) Handwashing, (Pf) and
 - (IV) Maintaining the food establishment in a clean condition and in good repair; (Pf)
- (ix) 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; (Pf)
- (x) Explaining the relationship between food safety and providing equipment that is:
 - (I) Sufficient in number and capacity, (Pf) and
 - (II) Properly designed, constructed, located, installed, operated, maintained, and cleaned; (Pf)
- (xi) Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment; (Pf)
- (xii) 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; (Pf)

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- (xiii) 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; (Pf)
 - (xiv) 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 these regulations; (Pf)
 - (xv) 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 chapter, or an agreement between the commissioner and the food establishment; (Pf)
 - (xvi) Explaining the responsibilities, rights, and authorities assigned by these regulations to the:
 - (I) Food employee, (Pf)
 - (II) Conditional employee, (Pf)
 - (III) Person in charge, (Pf)
 - (IV) Commissioner; (Pf) and
 - (xvii) Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and exclusion or restriction of food employees. (Pf)
- (c) Duties. Person in Charge. The person in charge shall ensure that:
1. Food establishment operations are not conducted in a private home, except as provided in T.C.A. § 53-8-117, or in a room used as living or sleeping quarters as specified under 0080-04-09-.06(2)(b)10; (Pf)
 2. Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that the person in charge may authorize brief visits and tours 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; (Pf)
 3. Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with these regulations; (Pf)
 4. Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing; (Pf)
 5. Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt; (Pf)

(Rule 0080-04-09-.02, continued)

6. Employees are properly cooking 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 0080-04-09-.04(2)(c) or 0080-04-09-.04(5)(b); (Pf)
 7. Employees are using proper methods to rapidly cool potentially time/temperature control for safety foods that are not held hot or are not for consumption within four hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling; (Pf)
 8. Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed as specified under 0080-04-09-.03(6)(c) that the food is not cooked sufficiently to ensure its safety; (Pf)
 9. 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; (Pf)
 10. 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 0080-04-09-.03(3)(d)6; (Pf)
 11. Except when approval is obtained from the commissioner as specified in 0080-04-09-.03(3)(a)1(v), 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; (Pf)
 12. Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; (Pf) and
 13. 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 part (2)(a)1. (Pf)
- (2) Employee Health.
- (a) Responsibility of Permit Holder, Person in Charge, and Conditional Employees.
1. 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:
 - (i) Has any of the following symptoms:
 - (I) Vomiting, (P)
 - (II) Diarrhea, (P)

(Rule 0080-04-09-.02, continued)

- (III) Jaundice, (P)
- (IV) Sore throat with fever, (P) or
- (V) 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, (P)
 - II. On exposed portions of the arms, unless the lesion is protected by an impermeable cover, (P) or
 - III. On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage; (P)
- (ii) Has an illness diagnosed by a health practitioner due to:
 - (I) Norovirus, (P)
 - (II) Hepatitis A virus, (P)
 - (III) Shigella spp., (P)
 - (IV) Enterohemorrhagic or Shiga toxin-producing Escherichia coli, (P)
 - (V) Salmonella Typhi; (P), or
 - (VI) Nontyphoidal Salmonella; (P)
- (iii) Had a previous illness, diagnosed by a health practitioner, within the past three months due to Salmonella Typhi, without having received antibiotic therapy, as determined by a health practitioner; (P)
- (iv) 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: (P)
 - (I) Norovirus within the past 48 hours of the last exposure, (P)
 - (II) Enterohemorrhagic or Shiga toxin-producing Escherichia coli, or Shigella spp. within the past three days of the last exposure, (P)
 - (III) Salmonella Typhi within the past 14 days of the last exposure, (P) or
 - (IV) Hepatitis A virus within the past 30 days of the last exposure; (P) or
- (v) 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:

(Rule 0080-04-09-.02, continued)

- (I) Norovirus within the past 48 hours of the last exposure, (P)
 - (II) Enterohemorrhagic or Shiga toxin-producing Escherichia coli, (P) or Shigella spp. within the past three days of the last exposure,
 - (III) Salmonella Typhi within the past 14 days of the last exposure, (P) or
 - (IV) Hepatitis A virus within the past 30 days of the last exposure. (P)
2. The person in charge shall notify the commissioner when a food employee is:
- (i) Jaundiced, (Pf) or
 - (ii) Diagnosed with an illness due to a pathogen as specified under items 1(ii)(I) - (V) of this subparagraph. (Pf)
3. The person in charge shall ensure that a conditional employee:
- (i) Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under subparts 1(i) - (iii) of this subparagraph, is prohibited from becoming a food employee until the conditional employee meets the criteria for the specific symptoms or diagnosed illness as specified under 0080-04-09-.02(2)(c); (P) and
 - (ii) 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 subparts 1(iv) – (v), is prohibited from becoming a food employee until the conditional employee meets the criteria as specified under 0080-04-09-.02(2)(c)9. (P)
4. 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 subparts 1(i) - (v) of this subparagraph is:
- (i) Excluded as specified under 0080-04-09-.02(2)(b)1-3, 4(i), 5(i), 6(i), or 7(i) and in compliance with the provisions specified under 0080-04-09-.02(2)(c)1-7; (P) or
 - (ii) Restricted as specified under 0080-04-09-.02(2)(b)4(ii), 5(ii), 6(ii), 7(ii), or 0080-04-09-.02(2)(b) 8 or 9 and in compliance with the provisions specified under 0080-04-09-.02(2)(c)4-9. (P)
5. A food employee or conditional employee shall report to the person in charge the information as specified under part 1 of this subparagraph. (Pf)
6. A food employee shall:
- (i) Comply with an exclusion as specified under 0080-04-09-.02(2)(b)1-3, 4(i), 5(i), 6(i), or 7(i) and with the provisions specified under 0080-04-09-.02(2)(c)4-9; (P) or
 - (ii) Comply with a restriction as specified under 0080-04-09-.02(2)(b)4(ii), 5(ii), 6(ii), 7(ii), or 0080-04-09-.02(2)(b) 8 or 9 and comply with the provisions specified under 0080-04-09-.02(2)(c)4-9. (P)

(Rule 0080-04-09-.02, continued)

- (b) Exclusions and Restrictions. The person in charge shall exclude or restrict a food employee from a food establishment in accordance with the following:
1. Except when the symptom is from a noninfectious condition, exclude a food employee if the food employee is:
 - (i) Symptomatic with vomiting or diarrhea; (P) or
 - (ii) Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, Shigella spp., or Enterohemorrhagic or Shiga toxin-producing E. coli. (P)
 2. Exclude a food employee who is:
 - (i) Jaundiced and the onset of jaundice occurred within the last seven 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; (P)
 - (ii) Diagnosed with an infection from hepatitis A virus within 14 calendar days from onset of any illness symptoms, or within seven calendar days of the onset of jaundice; (P) or
 - (iii) Diagnosed with an infection from hepatitis A virus without developing symptoms. (P)
 3. 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 0080-04-09-.02(2)(a)1(iii). (P)
 4. If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:
 - (i) Exclude the food employee who works in a food establishment serving a highly susceptible population; (P) or
 - (ii) Restrict the food employee who works in a food establishment not serving a highly susceptible population. (P)
 5. If a food employee is diagnosed with an infection from Shigella spp. and is asymptomatic:
 - (i) Exclude the food employee who works in a food establishment serving a highly susceptible population; (P) or
 - (ii) Restrict the food employee who works in a food establishment not serving a highly susceptible population. (P)
 6. If a food employee is diagnosed with an infection from Enterohemorrhagic or Shiga toxin-producing E. coli, and is asymptomatic:
 - (i) Exclude the food employee who works in a food establishment serving a highly susceptible population; (P) or

(Rule 0080-04-09-.02, continued)

- (ii) Restrict the food employee who works in a food establishment not serving a highly susceptible population. (P)
- 7. If a food employee is ill with symptoms of acute onset of sore throat with fever:
 - (i) Exclude the food employee who works in a food establishment serving a highly susceptible population; (P) or
 - (ii) Restrict the food employee who works in a food establishment not serving a highly susceptible population. (P)
- 8. 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 0080-04-09-.02(2)(a)1(i)(V), restrict the food employee. (P)
- 9. If a food employee is exposed to a foodborne pathogen as specified under 0080-04-09-.02(2)(a)1(iv) or (v), restrict the food employee who works in a food establishment serving a highly susceptible population. (P)
- (c) Removal, Adjustment, or Retention of Exclusions and Restrictions. The person in charge shall adhere to the following conditions when removing, adjusting, or retaining the exclusion or restriction of a food employee:
 - 1. Except when a food employee is diagnosed with an infection from hepatitis A virus or Salmonella Typhi:
 - (i) Reinstate a food employee who was excluded as specified under 0080-04-09-.02(2)(b)1(i) if the food employee:
 - (I) Is asymptomatic for at least 24 hours; (P) or
 - (II) Provides to the person in charge written medical documentation from a health practitioner that states the symptom is from a noninfectious condition. (P)
 - (ii) If a food employee was diagnosed with an infection from Norovirus and excluded as specified under 0080-04-09-.02(2)(b)1(ii):
 - (I) 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 subparts 4(i) or (ii) of this subparagraph are met; (P) or
 - (II) 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 subparts 4(i) or (ii) of this subparagraph are met. (P)
 - (iii) If a food employee was diagnosed with an infection from Shigella spp. and excluded as specified under 0080-04-09-.02(2)(b)1(ii):
 - (I) 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

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- specified under subparts 5(i) and (ii) of this subparagraph are met; (P) or
- (II) 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 subparts 5(i) and (ii), or 5(i) and (iii) of this subparagraph are met. (P)
- (iv) If a food employee was diagnosed with an infection from Enterohemorrhagic or Shiga toxin-producing Escherichia coli and excluded as specified under 0080-04-09-.02(2)(b)1(ii):
- (I) 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 subparts 6(i) or (ii) of this subparagraph are met; (P) or
 - (II) 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 subparts 6(i) or (ii) are met. (P)
2. Reinstatement a food employee who was excluded as specified under 0080-04-09-.02(2)(b)2 if the person in charge obtains approval from the commissioner and one of the following conditions is met;
- (i) The food employee has been jaundiced for more than seven calendar days; (P)
 - (ii) The anicteric food employee has been symptomatic with symptoms other than jaundice for more than 14 calendar days; (P) or
 - (iii) 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. (P)
3. Reinstatement a food employee who was excluded as specified under 0080-04-09-.02(2)(b)3 if:
- (i) The person in charge obtains approval from the commissioner; (P) and
 - (ii) 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. (P)
4. Reinstatement a food employee who was excluded as specified under 0080-04-09-.02(2)(b)1(ii) or 4(i) who was restricted under 0080-04-09-.02(2)(b)4(ii) if the person in charge obtains approval from the commissioner and one of the following conditions is met:
- (i) 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; (P)

(Rule 0080-04-09-.02, continued)

- (ii) 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; (P) or
 - (iii) 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. (P)
- 5. Reinstatement of a food employee who was excluded as specified under 0080-04-09-.02(2)(b)1(ii) or 5(i) or who was restricted under 0080-04-09-.02(2)(b)5(ii) if the person in charge obtains approval from the commissioner and one of the following conditions is met:
 - (i) 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 two consecutive negative stool specimen cultures that are taken:
 - (I) Not earlier than 48 hours after discontinuance of antibiotics, (P) and
 - (II) At least 24 hours apart; (P)
 - (ii) The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than seven calendar days have passed since the food employee became asymptomatic; (P) or
 - (iii) The food employee was excluded or restricted and did not develop symptoms and more than seven calendar days have passed since the food employee was diagnosed. (P)
- 6. Reinstatement of a food employee who was excluded or restricted as specified under 0080-04-09-.02(2)(b)1(ii) or 6(i) or who was restricted under 0080-04-09-.02(2)(b)6(ii) if the person in charge obtains approval from the commissioner and one of the following conditions is met:
 - (i) 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 two consecutive negative stool specimen cultures that are taken:
 - (I) Not earlier than 48 hours after discontinuance of antibiotics; (P) and
 - (II) At least 24 hours apart; (P)
 - (ii) The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than seven calendar days have passed since the food employee became asymptomatic; (P) or
 - (iii) The food employee was excluded or restricted and did not develop symptoms and more than seven days have passed since the food employee was diagnosed. (P)
- 7. Reinstatement of a food employee who was excluded or restricted as specified under 0080-04-09-.02(2)(b)7(i) or (ii) if the food employee provides to the person in

(Rule 0080-04-09-.02, continued)

charge written medical documentation from a health practitioner stating that the food employee meets one of the following conditions:

- (i) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than 24 hours; (P)
 - (ii) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection; (P) or
 - (iii) Is otherwise determined by a health practitioner to be free of a *Streptococcus pyogenes* infection. (P)
8. Reinstate a food employee who was restricted as specified under 0080-04-09-.02(2)(b)8 if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:
- (i) 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; (P)
 - (ii) An impermeable cover on the arm if the infected wound or pustular boil is on the arm; (P) or
 - (iii) A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body. (P)
9. Reinstate a food employee who was restricted as specified under 0080-04-09-.02(2)(b)9 and was exposed to one of the following pathogens as specified under 0080-04-09-.02(2)(a)1(iv) or (v):
- (i) Norovirus and one of the following conditions is met:
 - (I) More than 48 hours have passed since the last day the food employee was potentially exposed; (P) or
 - (II) More than 48 hours have passed since the food employee's household contact became asymptomatic. (P)
 - (ii) *Shigella* spp. or Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* and one of the following conditions are met:
 - (I) More than three calendar days have passed since the last day the food employee was potentially exposed; (P) or
 - (II) More than three calendar days have passed since the food employee's household contact became asymptomatic. (P)
 - (iii) *S. Typhi* and one of the following conditions are met:
 - (I) More than 14 calendar days have passed since the last day the food employee was potentially exposed; (P) or
 - (II) More than 14 calendar days have passed since the food employee's household contact became asymptomatic. (P)
 - (iv) Hepatitis A virus and one of the following conditions is met:

(Rule 0080-04-09-.02, continued)

- (I) The food employee is immune to hepatitis A virus infection because of a prior illness from hepatitis A; (P)
 - (II) The food employee is immune to hepatitis A virus infection because of vaccination against hepatitis A; (P)
 - (III) The food employee is immune to hepatitis A virus infection because of IgG administration; (P)
 - (IV) More than 30 calendar days have passed since the last day the food employee was potentially exposed; (P)
 - (V) More than 30 calendar days have passed since the food employee's household contact became jaundiced; (P) or
 - (VI) 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 items 9(iv)(IV) and (V) of this subpart, and the food employee receives additional training about:
 - I. Hepatitis A symptoms and preventing the transmission of infection, (P)
 - II. Proper handwashing procedures, (P) and
 - III. Protecting ready-to-eat food from contamination introduced by bare hand contact. (P)
- (3) Personal Cleanliness.
- (a) Clean Condition. Food employees shall keep their hands and exposed portions of their arms clean. (P)
 - (b) Cleaning Procedure.
 - 1. Except as specified in part 4 of this subparagraph, 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 or 0080-04-09-.05(2)(b)2 and 0080-04-09-.06(3)(a). (P)
 - 2. 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:
 - (i) Rinse under clean, running warm water; (P)
 - (ii) Apply an amount of cleaning compound recommended by the cleaning compound manufacturer; (P)
 - (iii) Rub together vigorously for at least 10 to 15 seconds while:
 - (I) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure, (P) and

(Rule 0080-04-09-.02, continued)

- (II) 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; (P)
 - (iv) Thoroughly rinse under clean, running warm water; (P) and
 - (v) Immediately follow the cleaning procedure with thorough drying using a method as specified under 0080-04-09-.06(3)(a)3. (P)
 - 3. 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.
 - 4. 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.
- (c) When to Wash. Food employees shall clean their hands and exposed portions of their arms as specified under 0080-04-09-.02(3)(b) immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles (P) and:
 - 1. After touching bare human body parts other than clean hands and clean, exposed portions of arms; (P)
 - 2. After using the toilet room; (P)
 - 3. After caring for or handling service animals or aquatic animals as specified in 0080-04-09-.02(4)(d)2; (P)
 - 4. Except as specified in 0080-04-09-.02(4)(a)2, after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; (P)
 - 5. After handling soiled equipment or utensils; (P)
 - 6. During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; (P)
 - 7. When switching between working with raw food and working with ready-to-eat food; (P)
 - 8. Before donning gloves for working with food; (P) and
 - 9. After engaging in other activities that contaminate the hands. (P)
- (d) Where to Wash. Food employees shall clean their hands in a handwashing sink or approved automatic handwashing facility and shall 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. (Pf)
- (e) Hand Antiseptics.
 - 1. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

(Rule 0080-04-09-.02, continued)

- (i) Comply with one of the following:
 - (I) 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; (Pf) or
 - (II) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, (Pf) and
 - (ii) Comply with one of the following:
 - (I) 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;(Pf) or
 - (II) 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, (Pf) 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, (Pf) and
 - III. Be applied only to hands that are cleaned as specified under 0080-04-09-.02(3)(b). (Pf)
2. If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under (e)(ii) of this paragraph, use shall be:
- (i) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; (Pf) or
 - (ii) Limited to situations that involve no direct contact with food by the bare hands.
3. 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. (Pf)
- (f) Maintenance.
- 1. Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. (Pf)
 - 2. Unless wearing intact gloves in good repair, a food employee shall not wear fingernail polish or artificial fingernails when working with exposed food. (Pf)
- (g) Prohibition. Except for a plain ring such as a wedding band, while preparing food, food employees shall not wear jewelry including medical information jewelry on their arms and hands.

(Rule 0080-04-09-.02, continued)

(h) Clean Condition. Food employees shall wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

(4) Hygienic Practices.

(a) Eating, Drinking, or Using Tobacco.

1. Except as specified in part 2 of this subparagraph, 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 cannot result.
2. A food employee may drink from a closed beverage container if the container is handled to prevent contamination of:
 - (i) The employee's hands;
 - (ii) The container; and
 - (iii) Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(b) 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 shall not work with exposed food; clean equipment, utensils, and linens; or unwrap single-service or single-use articles.

(c) Effectiveness.

1. Except as provided in part 2 of this subparagraph, 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.
2. 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.

(d) Handling Prohibition.

1. Except as specified in part 2 of this subparagraph, food employees shall not care for or handle animals that may be present such as patrol dogs, service animals, or pets that are allowed as specified in 0080-04-09-.06(5)(o)2(i)-(v). (Pf)
2. Food employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacean in display tanks if they wash their hands as specified under 0080-04-09-.02(3)(b) and 0080-04-09-.02(3)(c)3.

Authority: T.C.A. § 53-8-204. **Administrative History:** Original rule filed September 30, 1986; effective November 14, 1986. Amendment filed February 20, 2002; effective June 28, 2002.

(Rule 0080-04-09-.02, continued)

Amendments filed June 27, 2008; effective October 28, 2008. Repeal and new rule filed March 27, 2015; effective June 25, 2015.

0080-04-09-.03 FOOD.

- (1) Condition. Safe, Unadulterated, and Honestly Presented. Food shall be safe, unadulterated, and, as specified under 0080-04-09-.03(6)(a)2, honestly presented. (P)
- (2) Sources, Specifications, and Original Containers and Records.
 - (a) Sources.
 1. Compliance with Food Law.
 - (i) Food shall be obtained from sources that comply with law. (P)
 - (ii) Food prepared in a non-permitted private home shall not be used or offered for human consumption in a food establishment. (P)
 - (iii) 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 0080-04-09-.03(2)(b)7 and 8. (Pf)
 - (iv) Fish, other than those specified in 0080-04-09-.03(4)(b), that are intended for consumption in raw or undercooked form and allowed as specified in 0080-04-09-.03(4)(a)1(iv), may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified under 0080-04-09-.03(4)(b); or if they are frozen on the premises as specified under 0080-04-09-.03(4)(b) and records are retained as specified under 0080-04-09-.03(4)(b)2.
 - (v) Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in 0080-04-09-.03(4)(a)1(iii) shall be:
 - (I) 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; (Pf) or
 - (II) Deemed acceptable by the commissioner based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef; (Pf) and
 - (III) If individually cut in a food establishment:
 - I. Cut from whole-muscle, intact beef that is labeled by a food processing plant as specified in item (v)(I) or identified as specified in item (v)(II) of this part, (Pf)
 - II. Prepared so they remain intact; (Pf) and
 - III. If packaged for undercooking in a food establishment, labeled in part (a)1(v)(I) or identified as specified in part (a)1(v)(II). (Pf)

(Rule 0080-04-09-.03, continued)

- (vi) 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).
 - (vii) 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).
2. Food in a Hermetically Sealed Container. Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant. (P)
 3. Fluid Milk and Milk Products. Fluid milk and milk products shall be obtained from sources that comply with Grade A standards as specified in law. (P)
 4. Fish.
 - (i) Fish received for sale or service shall be: (P)
 - (I) Commercially and legally caught or harvested; (P) or
 - (II) Approved for sale or service. (P)
 - (ii) Molluscan shellfish that are recreationally caught shall not be received for sale or service. (P)
 5. Molluscan Shellfish.
 - (i) 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. (P)
 - (ii) Molluscan shellfish received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List. (P)
 6. Wild Mushrooms.
 - (i) Except as specified in subpart (ii) of this part, 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. (P)
 - (ii) This part does not apply to:
 - (I) 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
 - (II) 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.
 7. Game Animals.

(Rule 0080-04-09-.03, continued)

- (i) If game animals are received for sale or service they shall be:
 - (I) Commercially raised for food (P) and:
 - I. Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, (P) or
 - II. Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, (P) and
 - III. Raised, slaughtered, and processed according to:
 - A. Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, (P) and
 - B. 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; (P)
 - (II) 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 of rabbits that are "inspected and certified" in accordance with 9 CFR 354 voluntary inspection of rabbits and edible products thereof; (P)
 - (III) As allowed by law, for wild game animals that are live-caught:
 - I. Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction, (P) and
 - II. Slaughtered and processed according to:
 - A. Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, (P) and
 - B. 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; (P) or
 - (IV) As allowed by law, for field-dressed wild game animals under a routine inspection program that ensures the animals:

(Rule 0080-04-09-.03, continued)

- I. Receive a postmortem examination by an approved veterinarian or veterinarian's designee, (P) or
 - II. 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, (P) and
 - III. 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. (P)
- (ii) A game animal shall 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.
- (b) Specifications for Receiving.
1. Temperature.
 - (i) Except as specified in subpart (ii) of this part, refrigerated, time/temperature control for safety food shall be at a temperature of 5°C (41°F) or below when received. (P)
 - (ii) If a temperature other than 5°C (41°F) for a time/temperature control for safety food is specified in law governing its distribution, such as laws governing milk and molluscaun shellfish, the food may be received at the specified temperature.
 - (iii) Raw eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 5°C (41°F) or less. (P)
 - (iv) Time/temperature control for safety food that is cooked to a temperature and for a time specified under 0080-04-09-.03(4)(a)1-3 and received hot shall be at a temperature of 57°C (135°F) or above. (P)
 - (v) A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen. (Pf)
 - (vi) Upon receipt, time/temperature control for safety food shall be free of evidence of previous temperature abuse. (Pf)
 2. Additives. Food shall 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. (P)
 3. Eggs. Eggs shall be received clean and sound and shall 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. (P)
 4. Eggs and Milk Products, Pasteurized.

(Rule 0080-04-09-.03, continued)

- (i) Egg Products shall be obtained pasteurized. (P)
 - (ii) Fluid and dry milk and milk products shall:
 - (I) Be obtained pasteurized; (P) and
 - (II) Comply with Grade A standards as specified in law. (P)
 - (iii) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135 - Frozen desserts. (P)
 - (iv) 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. (P)
5. 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. (Pf)
6. Ice. Ice for use as a food or a cooling medium shall be made from drinking water. (P)
7. Shucked Shellfish, Packaging and Identification.
- (i) Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the: (Pf)
 - (I) Name, address, and certification number of the shucker, packer or re-packer of the molluscan shellfish; (Pf) and
 - (II) The "sell by" or "best if used 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. (Pf)
 - (ii) 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 subpart (i) of this part 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.
8. Shellstock Identification.
- (i) Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or 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: (Pf)
 - (I) Except as specified under subpart (iii) of this part, on the harvester's tag or label, the following information in the following order: (Pf)
 - I. The harvester's identification number that is assigned by the shellfish control authority, (Pf)

(Rule 0080-04-09-.03, continued)

- II. The date of harvesting, (Pf)
 - III. 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, (Pf)
 - IV. The type and quantity of shellfish, (Pf) and
 - V. 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"; (Pf) and
- (II) Except as specified in subpart (iv) of this part, on each dealer's tag or label, the following information in the following order: (Pf)
- I. The dealer's name and address, and the certification numbers assigned by the shellfish control authority, (Pf)
 - II. The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested, (Pf)
 - III. The same information as specified for a harvester's tag under subitems 8(i)(I)II-IV of this subparagraph, (Pf) and
 - IV. 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." (Pf)
- (ii) 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 subpart 8(i) of this subparagraph 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).
- (iii) 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.
- (iv) If the harvester's tag or label is designed to accommodate each dealer's identification as specified under subitems 8(i)(II)I and II of this subparagraph, individual dealer tags or labels need not be provided.
9. 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.
10. Commercially Processed - Pre-packaged juice shall:
- (i) Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120 Hazard Analysis and Critical Control (HACCP) Systems; (Pf) and

(Rule 0080-04-09-.03, continued)

- (ii) 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. (P)
- (c) Original Containers and Records.
1. Molluscan Shellfish, Original Container.
 - (i) Except as specified in subparts (ii) - (iv) of this part, molluscan shellfish shall not be removed from the container in which they are received other than immediately before sale or preparation for service.
 - (ii) 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:
 - (I) The source of the shellstock on display is identified as specified under 0080-04-09-.03(2)(b)8 and recorded as specified under 0080-04-09-.03(2)(c)2; and
 - (II) The shellstock are protected from contamination.
 - (iii) 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:
 - (I) The labeling information for the shellfish on display as specified under 0080-04-09-.03(2)(b)7 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and
 - (II) The shellfish are protected from contamination.
 - (iv) 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:
 - (I) The labeling information for the shellfish is on each consumer self-service container as specified under 0080-04-09-.03(2)(b)7 and 0080-04-09-.03(6)(b)1 and 0080-04-09-.03(6)(b)2(i)-(v);
 - (II) The labeling information as specified under 0080-04-09-.03(2)(b)7 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;
 - (III) The labeling information and dates specified under item (iv)(II) of this part are maintained for 90 days; and
 - (IV) The shellfish are protected from contamination.
 2. Shellstock, Maintaining Identification.
 - (i) Except as specified under item (iii)(II) of this part, shellstock tags or labels shall remain attached to the container in which the shellstock are received until the container is empty. (Pf)

(Rule 0080-04-09-.03, continued)

- (ii) The date when the last shellstock from the container is sold or served shall be recorded on the tag or label. (Pf)
 - (iii) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under subpart (ii) of this part, by: (Pf)
 - (I) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under subpart (ii) of this part; (Pf) and
 - (II) If shellstock are removed from its tagged or labeled container:
 - I. Preserving source identification by using a record keeping system as specified under item (iii)(I) of this part, (Pf) and
 - II. 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. (Pf)
- (3) Protection from Contamination after Receiving.
- (a) Preventing Contamination by Employees.
 - 1. Preventing Contamination from Hands.
 - (i) Food employees shall wash their hands as specified under 0080-04-09-.02(3)(b).
 - (ii) Except when washing fruits and vegetables as specified under 0080-04-09-.03(3)(b)5 or as specified in subpart (v) of this part, food employees shall not contact exposed, ready-to-eat with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment. (P)
 - (iii) Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form. (Pf)
 - (iv) Subpart (ii) of this part does not apply to a food employee who contacts exposed, ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient to a food that is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 74°C (165°F).
 - (v) Food employees not serving a highly susceptible population may contact exposed, ready-to-eat food with their bare hands if:
 - (I) The permit holder obtains prior approval from the commissioner;
 - (II) Written procedures are maintained in the food establishment and made available to the commissioner upon request that include:

(Rule 0080-04-09-.03, continued)

- I. For each bare hand contact procedure, a listing of the specific ready-to-eat foods that are touched by bare hands,
 - II. Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under 0080-04-09-.05(2)(c)1, 0080-04-09-.05(2)(d)1, 0080-04-09-.05(2)(e)1, 0080-04-09-.06(3)(a)2, 0080-04-09-.06(3)(a)3, and 0080-04-09-.06(3)(a)5, are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;
- (III) A written employee health policy that details how the food establishment complies with 0080-04-09-.02(2)(a), (b), and (c) including:
- I. 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 0080-04-09-.02(2)(a)1,
 - II. Documentation that food employees and conditional employees acknowledge their responsibilities as specified under 0080-04-09-.02(2)(a)5 and 6, and
 - III. Documentation that the person in charge acknowledges the responsibilities as specified under 0080-04-09-.02(2)(a)2, 3, and 4, and 0080-04-09-.02(2)(b) and 0080-04-09-.02(2)(c);
- (IV) Documentation that food employees acknowledge that they have received training in:
- I. The risks of contacting the specific ready-to-eat foods with bare hands,
 - II. Proper handwashing as specified under 0080-04-09-.02(3)(b),
 - III. When to wash their hands as specified under 0080-04-09-.02(3)(c),
 - IV. Where to wash their hands as specified under 0080-04-09-.02(3)(d),
 - V. Proper fingernail maintenance as specified under 0080-04-09-.02(3)(f),
 - VI. Prohibition of jewelry as specified under 0080-04-09-.02(3)(g), and
 - VII. Good hygienic practices as specified under 0080-04-09-.02(4)(a) and 0080-04-09-.02(4)(b);
- (V) Documentation that hands are washed before food preparation and as necessary to prevent cross contamination by food employees as specified under 0080-04-09-.02(3)(a), 0080-04-09-.02(3)(b), 0080-

(Rule 0080-04-09-.03, continued)

04-09-.02(3)(c), and 0080-04-09-.02(3)(d) during all hours of operation when the specific ready-to-eat foods are prepared;

(VI) 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:

- I. Double handwashing,
- II. Nail brushes,
- III. A hand antiseptic after handwashing as specified under 0080-04-09-.02(3)(e),
- IV. Incentive programs such as paid sick leave that assist or encourage food employees not to work when they are ill, or
- V. Other control measures approved by the commissioner; and
- VI. Documentation that corrective action is taken when items (v)(I) - (VI) of this part are not followed.

2. Preventing Contamination When Tasting. A food employee shall not use a utensil more than once to taste food that is to be sold or served. (P)

(b) Preventing Food and Ingredient Contamination.

1. Packaged and Unpackaged Food – Separation, Packaging, and Segregation.

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

(I) Except as specified in subitem (I)III below, separating raw animal foods during storage, preparation, holding, and display from:

- I. Raw ready-to-eat 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, (P) and
- II. Cooked ready-to-eat food; (P)
- III. Frozen, commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.

(II) 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:

- I. Using separate equipment for each type, (P) or
- II. Arranging each type of food in equipment so that cross contamination of one type with another is prevented, (P) and
- III. Preparing each type of food at different times or in separate areas;

(Rule 0080-04-09-.03, continued)

- (III) Cleaning equipment and utensils as specified under 0080-04-09-.04(6)(b)1(i) and sanitizing as specified under 0080-04-09-.04(7)(c);
 - (IV) Except as specified under 0080-04-09-.03(5)(a)5(ii)(II) and in subpart (ii) of this part, storing the food in packages, covered containers, or wrappings;
 - (V) Cleaning hermetically sealed containers of food of visible soil before opening;
 - (VI) Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;
 - (VII) Storing damaged, spoiled, or recalled food being held in the food establishment as specified under 0080-04-09-.06(4)(d); and
 - (VIII) Separating fruits and vegetables, before they are washed as specified under 0080-04-09-.03(3)(b)5 from ready-to-eat foods.
- (ii) Item (i)(IV) of this part does not apply to:
- (I) Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;
 - (II) Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;
 - (III) Whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;
 - (IV) Food being cooled as specified under 0080-04-09-.03(5)(a)5(ii)(II); or
 - (V) Shellstock.
2. 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. Pasteurized Eggs, Substitute for Raw Eggs for Certain Recipes. Pasteurized eggs or egg product 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:
- (i) Cooked as specified under 0080-04-09-.03(4)(a)1(i) or (ii); (P) or
 - (ii) Included in 0080-04-09-.03(4)(a)1(iv). (P)
4. Protection from Unapproved Additives.
- (i) Food shall be protected from contamination that may result from the addition of, as specified in 0080-04-09-.03(2)(b)2:

(Rule 0080-04-09-.03, continued)

- (I) Unsafe or unapproved food or color additives; (P) and
 - (II) Unsafe or unapproved levels of approved and color additives. (P)
 - (ii) A food employee shall not:
 - (I) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1; (P) or
 - (II) Except for grapes, serve or sell food specified under item (I) of this subpart that is treated with sulfiting agents before receipt by the food establishment. (P)
5. Washing Fruits and Vegetables.
- (i) Except as specified in subpart (ii) of this part 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.
 - (ii) Fruits and vegetables may be washed by using chemicals as specified under 0080-04-09-.07(2)(d)2.
- (c) Preventing Contamination from Ice Used as Coolant.
- 1. 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 shall not be used as food. (P)
 - 2. Storage or Display of Food in Contact with Water or Ice.
 - (i) Packaged food shall 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.
 - (ii) Except as specified in subparts (iii) and (iv) of this part, unpackaged food shall not be stored in direct contact with undrained ice.
 - (iii) 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.
 - (iv) 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.
- (d) Preventing Contamination from Equipment, Utensils, and Linens.
- 1. Food Contact with Equipment and Utensils. Food shall only contact surfaces of:
 - (i) Equipment and utensils that are cleaned as specified under 0080-04-09-.04(6) and sanitized as specified under 0080-04-09-.04(7); (P) or

(Rule 0080-04-09-.03, continued)

- (ii) Single-service and single-use articles. (P)
2. In-Use Utensils, Between-Use Storage. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:
- (i) Except as specified under subpart (ii) of this part, in the food with their handles above the top of the food and the container;
 - (ii) In food that is not 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;
 - (iii) 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 0080-04-09-.04(6)(b) and 0080-04-09-.04(7)(b);
 - (iv) In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;
 - (v) In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not time/temperature control for safety food; or
 - (vi) 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 0080-04-09-.04(6)(b)1(iv)(VII).
3. Linens and Cloth Napkins, Use Limitation. Linens and cloth napkins shall 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.
4. Wiping Cloths, Use Limitation.
- (i) Cloths in-use for wiping food spills from tableware and carry-out containers that occur as food is being served shall be:
 - (I) Maintained dry; and
 - (II) Used for no other purpose.
 - (ii) Cloths in-use for wiping counters and other equipment surfaces shall be:
 - (I) Held between uses in a chemical sanitizer solution at a concentration specified under 0080-04-09-.04(5)(a)14; and
 - (II) Laundered daily as specified under 0080-04-09-.04(8)(b)4.
 - (iii) Cloths in-use for wiping surfaces in contact with raw animal foods shall be kept separate from cloths used for other purposes.
 - (iv) Dry wiping cloths and the chemical sanitizing solutions specified in item (ii)(I) of this part in which wet wiping cloths are held between uses shall be free of food debris and visible soil.

(Rule 0080-04-09-.03, continued)

- (v) Containers of chemical sanitizing solutions specified in item (ii)(I) of this part 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.
 - (vi) Single-use disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer's label use instructions.
5. Gloves, Use Limitation.
- (i) If used, single-use gloves shall be used for only one task such as working with ready-to-eat or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation. (P)
 - (ii) Except as specified in subpart (iii) of this part, 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 0080-04-09-.03(4) such as frozen food or a primal cut of meat.
 - (iii) 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.
 - (iv) Cloth gloves shall not be used in direct contact with food unless the food is subsequently cooked as required under 0080-04-09-.03(4) such as frozen food or a primal cut of meat.
6. Using Clean Tableware for Second Portions and Refills.
- (i) 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 shall not use tableware, including single-service articles, soiled by the consumer, to provide second portions or refills.
 - (ii) Except as specified in subpart (iii) of this part, self-service consumers shall not be allowed to use soiled tableware, including single-service articles, to obtain additional food from the display and serving equipment.
 - (iii) Drinking cups and containers may be reused by self-service consumers if refilling is a contamination-free process as specified under 0080-04-09-.04(2)(d)3(i),(ii) and (iv).
7. Refilling Returnables.
- (i) A take-home food container returned to a food establishment shall not be refilled at a food establishment with a time/temperature control for safety food.
 - (ii) Except as specified in subpart (iii) of this part, a take-home food container refilled with food that is not time/temperature control for safety food shall be cleaned as specified under 0080-04-09-.04(6)(c)7(ii).

(Rule 0080-04-09-.03, continued)

- (iii) 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 0080-04-09-.04(2)(d)3(i), (ii) and (iv).
- (e) Preventing Contamination from the Premises.
- 1. Food Storage.
 - (i) Except as specified in subparts (ii) and (iii) of this part, food shall be protected from contamination by storing the food:
 - (I) In a clean, dry location;
 - (II) Where it is not exposed to splash, dust, or other contamination; and
 - (III) At least 15 cm (6 inches) above the floor.
 - (ii) 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 0080-04-09-.04(2)(d)18.
 - (iii) 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.
 - 2. Food Storage, Prohibited Areas. Food shall not be stored:
 - (i) In locker rooms;
 - (ii) In toilet rooms;
 - (iii) In dressing rooms;
 - (iv) In garbage rooms;
 - (v) In mechanical rooms;
 - (vi) Under sewer lines that are not shielded to intercept potential drips;
 - (vii) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
 - (viii) Under open stairwells; or
 - (ix) Under other sources of contamination.
 - 3. Food Preparation. During preparation, unpackaged food shall be protected from environmental sources of contamination.
- (f) Preventing Contamination by Consumers.
- 1. 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

(Rule 0080-04-09-.03, continued)

- of packaging; counter, service line, or salad bar food guards; display cases; or other effective means. (P)
2. Condiments, Protection. 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.
 3. Consumer Self-Service Operations.
 - (i) Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish shall not be offered for consumer self-service. This subpart does not apply to:
 - (I) Consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish;
 - (II) 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
 - (III) Raw, frozen, shell-on shrimp, or lobster.
 - (ii) 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. (Pf)
 - (iii) Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures. (Pf)
 4. Returned Food and Re-Service of Food.
 - (i) Except as specified in subpart (ii) of this part, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer shall not be offered as food for human consumption. (P)
 - (ii) Except as specified under 0080-04-09-.03(8)(a)7, a container of food that is not time/temperature control for safety food may be re-served from one consumer to another if:
 - (I) 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
 - (II) The food, such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition.
- (g) Preventing Contamination from Other Sources. Miscellaneous Sources of Contamination. Food shall be protected from contamination that may result from a factor or source not specified under 0080-04-09-.03(3).
- (4) Destruction of Organisms of Public Health Concern.
 - (a) Cooking.
 1. Raw Animal Foods.

(Rule 0080-04-09-.03, continued)

- (i) Except as specified under subparts (ii), (iii) and (iv) of this part, 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:
 - (I) 63°C (145°F) or above for 15 seconds for: (P)
 - I. Raw eggs that are broken and prepared in response to a consumer's order and for immediate service, (P) and
 - II. as specified under items (i)(I) and (III) and subpart (ii), and in subpart (iii) of this part, fish and meat including game animals commercially raised for food as specified under 0080-04-09-.03(2)(a)7(i)(I) and game animals under a voluntary inspection program as specified under 0080-04-09-.03(2)(a)7(i)(II); (P)
 - (II) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites, mechanically tenderized, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under 0080-04-09-.03(2)(a)7(i)(I), and game animals under a voluntary inspection program as specified 0080-04-09-.03(2)(a)7(i)(II) and raw eggs that are not prepared as specified under subitem 1(i)(I) of this subparagraph: (P)

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

; or

- (III) 74°C (165°F) or above for 15 seconds for poultry, baluts, wild game animals as specified under 0080-04-09-.03(2)(a)7(i)(III) and (IV), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry, or ratites. (P)
- (ii) Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:
 - (I) 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: (P)

(Rule 0080-04-09-.03, continued)

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 4.5 kg (10lbs)	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

¹Relative 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

- (II) 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: (P)

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		

¹Holding time may include postoven heat rise.

- (iii) A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:
 - (I) The food establishment serves a population that is not a highly susceptible population,
 - (II) The steak is labeled to indicate that it meets the definition of "whole-muscle, intact beef" as specified under 0080-04-09-.03(2)(a)1(v), and
 - (III) 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.

(Rule 0080-04-09-.03, continued)

- (iv) A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartar; 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 subpart (iii) of this part, may be served or offered for sale upon consumer request or selection in a ready-to-eat form if:
 - (I) As specified under 0080-04-09-.03(8)(a)3(i) and (ii) , the food establishment serves a population that is not a highly susceptible population;
 - (II) The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat; (Pf) and
 - (III) The consumer is informed as specified under 0080-04-09-.03(6)(c) that to ensure its safety, the food should be cooked as specified under subpart (i) or (ii) of this part; or
 - (IV) The commissioner grants a variance from subpart (i) or (ii) of this part as specified in 0080-04-09-.08(1)(c)1 based on a HACCP plan that:
 - I. Is submitted by the permit holder and approved as specified under 0080-04-09-.08(1)(c)2,
 - II. Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food, and
 - III. Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions of the variance.
2. Microwave Cooking. Raw animal foods cooked in a microwave oven shall be:
- (i) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;
 - (ii) Covered to retain surface moisture;
 - (iii) Heated to a temperature of at least 74°C (165°F) in all parts of the food; and
 - (iv) Allowed to stand covered for two minutes after cooking to obtain temperature equilibrium.
3. Plant Food Cooking for Hot Holding. Fruits and vegetables cooked for hot holding shall be cooked to a temperature of 57°C (135°F). (Pf)
4. Non-Continuous Cooking of Raw Animal Foods. Raw animal foods cooked using a non-continuous cooking process shall be:
- (i) Subject to an initial heating process that is no longer than sixty minutes in duration; (P)

(Rule 0080-04-09-.03, continued)

- (ii) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked time/temperature control for safety food under 0080-04-09-.03(5)(a)4; (P)
- (iii) After cooling, held frozen or cold, as specified for time/temperature control for safety food under 0080-04-09-.03(5)(a)6(i)(II); (P)
- (iv) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature of at least 74°C (165°F) for 15 seconds; (P)
- (v) Cooled according to the time and temperature parameters specified for cooked time /temperature control for safety food under 0080-04-09-.03(5)(a)4 if not either hot held as specified under 0080-04-09-.03(5)(a)6(i)(I), served immediately, or held using time as a public health control as specified under 0080-04-09-.03(5)(a)9 after complete cooking; (P) and
- (vi) Prepared and stored according to written procedures that:
 - (I) Have obtained prior approval from the commissioner; (Pf)
 - (II) Are maintained in the food establishment and are available to the commissioner upon request; (Pf)
 - (III) Describe how the requirements specified under subparts (i)-(v) of this part are to be monitored and documented by the permit holder and the corrective actions to be taken if the requirements are not met; (Pf)
 - (IV) Describe how the foods, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as foods that must be cooked as specified under subpart (iv) of this part prior to being offered for sale or service; (Pf) and
 - (V) Describe how the foods, after initial heating but prior to cooking as specified under subpart (iv) of this part, are to be separated from ready-to-eat foods as specified under 0080-04-09-.03(3)(b). (Pf)

(b) Freezing.

1. Parasite Destruction.

- (i) Except as specified in subpart (ii) of this part, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish shall be:
 - (I) Frozen and stored at a temperature of -20°C (-4°F) or below for a minimum of 168 hours (7 days) in a freezer; (P)
 - (II) 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; (P) or
 - (III) 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. (P)
- (ii) Subpart (i) of this part does not apply to:

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- (I) Molluscan shellfish;
 - (II) Tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), Scallops consisting only of the shucked abductor muscle, or *Thunnus thynnus* (Bluefin tuna, Northern); or
 - (III) Aquacultured fish, such as salmon, that:
 - I. If raised in open water, are raised in net-pens, or
 - II. Are raised in land-based operations such as ponds or tanks, and
 - III. Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish.
 - (IV) Fish eggs that have been removed from the skein and rinsed.
2. Records, Creation and Retention.
- (i) Except as specified in 0080-04-09-.03(4)(b)1(ii) and subpart (ii) of this part, 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. (Pf)
 - (ii) 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 0080-04-09-.03(4)(b)1 may substitute for the records specified under subpart (i) of this part.
 - (iii) 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 0080-04-09-.03(4)(b)1(ii)(III), a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 0080-04-09-.03(4)(b)1(ii)(III) 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. (Pf)
3. 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.
- (c) Reheating for Hot Holding.
- 1. Except as specified under parts 1 and 3 and in part 5 of this subparagraph, 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. (P)
 - 2. Except as specified under part 3 of this subparagraph, time/temperature control for safety food reheated in a microwave oven for hot holding shall be reheated so

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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 two minutes after reheating. (P)

3. 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 commissioner that has jurisdiction over the plant, shall be heated to a temperature of at least 57°C (135°F) for hot holding. (P)
4. Reheating for hot holding as specified under parts 1 through 3 of this subparagraph shall be completed within two hours and the time the food is between 5°C (41°F) or 7°C (45°F) and the temperatures specified under parts 1 through 3 of this subparagraph shall not exceed two hours. (P)
5. Remaining unsliced portions of meat roasts that are cooked as specified under 0080-04-09-.03(4)(a)1(ii) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 0080-04-09-.03(4)(a)1(ii).

(d) Other Methods. Treating Juice. Juice packaged in a food establishment shall be:

1. Treated under a HACCP PLAN as specified in 0080-04-09-.08(2)(d)2-5 to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; (P) or
2. Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance: (Pf)
 - (i) As specified under 0080-04-09-.03(6)(c), (Pf) and
 - (ii) 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." (Pf)

(5) Limitation of Growth of Organisms of Public Health Concern.

(a) Temperature and Time Control.

1. Frozen Food. Stored frozen foods shall be maintained frozen.
2. Time/Temperature Control for Safety Food, Slacking. Frozen time/temperature control for safety food that is slacked to moderate the temperature shall be held:
 - (i) Under refrigeration that maintains the food temperature at 5°C (41°F) or less.
 - (ii) At any temperature if the food remains frozen.
3. Thawing. Except as specified in subpart (iv) of this part, time/temperature control for safety food shall be thawed:
 - (i) Under refrigeration that maintains the food temperature at 5°C (41°F) or less.

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- (ii) Completely submerged under running water:
 - (I) At a water temperature of 21°C (70°F) or below,
 - (II) With sufficient water velocity to agitate and float off loose particles in an overflow,
 - (III) Such that for ready-to-eat food, the temperature of thawed portions do not rise above 5°C (41°F), and
 - (IV) Such that for raw animal food requiring cooking as specified under 0080-04-09-.03(4)(a)1(i) or (ii), thawed portions are not above 5°C (41°F) , for more than four hours including:
 - I. The time the food is exposed to the running water and the time needed for preparation for cooking, or
 - II. The time it takes under refrigeration to lower the food temperature to 5°C (41°F);
 - (iii) As part of a cooking process if the food that is frozen is:
 - (I) Cooked as specified under 0080-04-09-.03(4)(a)1(i) or (ii) or under 0080-04-09-.03(4)(a)2, or
 - (II) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or
 - (iv) Using any procedure if a portion of frozen ready-eat-food is thawed and prepared for immediate service in response to an individual consumer's order.
4. Cooling.
- (i) Cooked time/temperature control for safety food shall be cooled:
 - (I) Within two hours from 57°C (135°F) to 21°C (70°F); (P) and
 - (II) Within a total of six hours from 57°C (135°F) to 5°C (41°F) or less. (P)
 - (ii) Time/temperature control for safety food shall be cooled within four hours to 5°C (41°F) or less, if prepared from ingredients at ambient temperature such as reconstituted foods and canned tuna. (P)
 - (iii) Except as specified under subpart (iv) of this part, a 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 under 0080-04-09-.03(2)(b)1(ii), shall be cooled within four hours to 5°C (41°F) or less. (P)
 - (iv) Raw eggs shall be received as specified under 0080-04-09-.03(2)(b)1(iii) and immediately placed in refrigerated equipment that maintains an ambient air temperature of 5°C (41°F) or less. (P)

(Rule 0080-04-09-.03, continued)

5. Cooling Methods.
 - (i) Cooling shall be accomplished in accordance with the time and temperature criteria specified under 0080-04-09-.03(5)(a)4 by using one or more of the following methods based on the type of food being cooled:
 - (I) Placing the food in shallow pans; (Pf)
 - (II) Separating the food into smaller or thinner portions; (Pf)
 - (III) Using rapid cooling equipment; (Pf)
 - (IV) Stirring the food in a container placed in an ice water bath; (Pf)
 - (V) Using containers that facilitate heat transfer; (Pf)
 - (VI) Adding ice as an ingredient; (Pf) or
 - (VII) Other effective methods. (Pf)
 - (ii) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:
 - (I) Arranged in the equipment to provide maximum heat transfer through the container walls; and
 - (II) Loosely covered, or uncovered if protected from overhead contamination as specified under 0080-04-09-.03(3)(e)1(i)(II), during the cooling period to facilitate heat transfer from the surface of the food.
6. Time/Temperature Control for Safety Food, Hot and Cold Holding.
 - (i) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 0080-04-09-.03(5)(a)9, and except as specified under subpart (ii) and in subpart (iii) of this part, time/temperature control for safety food shall be maintained:
 - (I) At 57°C (135°F) or above, except that roasts cooked to a temperature and for a time specified in 0080-04-09-.03(4)(a)1(ii) or reheated as specified in 0080-04-09-.03(4)(c)5 may be held at a temperature of 54°C (130°F) or above; (P) or
 - (II) At 5°C (41°F) or less. (P)
 - (ii) Eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of 5°C (41°F) or less. (P)
 - (iii) Time/temperature control for safety food in a homogenous liquid form may be maintained outside of the temperature control requirements, as specified under subpart (i) of this part, while contained within specially designed equipment that complies with the design and construction requirements as specified under 0080-04-09-.04(2)(d)3(v).

(Rule 0080-04-09-.03, continued)

7. Ready-to-Eat, Time/Temperature Control for Safety Food Date Marking.
 - (i) Except when packaging food using a reduced oxygen packing method as specified under 0080-04-09-.03(5)(b)2, and except as specified in subparts (iv) and (v) of this part, refrigerated, ready-to-eat, time/temperature control for safety food prepared and held in a food establishment for more than 24 hours shall be 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 combination of 5°C (41°F) or less for a maximum of 7 days. The day of preparation shall be counted as day 1. (Pf)
 - (ii) Except as specified in subparts (iv) – (vi) of this part, refrigerated, ready-to-eat, 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 subpart (i) of this part and:
 - (I) The day the original container is opened in the food establishment shall be counted as day 1; (Pf) and
 - (II) The day or date marked by the food establishment shall not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on food safety. (Pf)
 - (iii) A refrigerated, ready-to-eat, time/temperature control for safety food ingredient or a portion of a refrigerated, ready-to-eat, 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. (Pf)
 - (iv) A date marking system that meets the criteria stated in subparts (i) and (ii) of this part may include:
 - (I) Using a method approved by the commissioner for refrigerated, ready-to-eat 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;
 - (II) Marking the date or day of preparation, 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 subpart (i) of this part;
 - (III) 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 subpart (ii) of this part; or
 - (IV) Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the commissioner upon request.

(Rule 0080-04-09-.03, continued)

- (v) Subparts (i) and (ii) of this part do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.
 - (vi) Subpart (ii) of this part does not apply to the following foods prepared and packaged by a food processing plant inspected by the commissioner:
 - (I) 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;
 - (II) 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;
 - (III) 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;
 - (IV) Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as yogurt, sour cream, and buttermilk;
 - (V) Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products defined in 21 CFR 114 Acidified foods;
 - (VI) 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
 - (VII) 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.
8. Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.
- (i) A food specified in 0080-04-09-.03(5)(a)7(i) or (ii) shall be discarded if it:
 - (I) Exceeds the temperature and time combination specified in 0080-04-09-.03(5)(a)7(i), except time that the product is frozen; (P)
 - (II) Is in a container or package that does not bear a date or day; (P) or
 - (III) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in 0080-04-09-.03(5)(a)7(i). (P)
 - (ii) Refrigerated, ready-to-eat, 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 0080-04-09-.03(5)(a)7(i).
9. Time as a Public Health Control.

(Rule 0080-04-09-.03, continued)

- (i) Except as specified under subpart (iv) of this part, if time without temperature control is used as the public health control for a working supply of time/temperature control for safety food before cooking, or for ready-to-eat time/temperature control for safety food that is displayed or held for sale or service:
 - (I) Written procedures shall be prepared in advance, maintained in the food establishment and made available to the commissioner upon request that specify: (Pf)
 - I. Methods of compliance with items (ii)(I)-(III) or (iii)(I)-(V) of this part; (Pf) and
 - II. Methods of compliance with 0080-04-09-.03(5)(a)4 for food that is prepared, cooked, and refrigerated before time is used as a public health control. (Pf)
- (ii) If time without temperature control is used as the public health control up to a maximum of four hours:
 - (I) The food shall have an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control; (P)
 - (II) The food shall be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control; (Pf)
 - (III) The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within four hours from the point in time when the food is removed from temperature control; (P) and
 - (IV) The food in unmarked containers or packages, or marked to exceed a 4-hour limit shall be discarded. (P)
- (iii) If time without temperature control is used as the public health control up to a maximum of six hours:
 - (I) The food shall have an initial temperature of 5°C (41°F) or less when removed from temperature control and the food temperature shall not exceed 21°C (70°F) within a maximum time period of six hours; (P)
 - (II) The food shall be monitored to ensure the warmest portion of the food does not exceed 21°C (70°F) during the six hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 21°C (70°F) during the 6-hour holding period; (Pf)
 - (III) The food shall be marked or otherwise identified to indicate: (Pf)
 - I. The time when the food is removed from 5°C (41°F) or less cold holding temperature control, (Pf) and
 - II. The time that is six hours past the point in time when the food is removed from cold holding temperature control; (Pf)

(Rule 0080-04-09-.03, continued)

- (IV) The food shall be:
 - I. Discarded if the temperature of the food exceeds 21°C (70°F), (P) or
 - II. Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of six hours from the point in time when the food is removed from 5°C (41°F) or less cold holding temperature control; (P) and
 - (V) The food in unmarked containers or packages, or marked with a time that exceeds the 6-hour limit shall be discarded. (P)
 - (iv) A food establishment that serves a highly susceptible population shall not use time as specified under subpart (i), (ii) or (iii) of this part as the public health control for raw eggs.
- (b) Specialized Processing Methods.
1. Variance Requirement. A food establishment shall obtain a variance from the commissioner as specified in 0080-04-09-.08(1)(c)1 and under 0080-04-09-.08(1)(c)2 before: (Pf)
 - (i) Smoking food as a method of food preservation rather than as a method of flavor enhancement; (Pf)
 - (ii) Curing food; (Pf)
 - (iii) Using food additives or adding components such as vinegar: (Pf)
 - (I) As a method of food preservation rather than as a method of flavor enhancement, (Pf) or
 - (II) To render a food so that it is not time/temperature control of safety food; (Pf)
 - (iv) Packaging food using a reduced oxygen packing method except where the growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled as specified under 0080-04-09-.03(5)(b)2; (Pf)
 - (v) Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption; (Pf)
 - (vi) Custom processing animals that are for personal use as food and not for sale or service in a food establishment; (Pf)
 - (vii) Preparing food by another method that is determined by the commissioner to require a variance; (Pf) or
 - (viii) Sprouting seeds or beans. (Pf)
 2. *Clostridium botulinum* and *Listeria monocytogenes* Controls. Reduced Oxygen Packaging Without a Variance, Criteria.

(Rule 0080-04-09-.03, continued)

- (i) Except for a food establishment that obtains a variance as specified under 0080-04-09-.03(5)(b)1, a food establishment that packages time/temperature control for safety food using a reduced oxygen packaging method shall control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*. (P)
- (ii) A food establishment that packages time/temperature control for safety food using a reduced oxygen packaging method shall have a HACCP plan that contains the information specified under 0080-04-09-.08(2)(d)4 and that: (Pf)
 - (I) Identifies the food to be packaged; (Pf)
 - (II) Except as specified under subparts (iii) – (v) of this part, requires that the packaged food shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: (Pf)
 - I. Has an A_w of 0.91 or less, (Pf)
 - II. Has a pH of 4.6 or less, (Pf)
 - III. 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, (Pf) or
 - IV. Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables; (Pf)
 - (III) 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: (Pf)
 - I. Maintain the food at 5°C (41°F) or below, (Pf) and
 - II. 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; (Pf)
 - (IV) Limits the refrigerated shelf life to no more than 14 calendar days from packing to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first; (P)
 - (V) Includes operational procedures that:
 - I. Prohibit contacting ready-to-eat food with bare hands as specified under 0080-04-09-.03(3)(a)1(ii), (Pf)
 - II. Identify a designated work area and the method by which: (Pf)
 - A. Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, (Pf) and

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- B. Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, (Pf) and
 - C. Delineate cleaning and sanitation procedures for food-contact surfaces; (Pf) and
- (VI) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the: (Pf)
- I. Concepts required for a safe operation, (Pf)
 - II. Equipment and facilities, (Pf) and
 - III. Procedures specified under item 2(ii)(V) of this subparagraph and 0080-04-09-.08(2)(d)4. (Pf)
- (iii) Except for fish that is frozen before, during, and after packaging, a food establishment shall not package fish using a reduced oxygen packaging method. (P)
- (iv) Except as specified under subpart (iii) of this part, a food establishment that packages food using a cook-chill or sous vide process shall:
- (I) Implement a HACCP plan that contains the information as specified under 0080-04-09-.08(2)(d)4; (Pf)
 - (II) Ensure the food is:
 - I. 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 packaged product to another business entity or the consumer, (Pf)
 - II. Cooked to heat all parts of the food to a temperature and for a time as specified under 0080-04-09-.03(4)(a)1, (Pf)
 - III. Protected from contamination before and after cooking as specified under 0080-04-09-.03(3) and (4), (P)
 - IV. Placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below 57°C (135°F), (P)
 - V. Cooled to 5°C (41°F) in the sealed package or bag as specified under 0080-04-09-.03(5)(a)4 and subsequently: (P)
 - VI. Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of packaging; (P)
 - VII. Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for

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- no more than 72 hours, at which time the food must be consumed or discarded; (P)
- VIII. Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from packaging, at which time the food must be consumed or discarded; (P) or
 - IX. Held frozen with no shelf life restriction while frozen until consumed or used. (P)
 - X. 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, (Pf)
 - XI. 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, (Pf) and
- (III) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan and:
 - I. Make such records available to the commissioner upon request (Pf) and
 - II. Hold such records for at least six months; (Pf) and
 - (IV) Implement written operational procedures as specified under item 2(ii)(V) of this subparagraph and a training program as specified under item 2(ii)(VI) of this subparagraph.
- (v) A food establishment that packages cheese using a reduced oxygen packaging method shall:
- (I) Limit 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; (P)
 - (II) Have a HACCP plan that contains the information specified under 0080-04-09-.08(2)(d)4 and as specified under 0080-04-09-.03(5)(b)2(ii)(I), (III)I, (V) and (VI); (Pf)
 - (III) Labels the package on the principal display panel with a “use by” date that does not exceed 30 days from its packaging or the original manufacturer’s “sell by” or “use by” date, whichever occurs first; (Pf) and
 - (IV) Discards the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging. (Pf)

(Rule 0080-04-09-.03, continued)

(6) Food Identity, Presentation, and On-Premises Labeling.

(a) Accurate Representation.

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

(b) Labeling.

1. Food packaged in a food establishment, shall be labeled as specified in law, including 21 CFR 101 - Food labeling, and 9 CFR 317 Labeling, marking devices, and containers.
2. Label information shall include:
 - (i) The common name of the food, or absent a common name, an adequately descriptive identity statement;
 - (ii) 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;
 - (iii) An accurate declaration of the quantity of contents;
 - (iv) The name and place of business of the manufacturer, packer, or distributor; and
 - (v) 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. (Pf)
 - (vi) 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.
 - (vii) For any salmonid fish containing canthaxanthin as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin.
3. Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:
 - (i) The manufacturer's or processor's label that was provided with the food; or

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- (ii) A card, sign, or other method of notification that includes the information specified under subparts 2(i), (ii), and (v) of this subparagraph.
- 4. Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:
 - (i) A health, nutrient content, or other claim is not made;
 - (ii) There are no state or local laws requiring labeling; and
 - (iii) 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.
- 5. Other Forms of Information.
 - (i) If required by law, consumer warnings shall be provided.
 - (ii) Food establishment or manufacturers' dating information on foods shall not be concealed or altered.
- (c) Consumer Advisory. Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.
 - 1. Except as specified in 0080-04-09-.03(4)(a)1(iii) and 0080-04-09-.03(4)(a)1(iv)(IV) and under 0080-04-09-.03(8)(a)3, 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 parts 2 and 3 of this subparagraph using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. (Pf)
 - 2. Disclosure shall include:
 - (i) 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)"; (Pf) or
 - (ii) 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. (Pf)
 - 3. Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:
 - (i) Regarding the safety of these items, written information is available upon request; (Pf)
 - (ii) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness; (Pf) or

(Rule 0080-04-09-.03, continued)

- (iii) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions. (Pf)
- (7) Contaminated Food. Disposition. Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.
 - (a) A food that is unsafe, adulterated, or not honestly presented as specified under 0080-04-09-.03(1) shall be discarded or reconditioned according to an approved procedure. (P)
 - (b) Food that is not from an approved source as specified under 0080-04-09-.03(2)(a) shall be discarded. (P)
 - (c) Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 0080-04-09-.02(2)(b) shall be discarded. (P)
 - (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. (P)
- (8) Special Requirements for Highly Susceptible Populations.
 - (a) Pasteurized Foods, Prohibited Re-Service, and Prohibited Food. In a food establishment that serves a highly susceptible population:
 - 1. The following criteria apply to juice:
 - (i) 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;
 - (ii) 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 0080-04-09-.03(4)(d)2 shall not be served or offered for sale; (P) and
 - (iii) 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 0080-04-09-.08(2)(d)2 - 5 and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls. (P)
 - 2. Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of: (P)
 - (i) Foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages, (P) and
 - (ii) Except as specified in part 6 of this subparagraph, recipes in which more than one egg is broken and the egg are combined; (P)

(Rule 0080-04-09-.03, continued)

3. The following foods shall not be served or offered for sale in a ready-to-eat form: (P)
 - (i) Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartar, (P)
 - (ii) A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw eggs, and meringue; (P) and
 - (iii) Raw seed sprouts. (P)
4. Food employees shall not contact ready-to-eat food as specified under 0080-04-09-.03(3)(a)1(ii) and (v). (P)
5. Time only, as the public health control as specified under 0080-04-09-.03(5)(a)9(iv), shall not be used for raw eggs.
6. Subpart 2(ii) of this subparagraph does not apply if:
 - (i) The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified under 0080-04-09-.03(4)(a)1(i)(I), and served immediately, such as an omelet, soufflé, or scrambled eggs; (P)
 - (ii) 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
 - (iii) The preparation of the food is conducted under a HACCP plan that:
 - (I) Identifies the food to be prepared,
 - (II) Prohibits contacting ready-to-eat food with bare hands,
 - (III) 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 0080-04-09-.03(4)(a)1(i)(II),
 - (IV) Contains the information specified under 0080-04-09-.08(2)(d)4 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
 - (V) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

(Rule 0080-04-09-.03, continued)

7. Except as specified in part 8 of this subparagraph, food may be re-served as specified under 0080-04-09-.03(3)(f)4(ii)(I) and (II).
8. Food shall not be re-served under the following conditions:
 - (i) Any food served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation shall not be re-served to others outside.
 - (ii) Packages of food from any patients, clients, or other consumers shall not be re-served to persons in protective environment isolation.

Authority: T.C.A. § 53-8-204. **Administrative History:** Original rule filed September 30, 1986; effective November 14, 1986. Amendment filed February 20, 2002; effective June 28, 2002. Amendment filed June 27, 2008; effective October 28, 2008. Repeal and new rule filed March 27, 2015; effective June 25, 2015.

0080-04-09-.04 EQUIPMENT, UTENSILS, AND LINENS.

- (1) Materials for Construction and Repair.
 - (a) Multiuse.
 1. Characteristics.
 - (i) Materials that are used in the construction of utensils and food-contact surfaces of equipment shall not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be: (P)
 - (I) Safe; (P)
 - (II) Durable, corrosion-resistant, and nonabsorbent;
 - (III) Sufficient in weight and thickness to withstand repeated warewashing;
 - (IV) Finished to have a smooth, easily cleanable surface; and
 - (V) Resistant to pitting, chipping, crazing, scratching, scoring, distortion and decomposition.
 - (ii) Cast Iron, Use Limitation.
 - (I) Except as specified in items (II) and (III) of this subpart, cast iron shall not be used for utensils or food-contact surfaces of equipment.
 - (II) Cast iron may be used as a surface for cooking.
 - (III) 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.
 - (iii) Lead, Use Limitation.

(Rule 0080-04-09-.04, continued)

- (I) 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: (P)

Utensil Category	Ceramic Article Description	Maximum Lead Mg/L
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls \geq 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

- (II) Pewter alloys containing lead in excess of 0.05% shall not be used as a food-contact surface. (P)
- (III) Solder and flux containing lead in excess of 0.2% shall not be used as a food-contact surface.
- (iv) Copper, Use Limitation.
 - (I) Except as specified in item (II) of this subpart, copper and copper alloys such as brass shall 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.
 - (II) 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.
- (v) Galvanized Metal, Use Limitation. Galvanized metal shall not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.
- (vi) Sponges, Use Limitation. Sponges shall not be used in contact with cleaned and sanitized or in-use food-contact surfaces.
- (vii) Wood, Use Limitation.
 - (I) Except as specified in items (II), (III) and (IV) of this subpart, wood and wood wicker shall not be used as a food-contact surface.
 - (II) Hard maple or an equivalently hard, close-grained wood may be used for:

(Rule 0080-04-09-.04, continued)

- I. Cutting boards; cutting blocks; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and
 - II. Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.
- (III) 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.
- (IV) If the nature of the food requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw food may be kept in:
- I. Untreated wood containers; or
 - II. Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for wood.
- (viii) 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.
- (ix) 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.
- (b) Single Service and Single-Use.
1. Characteristics. Materials that are used to make single-service and single-use articles:
 - (i) Shall not:
 - (I) Allow the migration of deleterious substances, (P) or
 - (II) Impart colors, odors, or tastes to food; and
 - (ii) Shall be:
 - (I) Safe, (P) and
 - (II) Clean.
- (2) Design and Construction.
- (a) Durability and Strength.
1. Equipment and Utensils. Equipment and Utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

(Rule 0080-04-09-.04, continued)

2. Food temperature measuring devices shall 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. (P)

(b) Cleanability.

1. Food-Contact Surfaces.

(i) Multiuse food-contact surfaces shall be:

- (I) Smooth; (Pf)
- (II) Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections; (Pf)
- (III) Free of sharp internal angles, corners, and crevices; (Pf)
- (IV) Finished to have smooth welds and joints; (Pf) and
- (V) Except as specified in subpart (ii) of this part, accessible for cleaning and inspection by one of the following methods:
 - I. Without being disassembled, (Pf)
 - II. By disassembling without the use of tools, (Pf) or
 - III. By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches. (Pf)

- (ii) Item (i)(V) of this part does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.

2. CIP Equipment.

(i) CIP equipment shall meet the characteristics specified under 0080-4-9-.04(2)(b)1 and shall be designed and constructed so that:

- (I) Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces, (Pf) and
- (II) The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions; and

- (ii) 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.

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

(Rule 0080-04-09-.04, continued)

4. Hot Oil Filtering Equipment. Hot oil filtering equipment shall meet the characteristics specified under 0080-4-9-.04(2)(b)1 or 2 and shall be readily accessible for filter replacement and cleaning of the filter.
 5. Can Openers. Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.
 6. 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.
 7. Kick Plates, Removable. Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:
 - (i) Removable by one of the methods specified under 0080-4-9-.04(2)(b)1(i)(V) or capable of being rotated open; and
 - (ii) Removable or capable of being rotated open without unlocking equipment doors.
 8. Ventilation Hood Systems, Filters. Filters or other grease extracting equipment shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.
- (c) Accuracy.
1. Temperature Measuring Devices, Food.
 - (i) Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to $\pm 1^{\circ}\text{C}$ in the intended range of use. (Pf)
 - (ii) Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to $\pm 2^{\circ}\text{F}$ in the intended range of use. (Pf)
 2. Temperature Measuring Devices, Ambient Air and Water.
 - (i) 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 $\pm 1.5^{\circ}\text{C}$ in the intended range of use. (Pf)
 - (ii) Ambient air and water temperature measuring devices that are scaled only in Fahrenheit shall be accurate to $\pm 3^{\circ}\text{F}$ in the intended range of use. (Pf)
 3. Pressure Measuring Devices, Mechanical Warewashing Equipment. Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse shall have increments of 7 kilopascals (1 pound per square inch) or smaller and shall be accurate to ± 14 kilopascals (± 2 pounds per square inch) in the range indicated on the manufacturer's data plate.
- (d) Functionality.
1. Ventilation Hood Systems, Drip Prevention. Exhaust ventilation hood systems in food preparation and warewashing areas including components such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation

(Rule 0080-04-09-.04, continued)

from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.

2. Equipment Openings, Closures and Deflectors.

- (i) A cover or lid for equipment shall overlap the opening and be sloped to drain.
- (ii) 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).
- (iii) Except as specified under subpart (iv) of this part, 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.
- (iv) If a watertight joint is not provided:
 - (I) 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
 - (II) The opening shall be flanged as specified under subpart (ii) of this part.

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

- (i) 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;
- (ii) The delivery tube, chute and orifice shall be protected from manual contact such as by being recessed;
- (iii) 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:
 - (I) 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
 - (II) Available for self-service during hours when it is not under the full-time supervision of a food employee; and
- (iv) 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.

(Rule 0080-04-09-.04, continued)

- (v) Dispensing equipment in which time/temperature control for safety food in a homogenous liquid form is maintained outside of the temperature control requirements as specified under 0080-04-09-.03(5)(a)6 shall:
 - (I) Be specifically designed and equipped to maintain the commercial sterility of aseptically packaged food in a homogenous liquid form for a specified duration from the time of opening the packaging within the equipment; (P) and
 - (II) Conform to the requirements for this equipment as specified in NSF/ANSI 18-2006 – Manual Food and Beverage Dispensing Equipment. (P)
- 4. 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.
- 5. Beverage Tubing, Separation. Except for cold plates that are constructed integrally with an ice storage bin, beverage tubing and cold-plate beverage cooling devices shall not be installed in contact with stored ice.
- 6. Ice Units, Separation of Drains. Liquid waste drain lines shall not pass through an ice machine or ice storage bin.
- 7. 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.
- 8. Molluscan Shellfish Tanks.
 - (i) Except as specified under subpart (ii) of this part, molluscan shellfish life support system display tanks shall not be used to store or 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. (P)
 - (ii) Molluscan shellfish life-support system display tanks that are used to store or display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the commissioner as specified in 0080-04-09-.08(1)(c)1 and a HACCP plan that: (Pf)
 - (I) Is submitted by the permit holder and approved as specified under 0080-04-09-.08(1)(c)2; (Pf) and
 - (II) Ensures that:
 - I. Water used with fish other than molluscan shellfish does not flow into the molluscan tank, (Pf)
 - II. The safety and quality of the shellfish as they were received are not compromised by the use of the tank, (Pf) and
 - III. The identity of the source of the shellstock is retained as specified under 0080-04-09-.03(2)(c)2. (Pf)

(Rule 0080-04-09-.04, continued)

9. Temperature Measuring Devices.
 - (i) 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.
 - (ii) Except as specified in subpart (iii) of this part, cold or hot holding equipment used for 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.
 - (iii) Subpart (ii) of this part 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.
 - (iv) Temperature measuring devices shall be designed to be easily readable.
 - (v) 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. (Pf)
10. Warewashing Machines, 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:
 - (i) Temperatures required for washing, rinsing, and sanitizing;
 - (ii) Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and
 - (iii) Conveyor speed for conveyor machines or cycle time for stationary rack machines.
11. 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.
12. Warewashing Machines, Temperature Measuring Devices. A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:
 - (i) In each wash and rinse tank; (Pf) and
 - (ii) As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank. (Pf)

(Rule 0080-04-09-.04, continued)

13. Manual Warewashing Equipment, Heaters and Baskets. If hot water is used for sanitation in manual warewashing operations, the sanitizing compartment of the sink shall be:
 - (i) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F); (Pf) and
 - (ii) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water. (Pf)
 14. Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers. A warewashing machine that is installed after adoption of these regulations, shall be equipped to:
 - (i) Automatically dispense detergents and sanitizers; (Pf) and
 - (ii) 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. (Pf)
 15. Warewashing Machine Flow Pressure Device.
 - (i) 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
 - (ii) 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.
 - (iii) Subparts (i) and (ii) of this part do not apply to a machine that uses only a pumped or recirculated sanitizing rinse.
 16. Warewashing Sinks and Drainboards, Self-Draining. Warewashing sinks and drainboards of warewashing sinks and machines shall be self-draining.
 17. 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.
 18. Case Lot Handling Apparatuses, Movability. 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.
- (e) Acceptability. Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with 0080-04-09-.04(1) and (2).
- (3) Numbers and Capacities.
- (a) Equipment.

(Rule 0080-04-09-.04, continued)

1. Cooling, Heating, and Holding Capacities. Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity to provide food temperatures as specified under 0080-04-09-.03. (Pf)
 2. Manual Warewashing, Sink Compartment Requirements.
 - (i) A sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils. (Pf)
 - (ii) Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. (Pf)
 - (iii) Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include:
 - (I) High-pressure detergent sprayers;
 - (II) Low- or line-pressure spray detergent foamers;
 - (III) Other task-specific cleaning equipment;
 - (IV) Brushes or other implements.
 3. Drainboards. Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary utensil holding before cleaning and after sanitizing.
 4. Ventilation Hood Systems, Adequacy. Ventilation hood systems and devices shall prevent grease or condensation from collecting on equipment, walls, and ceilings.
 5. Clothes Washers and Dryers.
 - (i) Except as specified in subpart (ii) of this part, if work clothes or linens are laundered on the premises, a mechanical clothes washer and dryer shall be provided and used.
 - (ii) If on-premises laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under 0080-04-09-.04(9)(a)2, a mechanical clothes washer and dryer need not be provided.
- (b) Utensils, Temperature Measuring Devices, and Testing Devices.
1. Utensils, Consumer Self-Service. A food dispensing utensil shall be available for each container displayed at a consumer self-service unit such as a buffet or salad bar. (Pf)
 2. Food Temperature Measuring Devices.
 - (i) Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under 0080-04-09-.03. (Pf)

(Rule 0080-04-09-.04, continued)

- (ii) 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. (Pf)
 - 3. Temperature Measuring Devices, Manual Warewashing. In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.
 - 4. Sanitizing Solutions, Testing Devices. A test kit or other device that accurately measures the concentration in mg/L of sanitizing solutions shall be provided. (Pf)
- (4) Location and Installation.
- (a) Location.
 - 1. Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.
 - (i) Except as specified in subpart (ii) of this part, 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 shall not be located:
 - (I) In locker rooms;
 - (II) In toilet rooms;
 - (III) In garbage rooms;
 - (IV) In mechanical rooms;
 - (V) Under sewer lines that are not shielded to intercept potential drips;
 - (VI) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
 - (VII) Under open stairwells; or
 - (VIII) Under other sources of contamination.
 - (ii) A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.
 - (iii) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.
 - (b) Installation.
 - 1. Fixed Equipment, Spacing or Sealing.
 - (i) Equipment that is fixed because it is not easily movable shall be installed so that it is:

(Rule 0080-04-09-.04, continued)

- (I) Spaced to allow access for cleaning along the sides, behind, and above the equipment;
 - (II) Spaced from adjoining equipment, walls, and ceilings a distance of not more than one millimeter or one thirty-second inch; or
 - (III) Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.
- (ii) 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:
 - (I) Sealed; or
 - (II) Elevated on legs as specified under 0080-04-09-.04(4)(b)2(iv).
2. Fixed Equipment, Elevation or Sealing.
- (i) Except as specified in subparts (ii) and (iii) of this part, 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.
 - (ii) 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).
 - (iii) 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.
 - (iv) Except as specified in subpart (v) of this part, 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.
 - (v) The clearance space between the table and counter-mounted equipment may be:
 - (I) 7.5 centimeters (3 inches) if the horizontal distance of the table top under the equipment is no more than 50 centimeters (20 inches) from the point of access for cleaning; or
 - (II) 5 centimeters (2 inches) if the horizontal distance of the table top under the equipment is no more than 7.5 centimeters (3 inches) from the point of access for cleaning.
- (5) Maintenance and Operation.
- (a) Equipment.
 - 1. Good Repair and Proper Adjustment.
 - (i) Equipment shall be maintained in a state of repair and condition that meets the requirements specified under 0080-04-09-.04(1) and (2).

(Rule 0080-04-09-.04, continued)

- (ii) Equipment components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.
 - (iii) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.
- 2. Cutting Surfaces. Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded if they are not capable of being resurfaced.
- 3. Microwave Ovens. Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 Microwave ovens.
- 4. Warewashing Equipment, Cleaning Frequency. A warewashing machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, or raw foods, or laundering wiping cloths; and drainboards or other equipment used to substitute for drainboards as specified under 0080-04-09-.04(3)(a)3 shall be cleaned:
 - (i) Before use;
 - (ii) 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
 - (iii) If used, at least every 24 hours.
- 5. Warewashing Machines, Manufacturers' Operating Instructions.
 - (i) A warewashing machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.
 - (ii) A warewashing machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.
- 6. Warewashing Sinks, Use Limitation.
 - (i) A warewashing sink shall not be used for handwashing as specified under 0080-04-09-.02(3)(d).
 - (ii) If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink shall be cleaned as specified under 0080-04-09-.04(5)(a)4 before and after each time it is used to wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified under 0080-04-09-.04(7) before and after using the sink to wash produce or thaw food.
- 7. Warewashing Equipment, Cleaning Agents. When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 0080-04-09-.04(3)(a)2(iii) shall contain a wash solution of soap, detergent, acid cleaner,

(Rule 0080-04-09-.04, continued)

- alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions. (Pf)
8. Warewashing Equipment, Clean Solutions. The wash, rinse, and sanitize solutions shall be maintained clean.
 9. Manual Warewashing Equipment, Wash Solution Temperature. The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions. (Pf)
 10. Mechanical Warewashing Equipment, Wash Solution Temperature.
 - (i) The temperature of the wash solution in spray type warewashers that use hot water to sanitize shall not be less than:
 - (I) For a stationary rack, single temperature machine, 74°C (165°F); (Pf)
 - (II) For a stationary rack, dual temperature machine, 66°C (150°F); (Pf)
 - (III) For a single tank, conveyor, dual temperature machine, 71°C (160°F); (Pf) or
 - (IV) For a multitank, conveyor, multitemperature machine, 66°C (150°F). (Pf)
 - (ii) The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize shall not be less than 49°C (120°F). (Pf)
 11. Manual Warewashing Equipment, Hot Water Sanitization Temperatures. If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above. (P)
 12. Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.
 - (i) Except as specified in subpart (ii) of this part, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold shall not be more than 90°C (194°F), or less than: (Pf)
 - (I) For a stationary rack, single temperature machine, 74°C (165°F); (Pf)
or
 - (II) For all other machines, 82°C (180°F). (Pf)
 - (ii) The maximum temperature specified under subpart (i) of this part, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.
 13. Mechanical Warewashing Equipment, Sanitization Pressure. The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine, as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve, shall be within the range specified on the machine manufacturer's data plate and shall not be less than 35 kilopascals (5 pounds per square inch) or more than 200 kilopascals (30 pounds per square inch).

(Rule 0080-04-09-.04, continued)

14. Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness. A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified under 0080-04-09-.04(7)(c)3 shall meet the criteria specified under 0080-04-09-.07(2)(d)1 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows: (P)

(i) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart; (P)

Concentration Range mg/L	Minimum Temperature	
	pH 10 or less °C (°F)	pH 8 or less °C (°F)
25 -49	49 (120)	49 (120)
50 -99	38 (100)	24 (75)
100	13 (55)	13 (55)

(ii) An iodine solution shall have a:

- (I) Minimum temperature of 20°C (68°F), (P)
- (II) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, (P) and
- (III) Concentration between 12.5 mg/L and 25 mg/L; (P)

(iii) A quaternary ammonium compound solution shall:

- (I) Have a minimum temperature of 24°C (75°F), (P)
- (II) Have a concentration as specified under 0080-04-09-.07(2)(d)1 and as indicated by the manufacturer's use directions included in the labeling, (P) and
- (III) Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the EPA-registered label use instructions; (P)

(iv) If another solution of a chemical specified under subparts (i) - (iii) of this part is used, the permit holder shall demonstrate to the commissioner that the solution achieves sanitization and the use of the solution shall be approved; (P) or

(v) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions. (P)

15. Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers. If a detergent-sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step shall be the same detergent-sanitizer that is used in the washing step.

16. Warewashing Equipment, Determining Chemical Sanitizer Concentration. Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device. (Pf)

(Rule 0080-04-09-.04, continued)

- (b) Utensils and Temperature and Pressure Measuring Devices.
 - 1. Good Repair and Calibration.
 - (i) Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under 0080-04-09-.04(1) and (2) or shall be discarded.
 - (ii) Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy. (Pf)
 - (iii) 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.
 - 2. Single-Service and Single-Use Articles, Required Use. A food establishment without facilities specified under 0080-04-09-.04(6) and (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. (P)
 - 3. Single-Service and Single-Use Articles, Use Limitation.
 - (i) Single-service and single-use articles shall not be reused.
 - (ii) 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. Shells, Use Limitation. Mollusk and crustacea shells shall not be used more than once as serving containers.
- (6) Cleaning of Equipment and Utensils.
- (a) Objective.
 - 1. Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.
 - (i) Equipment food-contact surfaces and utensils shall be clean to sight and touch. (Pf)
 - (ii) The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.
 - (iii) Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris.
 - (b) Frequency.
 - 1. Equipment Food-Contact Surfaces and Utensils.
 - (i) Equipment food-contact surfaces and utensils shall be cleaned:

(Rule 0080-04-09-.04, continued)

- (I) Except as specified in subpart (ii) of this part, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry; (P)
 - (II) Each time there is a change from working with raw foods to working with ready-to-eat foods; (P)
 - (III) Between uses with raw fruits and vegetables and with time/temperature control for safety food; (P)
 - (IV) Before using or storing a food temperature measuring device; (P) and
 - (V) At any time during the operation when contamination may have occurred. (P)
- (ii) Item (i)(I) of this part 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 0080-04-09-.03(4)(a)1 than the previous food, such as preparing raw fish followed by cutting raw poultry on the same cutting board.
 - (iii) Except as specified in subpart (iv) of this part, if used with time/temperature control for safety food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every four hours. (P)
 - (iv) Surfaces of utensils and equipment contacting time/temperature control for safety food may be cleaned less frequently than every four hours if:
 - (I) In storage, containers of time/temperature control for safety food and their contents are maintained at temperatures specified under 0080-04-09-.03 and the containers are cleaned when they are empty;
 - (II) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:
 - I. 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

(Rule 0080-04-09-.04, continued)

- II. The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment.
- (III) Containers in serving situations such as salad bars, delis, and cafeteria lines hold ready-to-eat time/temperature control for safety food that is maintained at the temperatures specified under 0080-04-09-.03, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours;
- (IV) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under 0080-04-09-.03;
- (V) Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues;
- (VI) The cleaning schedule is approved based on consideration of:
 - I. Characteristics of the equipment and its use,
 - II. The type of food involved,
 - III. The amount of food residue accumulation, and
 - IV. The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or
- (VII) In-use utensils are intermittently stored in a container of water in which the water is maintained at 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.
- (v) Except when dry cleaning methods are used as specified under 0080-04-09-.04(6)(c)1, surfaces of utensils and equipment contacting food that is not time/temperature control for safety food shall be cleaned:
 - (I) At any time when contamination may have occurred;
 - (II) At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles;
 - (III) Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers; and
 - (IV) In equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment:
 - I. At a frequency specified by the manufacturer, or

(Rule 0080-04-09-.04, continued)

- II. Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.
2. Cooking and Baking Equipment.
 - (i) 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 0080-04-09-.04(6)(b)1(iv)(VI).
 - (ii) The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.
 3. Nonfood-Contact Surfaces. Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues.
- (c) Methods.
1. Dry Cleaning.
 - (i) 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 time/temperature control for safety food.
 - (ii) Cleaning equipment used in dry cleaning food-contact surfaces shall not be used for any other purpose.
 2. Precleaning.
 - (i) 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.
 - (ii) If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked, or scrubbed with abrasives.
 3. Loading of Soiled Items, Warewashing Machines. Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:
 - (i) Exposes the items to the unobstructed spray from all cycles; and
 - (ii) Allows the items to drain.
 4. Wet Cleaning.
 - (i) 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.
 - (ii) 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.

(Rule 0080-04-09-.04, continued)

5. Washing, Procedures for Alternative Manual Warewashing Equipment. If washing in sink compartments or a warewashing machine is impractical such as when the equipment is fixed or the utensils are too large, washing shall be done in accordance with the following procedures:
 - (i) Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts;
 - (ii) Equipment components and utensils shall be scrapped or rough cleaned to remove food particle accumulation; and
 - (iii) Equipment and utensils shall be washed as specified under 0080-04-09-.04(6)(c)4(i).
6. Rinsing Procedures. Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one of the following procedures:
 - (i) Use of a distinct, separate water rinse after washing and before sanitizing if using:
 - (I) A 3-compartment sink,
 - (II) Alternative manual warewashing equipment equivalent to a 3-compartment sink, or
 - (III) A 3-step washing, rinsing, and sanitizing procedure in a warewashing system for CIP equipment.
 - (ii) Use of a detergent-sanitizer as specified under 0080-4-9-.04(5)(a)(15) if using:
 - (I) Alternative warewashing equipment as specified in 0080-4-9-.04(3)(a)(2)(iii) that is approved for use with a detergent-sanitizer, or
 - (II) A warewashing system for CIP equipment;
 - (iii) If using a warewashing machine that does not recycle the sanitizing solution as specified under subpart (iv) of this part, or alternative manual warewashing equipment such as sprayers, use of a nondistinct water rinse that is:
 - (I) Integrated in the application of the sanitizing solution, and
 - (II) Wasted immediately after each application; or
 - (iv) If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the sanitizing solution.
7. Returnables, Cleaning for Refilling.
 - (i) Except as specified in subparts (ii) and (iii) of this part, returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant. (P)

(Rule 0080-04-09-.04, continued)

- (ii) A food-specific container for beverages may be refilled at a food establishment if:
 - (I) Only a beverage that is not a time/temperature control for safety food is used as specified under 0080-04-09-.03(3)(d)7(i).
 - (II) The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;
 - (III) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;
 - (IV) The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and
 - (V) The container is refilled by:
 - I. An employee of the food establishment, or
 - II. The owner of the container if the beverage system includes a contamination-free transfer process that cannot be by-passed by the container owner.
 - (iii) Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.
- (7) Sanitization of Equipment and Utensils.
- (a) Objective – Food-Contact Surfaces and Utensils. Equipment food-contact surfaces and utensils shall be sanitized.
 - (b) Frequency – Before Use After Cleaning. Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning. (P)
 - (c) Methods – Hot Water and Chemical. After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:
 - 1. Hot water manual operations by immersion for at least 30 seconds and as specified under 0080-04-09-.04(5)(a)11;(P)
 - 2. Hot water mechanical operations by being cycled through equipment that is set up as specified under 0080-04-09-.04(5)(a)5, 12, and 13 and achieving a utensil surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator; (P) or
 - 3. 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 0080-04-09-.04(5)(a)14. Contact times shall be consistent with those on EPA-registered label use instructions by providing:

(Rule 0080-04-09-.04, continued)

- (i) Except as specified under subpart (ii) of this part, a contact time of at least 10 seconds for a chlorine solution specified under 0080-04-09-.04(5)(a)14(i), (P)
 - (ii) A contact time of at least seven 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), (P)
 - (iii) A contact time of at least 30 seconds for other chemical sanitizing solutions, (P) or
 - (iv) A contact time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in 0080-04-09-.01. (P)
- (8) Laundering.
- (a) Objective – Clean Linens. Clean linens shall be free from food residues and other soiling matter.
 - (b) Frequency – Specifications.
 - 1. Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.
 - 2. Cloth gloves used as specified in 0080-04-09-.03(3)(d)5(iv) shall be laundered before being used with a different type of raw animal food such as beef, fish, lamb, pork or poultry.
 - 3. Linens and cloth napkins that are used as specified under 0080-04-09-.03(3)(d)3 and cloth napkins shall be laundered between each use.
 - 4. Wet wiping cloths shall be laundered daily.
 - 5. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.
 - (c) Methods.
 - 1. Storage of Soiled Linens. Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single-service and single-use articles.
 - 2. Mechanical Washing.
 - (i) Except as specified in subpart (ii) of this part, linens shall be mechanically washed.
 - (ii) In food establishments in which only wiping cloths are laundered as specified in 0080-04-09-.04(3)(a)5(ii) 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 0080-04-09-.04(5)(a)4.
 - 3. Use of Laundry Facilities.

(Rule 0080-04-09-.04, continued)

- (i) Except as specified in subpart (ii) of this part, 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.
 - (ii) 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.
- (9) Protection of Clean Items.
 - (a) Drying.
 - 1. Equipment and Utensils, Air-Drying Required. After cleaning and sanitizing, equipment and utensils:
 - (i) 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
 - (ii) Shall not be cloth dried except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.
 - 2. Wiping Cloths, Air-Drying Locations. Wiping cloths laundered in a food establishment that does not have a mechanical clothes dryer as specified in 0080-04-09-.04(3)(a)5(ii) 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 0080-04-09-.04(5)(a)14.
 - (b) Lubricating and Reassembling.
 - 1. Food-Contact Surfaces. Lubricants as specified under 0080-04-09-.07(2)(e) shall be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces.
 - 2. Equipment. Equipment shall be reassembled so that food-contact surfaces are not contaminated.
 - (c) Storing.
 - 1. Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.
 - (i) Except as specified in subpart (iv) of this part, cleaned equipment and utensils, laundered linens, and single-service and single-use articles shall be stored:
 - (I) In a clean, dry location;
 - (II) Where they are not exposed to splash, dust, or other contamination; and
 - (III) At least 15 cm (6 inches) above the floor.

(Rule 0080-04-09-.04, continued)

- (ii) Clean equipment and utensils shall be stored as specified under subpart (i) of this part and shall be stored:
 - (I) In a self-draining position that allows air drying; and
 - (II) Covered or inverted.
 - (iii) Single-service and single-use articles shall be stored as specified under subpart (i) of this part and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.
 - (iv) 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 0080-04-09-.04(2)(d)18.
2. Prohibitions.
- (i) Except as specified in subpart (ii) of this part, cleaned and sanitized equipment, utensils, laundered linens, and single-services and single-use articles shall not be stored:
 - (I) In locker rooms;
 - (II) In toilet rooms;
 - (III) In garbage rooms;
 - (IV) In mechanical rooms;
 - (V) Under sewer lines that are not shielded to intercept potential drips;
 - (VI) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
 - (VII) Under open stairwells; or
 - (VIII) Under other sources of contamination.
 - (ii) Laundered linens and single-service and single-use article that are packaged or in a facility such as a cabinet may be stored in a locker room.
- (d) Preventing Contamination.
1. Kitchenware and Tableware.
- (i) 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.
 - (ii) 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.
 - (iii) Except as specified under subpart (ii) of this part, single-service articles that are intended for food- or lip-contact shall be furnished for consumer

(Rule 0080-04-09-.04, continued)

self-service with the original individual wrapper intact or from an approved dispenser.

2. Soiled and Clean Tableware. Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated.
3. Preset Tableware.
 - (i) Except as specified in subpart (ii) of this part, tableware that is preset shall be protected from contamination by being wrapped, covered, or inverted.
 - (ii) Preset tableware may be exposed if:
 - (I) Unused settings are removed when a consumer is seated; or
 - (II) Settings not removed when a consumer is seated are cleaned and sanitized before further use.
4. Rinsing Equipment and Utensils after Cleaning and Sanitizing. After being cleaned and sanitized, equipment and utensils shall not be rinsed before air drying or use unless:
 - (i) The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified under 0080-04-09-.04(2)(d) and 0080-04-09-.04(5)(a); and
 - (ii) The rinse is applied only after the equipment and utensils have been sanitized by the application of hot water or by the application of a chemical sanitizer solution whose EPA-registered label use instructions call for rinsing off the sanitizer after it is applied in a commercial warewashing machine.

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0080-04-09-.05 WATER, PLUMBING, AND WASTE.

- (1) Water.
 - (a) Source.
 1. Approved System. Drinking water shall be obtained from an approved source that is:
 - (i) A public water system; (P) or
 - (ii) A nonpublic water system that is constructed, maintained, and operated according to law. (P)
 2. System Flushing and Disinfection. A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system. (P)

(Rule 0080-04-09-.05, continued)

3. Bottled Drinking Water. Bottled drinking water used or sold in a food establishment shall be obtained from approved sources in accordance with 21 CFR 129 - Processing and Bottling of Bottled drinking water. (P)

(b) Quality.

1. Standards. Except as specified under 0080-04-09-.05(1)(b)2:
 - (i) Water from a public water system shall meet 40 CFR 141 - National Primary Drinking Water Regulations and state drinking water quality standards; and (P)
 - (ii) Water from a nonpublic water system shall meet state drinking water quality standards. (P)
2. Nondrinking Water.
 - (i) A nondrinking water supply may be used only if its use is approved. (P)
 - (ii) Nondrinking water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, and fire protection. (P)
3. Sampling. Except when used as specified under 0080-04-09-.05(1)(b)2, water from a nonpublic water system shall be sampled and tested at least annually and as required by state water quality regulations. (Pf)
4. Sample Report. The most recent sample report for the nonpublic water system shall be retained on file in the food establishment or the report shall be maintained as specified by state water quality regulations.

(c) Quantity and Availability.

1. Capacity.
 - (i) The water source and system shall be of sufficient capacity to meet the peak water demands of the food establishment. (Pf)
 - (ii) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the food establishment. (Pf)
2. Pressure. Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under 0080-04-09-.05(1)(d)2(i) and (ii) to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure. (Pf)

(d) Distribution, Delivery, and Retention.

1. System. Water shall be received from the source through the use of:
 - (i) An approved public water main; or (Pf)
 - (ii) One or more of the following that shall be constructed, maintained, and operated according to law: (Pf)

(Rule 0080-04-09-.05, continued)

- (I) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances, (Pf)
 - (II) Water transport vehicles, (Pf) or
 - (III) Water containers. (Pf)
2. Alternative Water Supply. Water meeting the requirements specified under 0080-04-09-.05(1)(a)-(c) shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a food establishment with a temporary interruption of its water supply through:
- (i) A supply of containers of commercially bottled drinking water; (Pf)
 - (ii) One or more closed portable water containers; (Pf)
 - (iii) An enclosed vehicular water tank; (Pf)
 - (iv) An on-premises water storage tank; or (Pf)
 - (v) Piping, tubing, or hoses connected to an adjacent approved source. (Pf)
- (2) Plumbing System.
- (a) Materials – Approved.
 - 1. A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to law. (P)
 - 2. A water filter shall be made of safe materials. (P)
 - (b) Design, Construction, and Installation.
 - 1. Approved System and Cleanable Fixtures.
 - (i) A plumbing system shall be designed, constructed, and installed according to law. (P)
 - (ii) A plumbing fixture such as a handwashing sink, toilet, or urinal shall be easily cleanable.
 - 2. Handwashing Sink, Installation.
 - (i) 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. (Pf)
 - (ii) A steam-mixing valve shall not be used at a handwashing sink.
 - (iii) 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.
 - (iv) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.
 - 3. Backflow Prevention, Air Gap. An air gap between the water supply inlet and the flood level rim of the plumbing fixture equipment, or nonfood equipment shall be

(Rule 0080-04-09-.05, continued)

- at least twice the diameter of the water supply inlet and shall not be less than 25 mm (1 inch). (P)
4. Backflow Prevention Device, Design Standard. A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device. (P)
 5. Conditioning Device, Design. A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.
- (c) Numbers and Capacities.
1. Handwashing Sinks.
 - (i) Except as specified in subpart (ii) of this part, at least one handwashing sink, a number of handwashing sinks necessary for their convenient use by employees in areas specified under 0080-04-09-.05(2)(d)1, and not fewer than the number of handwashing sinks required by law shall be provided. (Pf)
 - (ii) 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.
 - (iii) 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.
 2. Toilets and Urinals. At least one toilet and not fewer than the toilets required by law shall be provided. If the food service establishment has more than 16 seats, two restrooms must be available. If authorized by law and urinals are substituted for toilets, the substitution shall be done as specified in law.
 3. Service Sink.
 - (i) At least one service sink or one 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.
 - (ii) Toilets and urinals shall not be used as a service sink for the disposal of mop water and similar liquid waste.
 4. Backflow Prevention Device, When Required. A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food establishment, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law, by:
 - (i) Providing an air gap as specified under 0080-04-09-.05(2)(b)3; (P) or

(Rule 0080-04-09-.05, continued)

- (ii) Installing an approved backflow prevention device as specified under 0080-04-09-.05(2)(b)4. (P)
- 5. Backflow Prevention Device, Carbonator.
 - (i) If not provided with an air gap as specified under 0080-04-09-.05(2)(b)3, a dual 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.
 - (ii) A dual 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 (i) of this part.
- (d) Location and Placement.
 - 1. Handwashing sinks shall be located:
 - (i) To allow convenient use by employees in food preparation, food dispensing, and warewashing areas; (Pf) and
 - (ii) In, or immediately adjacent to, toilet rooms. (Pf)
 - 2. Backflow Prevention Device, Location. A backflow prevention device shall be located so that it may be serviced and maintained.
 - 3. Conditioning Device, Location. A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.
- (e) Operation and Maintenance.
 - 1. Using a Handwashing Sink.
 - (i) A handwashing sink shall be maintained so that it is accessible at all times for employee use. (Pf)
 - (ii) A handwashing sink shall not be used for purposes other than handwashing. (Pf)
 - (iii) An automatic handwashing facility shall be used in accordance with manufacturer's instructions. (Pf)
 - 2. Prohibiting a Cross Connection.
 - (i) A person shall 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. (P)
 - (ii) The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water. (Pf)
 - 3. Scheduling Inspection and Service for a Water System Device. A device such as a water treatment device or backflow preventer shall be scheduled for inspection

(Rule 0080-04-09-.05, continued)

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. (Pf)

4. Water Reservoir of Fogging Devices, Cleaning.

(i) A reservoir that is used to supply water to a device such as a produce fogger shall be:

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

(II) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under subpart (ii) of this part, whichever is more stringent. (P)

(ii) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

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

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

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

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

5. System Maintained in Good Repair. A plumbing system shall be:

(i) Repaired according to law; (P) and

(ii) Maintained in good repair. (P)

(3) Mobile Water Tanks and Mobile Food Establishment Water Tank.

(a) Materials that are used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances shall be:

1. Safe; (P)

2. Durable, corrosion-resistant, and nonabsorbent; and

3. Finished to have a smooth, easily cleanable surface.

(b) Design and Construction.

1. Enclosed System, Sloped to Drain. A mobile water tank shall be:

(i) Enclosed from the filling inlet to the discharge outlet; and

(ii) Sloped to an outlet that allows complete drainage of the tank.

(Rule 0080-04-09-.05, continued)

2. Inspection and Cleaning Port, Protected and Secured. If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:
 - (i) Flanged upward at least 13 mm (one-half inch); and
 - (ii) Equipped with a port cover assembly that is:
 - (I) Provided with a gasket and a device for securing the cover in place, and
 - (II) Flanged to overlap the opening and sloped to drain.
 3. "V" Type Threads, Use Limitation. A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.
 4. Tank Vent, Protected. If provided, a water tank vent shall terminate in a downward direction and shall be covered with:
 - (i) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area; or
 - (ii) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.
 5. Inlet and Outlet, Sloped to Drain.
 - (i) A water tank and its inlet and outlet shall be sloped to drain.
 - (ii) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.
 6. Hose, Construction and Identification. A hose used for conveying drinking water from a water tank shall be:
 - (i) Safe; (P)
 - (ii) Durable, corrosion-resistant, and nonabsorbent;
 - (iii) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;
 - (iv) Finished with a smooth interior surface; and
 - (v) Clearly and durably identified as to its use if not permanently attached.
- (c) Numbers and Capacities.
1. Filter, Compressed Air. A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is used to pressurize the water tank system. (P)
 2. Protective Cover or Device. A cap and keeper chain, closed cabinet, closed storage tube, or other approved protective cover or device shall be provided for a water inlet, outlet, and hose.

(Rule 0080-04-09-.05, continued)

3. Mobile Food Establishment Tank Inlet. A mobile food establishment's water tank inlet shall be:
 - (i) 19.1 mm (three-fourths inch) in inner diameter or less; and
 - (ii) Provided with a hose connection of a size or type that will prevent its use for any other service.
- (d) Operation and Maintenance.
 1. System Flushing and 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. (P)
 2. Using a Pump and Hoses, Backflow Prevention. A person shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.
 3. Protecting Inlet, Outlet, and Hose Fitting. If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under 0080-04-09-.05(3)(c)2.
 4. Tank, Pump, and Hoses, Dedication.
 - (i) Except as specified in subpart (ii) of this part, a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.
 - (ii) 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.
- (4) Sewage, Other Liquid Waste, and Rainwater.
 - (a) Mobile Holding Tank, Capacity and Drainage. A sewage holding tank in a mobile food establishment shall be:
 1. Sized 15 percent larger in capacity than the water supply tank; and
 2. Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.
 - (b) Retention Drainage and Delivery.
 1. Establishment Drainage System. Food establishment drainage systems, including grease traps, that convey sewage shall be designed and installed as specified under 0080-04-09-.05(2)(b)1(i).
 2. Backflow Prevention.
 - (i) Except as specified in subparts (ii), (iii), and (iv) of this part, a direct connection shall not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.

(Rule 0080-04-09-.05, continued)

- (ii) Subpart (i) of this part does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.
 - (iii) 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.
 - (iv) If allowed by law, a warewashing or culinary sink may have a direct connection.
 - 3. Grease Trap. If used, a grease trap shall be located to be easily accessible for cleaning.
 - 4. 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. (P)
 - 5. 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. (Pf)
 - 6. Flushing a Waste Retention Tank. A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.
 - (c) Approved Sewage Disposal System.
 - 1. Sewage shall be disposed through an approved facility that is:
 - (i) A public sewage treatment plant; (P) or
 - (ii) An individual sewage disposal system that is sized, constructed, maintained, and operated according to law. (P)
 - 2. 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) Refuse, Recyclables, and Returnables.
- (a) Facilities on the Premises.
 - 1. Indoor Storage Area. If located within the food establishment, a storage area for refuse, recyclables, and returnables shall meet the requirements specified under 0080-04-09-.06(1)(a), 0080-04-09-.06(2)(a)1-8, 0080-04-09-.06(2)(b)5 and 6.
 - 2. 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.
 - 3. Outdoor Enclosure. If used, an outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials.

(Rule 0080-04-09-.05, continued)

4. Receptacles.
 - (i) Except as specified in subpart (ii) of this part, receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, and nonabsorbent.
 - (ii) Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the food establishment, or within closed outside receptacles.
5. Outside Receptacles.
 - (i) Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the food establishment shall be designed and constructed to have tight-fitting lids, doors, or covers.
 - (ii) Receptacles and waste handling units for refuse and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.
6. Storage Areas, Rooms, and Receptacles, Capacity and Availability.
 - (i) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate.
 - (ii) A receptacle shall be provided in each area of the food establishment or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.
 - (iii) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.
7. Toilet Room Receptacle, Covered. A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.
8. Cleaning Implements and Supplies.
 - (i) Except as specified in subpart (ii) of this part, suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.
 - (ii) If approved, off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.
9. Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.
 - (i) An area designated for refuse, recyclables, returnables, and, except as specified in subpart (ii) of this part, a redeeming machine for recyclables or

(Rule 0080-04-09-.05, continued)

- returnables shall be located so that it is separate from food, equipment, utensils, linens, and single-service and single-use articles and a public health hazard or nuisance is not created.
- (ii) A redeeming machine may be located in the packaged food storage area or consumer area of a food establishment if food, equipment, utensils, linens, and single-service and single-use articles are not subject to contamination from the machines and a public health hazard or nuisance is not created.
 - (iii) The location of receptacles and waste handling units for refuse, recyclables, and returnables shall not create a public health hazard or nuisance or interfere with the cleaning of adjacent space.
10. 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.
11. Areas, Enclosures, and Receptacles, Good Repair. Storage areas, enclosures, and receptacles for refuse, recyclables, and returnables shall be maintained in good repair.
12. Outside Storage Prohibitions.
- (i) Except as specified in subpart (ii) of this part, refuse receptacles not meeting the requirements specified under 0080-04-09-.05(5)(a)4(i) such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue shall not be stored outside.
 - (ii) Cardboard or other packaging material that does not contain food residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.
13. Covering Receptacles. Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept covered:
- (i) Inside the food establishment if the receptacles and units:
 - (I) Contain food residue and are not in continuous use; or
 - (II) After they are filled; and
 - (ii) With tight-fitting lids or doors if kept outside the food establishment.
14. Using Drain Plugs. Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place.
15. 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 0080-04-09-.06(5)(n), and clean.
16. Cleaning Receptacles.

(Rule 0080-04-09-.05, continued)

- (i) Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of as specified under 0080-04-09-.05(4)(b)4.
 - (ii) Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.
- (b) Removal.
- 1. Frequency. Refuse, recyclables, and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.
 - 2. Receptacles or Vehicles. Refuse, recyclables, and returnables shall be removed from the premises by way of:
 - (i) Portable receptacles that are constructed and maintained according to law; or
 - (ii) A transport vehicle that is constructed, maintained, and operated according to law.
- (c) Facilities for Disposal and Recycling. 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.

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0080-04-09-.06 PHYSICAL FACILITIES.

- (1) Materials for Construction and Repair.
 - (a) Indoor Areas. Surface Characteristics.
 - 1. Except as specified in part 2 of this subparagraph, materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:
 - (i) Smooth, durable, and easily cleanable for areas where food establishment operations are conducted;
 - (ii) Closely woven and easily cleanable carpet for carpeted areas; and
 - (iii) Nonabsorbent for areas subject to moisture such as food preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, mobile food establishment servicing areas, and areas subject to flushing or spray cleaning methods.

(Rule 0080-04-09-.06, continued)

2. In a temporary food establishment:
 - (i) If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other approved materials that are effectively treated to control dust and mud; and
 - (ii) Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.
- (b) Outdoor Areas. Surface Characteristics.
 1. 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.
 2. Exterior surfaces of buildings and mobile food establishments shall be of weather-resistant materials and shall comply with law.
 3. Outdoor storage areas for refuse, recyclables, or returnables shall be of materials specified under 0080-04-09-.05(5)(a)2 and 3.
- (2) Design, Construction, and Installation.
 - (a) Cleanability.
 1. Floors, Walls, and Ceilings. Except as specified under part 4 of this subparagraph 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.
 2. Floors, Walls, and Ceilings, Utility Lines.
 - (i) Utility service lines and pipes shall not be unnecessarily exposed.
 - (ii) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.
 - (iii) Exposed horizontal utility service lines and pipes shall not be installed on the floor.
 3. Floor and Wall Junctures, Coved, and Enclosed or Sealed.
 - (i) 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 one mm (one thirty-second inch).
 - (ii) 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.
 4. Floor Carpeting, Restrictions, and Installation.
 - (i) A floor covering such as carpeting or similar material shall not be installed as a floor covering in food preparation areas, walk-in refrigerators,

(Rule 0080-04-09-.06, continued)

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.

- (ii) If carpeting is installed as a floor covering in areas other than those specified under subpart (i) of this part, it shall be:
 - (I) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and
 - (II) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.
5. Floor Covering, Mats and Duckboards. Mats and duckboards shall be designed to be removable and easily cleanable.
6. Wall and Ceiling Coverings and Coatings.
- (i) Wall and ceiling covering materials shall be attached so that they are easily cleanable.
 - (ii) Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and sealed to provide a smooth, nonabsorbent, easily cleanable surface.
7. Walls and Ceilings, Attachments.
- (i) Except as specified in subpart (ii) of this part, 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.
 - (ii) In a consumer area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.
8. Walls and Ceilings, Studs, Joists, and Rafters. Except for temporary food establishments, studs, joists, and rafters shall not be exposed in areas subject to moisture.
- (b) Functionality.
1. Light Bulbs, Protective Shielding.
- (i) Except as specified in subpart (ii) of this part, 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.
 - (ii) Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages, if:
 - (I) The integrity of the packages cannot be affected by broken glass falling onto them; and

(Rule 0080-04-09-.06, continued)

- (II) The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.
 - (iii) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.
- 2. Heating, Ventilating, Air Conditioning System Vents. Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment, or utensils.
- 3. Insect Control Devices, Design and Installation.
 - (i) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.
 - (ii) Insect control devices shall be installed so that:
 - (I) The devices are not located over a food preparation area; and
 - (II) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.
- 4. Toilet Rooms, Enclosed. 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.
- 5. Outer Openings, Protected.
 - (i) Except as specified in subparts (ii), (iii), and (v) and under subpart (iv) of this part, outer openings of a food establishment shall be protected against the entry of insects and rodents by:
 - (I) Filling or closing holes and other gaps along floors, walls, and ceilings;
 - (II) Closed, tight-fitting windows; and
 - (III) Solid, self-closing, tight-fitting doors.
 - (ii) Subpart (i) of this part 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.
 - (iii) Exterior doors used as exits need not be self-closing if they are:
 - (I) Solid and tight-fitting;

(Rule 0080-04-09-.06, continued)

- (II) Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the food establishment; and
 - (III) Limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.
 - (iv) Except as specified in subparts (ii) and (v) of this part, 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 subpart (i) of this part, the openings shall be protected against the entry of insects and rodents by:
 - (I) 16 mesh to 25.4 mm (16 mesh to 1 inch) screens;
 - (II) Properly designed and installed air curtains to control flying insects; or
 - (III) Other effective means.
 - (v) Subpart (iv) of this part does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting condition.
6. Exterior Walls and Roofs, Protective Barrier. Perimeter walls and roofs of a food establishment shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.
 7. 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.
 8. Outdoor Walking and Driving Surfaces, Graded to Drain. Exterior walking and driving surfaces shall be graded to drain.
 9. 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.
 10. Private Homes and Living or Sleeping Quarters, Use Prohibition. A private home, except as provided by T.C.A. § 53-8-117, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters shall not be used for conducting food establishment operations.
 11. 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 establishments operations by complete partitioning and solid self-closing doors.
- (3) Number and Capacities.
- (a) Handwashing Sinks.

(Rule 0080-04-09-.06, continued)

1. Handwashing sinks shall be provided as specified under 0080-04-09-.05(2)(c)1.
 2. Handwashing Cleanser, Availability. Each handwashing sink or group of two adjacent handwashing sinks shall be provided with a supply of hand cleaning liquid, powder, or bar soap.
 3. Hand Drying Provision. Each handwashing sink or group of adjacent handwashing sinks shall be provided with:
 - (i) Individual, disposable towels;
 - (ii) A continuous towel system that supplies the user with a clean towel; or
 - (iii) A heated-air hand drying device; or
 - (iv) A hand drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures.
 4. Handwashing Aids and Devices, Use Restrictions. A sink used for food preparation or utensil washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, shall not be provided with the handwashing aids and devices required for a handwashing sink as specified under 0080-04-09-.06(3)(a)2 and 3 and 0080-04-09-.05(5)(a)6(iii).
 5. 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. 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 0080-04-09-.05(5)(a)6(iii).
- (b) Toilets and Urinals.
1. Toilets and urinals shall be provided as specified under 0080-04-09-.05(2)(c)2.
 2. A supply of toilet tissue shall be available at each toilet. (Pf)
- (c) Lighting. The light intensity shall be:
1. 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;
 2. At least 215 lux (20 foot candles):
 - (i) 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,
 - (ii) Inside equipment such as reach-in and under-counter refrigerators; and
 - (iii) 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

(Rule 0080-04-09-.06, continued)

3. At least 540 lux (50 foot candles) at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders, or saws where employee safety is a factor.
- (d) Ventilation. If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.
- (e) Dressing Areas and Lockers.
 1. Dressing rooms or dressing areas shall be designated if employees routinely change their clothes in the establishment.
 2. Lockers or other suitable facilities shall be provided for the orderly storage of employee's clothing and other possessions.
- (f) A service sink or curbed cleaning facility shall be provided as specified under 0080-04-09-.05(2)(c)3(i).
- (4) Location and Placement.
 - (a) Handwashing sinks shall be conveniently located as specified under 0080-04-09-.05(2)(d)1.
 - (b) Toilet rooms shall be conveniently located and accessible to employees during all hours of operation.
 - (c) Employee Accommodations.
 1. Areas designated for employees to eat, drink, and use tobacco shall be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.
 2. Lockers 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 cannot occur.
 - (d) Distressed Merchandise. 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. (Pf)
 - (e) Refuse, Recyclables, and Returnables. Units, receptacles, and areas designated for storage of refuse and recyclable and returnable containers shall be located as specified under 0080-04-09-.05(5)(a)9.
- (5) Maintenance and Operation.
 - (a) Physical facilities shall be maintained in good repair.
 - (b) Cleaning, Frequency and Restrictions.
 1. Physical facilities shall be cleaned as often as necessary to keep them clean.

(Rule 0080-04-09-.06, continued)

2. 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.
- (c) Cleaning Floors, Dustless Methods.
1. Except as specified in part 2 of this subparagraph, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.
 2. Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:
 - (i) Without the use of dust-arresting compounds; and
 - (ii) In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.
- (d) Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.
1. Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.
 2. If vented to the outside, ventilation systems shall not create a public health hazard or nuisance or unlawful discharge.
- (e) Cleaning Maintenance Tools, Preventing Contamination. Food preparation sinks, handwashing sinks, and warewashing equipment shall not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.
- (f) Drying Mops. After use, mops shall be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies.
- (g) Absorbent Materials on Floors, Use Limitation. Except as specified in 0080-04-09-.06(5)(c)2, sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials shall not be used on floors.
- (h) Cleaning of Plumbing Fixtures. Plumbing fixtures such as handwashing sinks, toilets, and urinals shall be cleaned as often as necessary to keep them clean.
- (i) Closing Toilet Room Doors. Except during cleaning and maintenance operations, toilet room doors as specified under 0080-04-09-.06(2)(b)4 shall be kept closed.
- (j) Using Dressing Rooms and Lockers.
1. Dressing rooms shall be used by employees if the employees regularly change their clothes in the establishment.
 2. Lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.
- (k) Controlling Pests. The premises shall be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests shall be controlled to eliminate their presence on the premises by:

(Rule 0080-04-09-.06, continued)

1. Routinely inspecting incoming shipments of food and supplies;
 2. Routinely inspecting the premises for evidence of pests;
 3. Using methods, if pests are found, such as trapping devices or other means of pest control as specified under 0080-04-09-.07(2)(b)2(iii) and 0080-04-09-.07(2)(f)2 and 3; and
 4. Eliminating harborage conditions.
- (l) Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests. Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or the attraction of pests.
- (m) Storing Maintenance Tools. Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:
1. Stored so they do not contaminate food, equipment, utensils, linens, and single-service and single-use articles; and
 2. Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.
- (n) Maintaining Premises, Unnecessary Items and Litter. The premises shall be free of:
1. Items that are unnecessary to the operation or maintenance of the establishment such as equipment that is nonfunctional or no longer used; and
 2. Litter.
- (o) Prohibiting Animals.
1. Except as specified in parts 2 and 3 of this subparagraph, live animals shall not be allowed on the premises of a food establishment.
 2. Live animals are allowed in the following situations if the owner or operator does not permit animals to physically contact food, serving dishes, utensils, tableware, linens, unwrapped single-service and single-use articles or other food service items that may result in contamination of food or food-contact surfaces and does not permit animals to physically contact employees engaged in the preparation or handling of food:
 - (i) Fish or crustacea in aquariums or display tanks;
 - (ii) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas; and sentry dogs in outside fenced areas;
 - (iii) Service animals accompanying persons with disabilities in areas that are not used for food preparation;
 - (iv) Dogs (*Canis lupus familiaris*) and cats (*Felis catus*) in outdoor dining areas; provided that dogs and cats are physically restrained, and do not pass through any indoor areas of the food establishment. Except for service animals described in subpart (iii) of this part, nothing in this chapter

(Rule 0080-04-09-.06, continued)

prohibits a food establishment from prohibiting dogs and cats in outdoor dining areas; and

- (v) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals.
3. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result.

Authority: T.C.A. § 53-8-204. **Administrative History:** Original rule filed September 30, 1986; effective November 14, 1986. Amendment filed February 20, 2002; effective June 28, 2002. Amendments filed June 27, 2008; effective October 28, 2008. Repeal and new rule filed March 27, 2015; effective June 25, 2015.

0080-04-09-.07 POISONOUS OR TOXIC MATERIALS.

(1) Labeling and Identification.

- (a) Original Containers. Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label. Only those pesticides that have been registered with the EPA and with the Department shall be used. If the manufacturer's label is missing from a pesticide container, the container shall be identified with the manufacturer's product brand name, percentage of each active ingredient, and EPA registration number. (Pf)
- (b) 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. (Pf)

(2) Operational Supplies and Applications.

- (a) Storage. Poisonous or toxic materials shall be stored so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:
 - 1. Separating the poisonous or toxic materials by spacing or partitioning; (P) and
 - 2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This part 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. (P)
- (b) Presence and Use.
 - 1. Restriction.
 - (i) 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.

(Rule 0080-04-09-.07, continued)

- (ii) Subpart (i) of this part does not apply to packaged poisonous or toxic materials that are for retail sale.
2. Conditions of Use. Poisonous or toxic materials shall be:
- (i) Used according to:
 - (I) Law and this chapter,
 - (II) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food establishment, (P)
 - (III) The conditions of certification, if certification is required, for use of the pest control materials, (P) and
 - (IV) Additional conditions that may be established by the commissioner; and
 - (ii) Applied so that:
 - (I) A hazard to employees or other persons is not constituted, (P) and
 - (II) Contamination including toxic residues due to drip, drain, fog, splash or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted use pesticide, this is achieved by: (P)
 - I. Removing the items, (P)
 - II. Covering the items with impermeable covers, (P) or
 - III. Taking other appropriate preventive actions, (P) and
 - IV. Cleaning and sanitizing equipment and utensils after the application. (P)
 - (iii) A general use or 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 and Tennessee Rule Chapter 0080-06-16 Regulations Governing the Use of Pesticides. (Pf)
- (c) Container Prohibitions. Poisonous or Toxic Material Containers. A container previously used to store poisonous or toxic materials shall not be used to store, transport, or dispense food. Sanitizing solutions shall not be stored in or dispensed from containers previously containing other poisonous or toxic materials. (P)
- (d) Chemicals.
- 1. 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). (P)

(Rule 0080-04-09-.07, continued)

2. Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.
 - (i) 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. (P)
 - (ii) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.
3. Boiler Water Additives, Criteria. Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310 Boiler water additives. (P)
4. Drying Agents, Criteria. Drying agents used in conjunction with sanitization shall:
 - (i) Contain only components that are listed as one of the following:
 - (I) Generally recognized as safe for use in food as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, (P)
 - (II) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe, (P)
 - (III) Approved for use as a drying agent under a prior sanction specified in 21 CFR 181 - Prior-Sanctioned Food Ingredients, (P)
 - (IV) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175 178, (P) or
 - (V) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; (P) and
 - (ii) When sanitization is with chemicals, the approval required under item (i)(III) or (i)(V) of this part or the regulation as an indirect food additive required under item (i)(IV) of this part, shall be specifically for use with chemical sanitizing solutions. (P)
- (e) 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. (P)
- (f) Pesticides.
 1. Restricted use pesticides specified under 0080-04-09-.07(2)(b)2(iii) shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides. (P)
 2. Rodent Bait Stations. Rodent bait shall be placed outside and contained in a covered, tamper-resistant bait station. (P)

(Rule 0080-04-09-.07, continued)

3. Tracking Powders, Pest Control and Monitoring.
 - (i) Except as specified in subpart (ii) of this part, a tracking powder pesticide shall not be used in a food establishment. (P)
 - (ii) If used, a nontoxic tracking powder such as talcum or flour may not contaminate food, equipment, utensils, linens, and single-service and single-use articles.
 - (g) Medicines.
 1. Restriction and Storage.
 - (i) 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. (Pf)
 - (ii) Medicines that are in a food establishment for the employees' use shall be labeled as specified under 0080-04-09-.07(1)(a) and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. (P)
 2. Refrigerated Medicines, Storage. Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:
 - (i) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; (P) and
 - (ii) Located so they are inaccessible to children. (P)
 - (h) First aid supplies that are in a food establishment for the employees' use shall be:
 1. Labeled as specified under 0080-04-09-.07(1)(a); (Pf) and
 2. Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and linens, and single-service and single-use articles. (P)
 - (i) Other Personal Care Items. Except as specified under 0080-04-09-.07(2)(g)2 and 0080-04-09-.07(2)(h), employees shall store their personal care items in facilities as specified under 0080-04-09-.06(3)(e)2.
- (3) Stock and Retail Sale.
- Poisonous or toxic materials shall be stored and displayed for retail sale so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:
- (a) Separating the poisonous or toxic materials by spacing or partitioning; (P) 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. (P)

Authority: T.C.A. § 53-8-204. **Administrative History:** Original rule filed September 30, 1986; effective November 14, 1986. Amendment filed February 20, 2002; effective June 28, 2002. Amendment

(Rule 0080-04-09-.07, continued)

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0080-04-09-.08 COMPLIANCE AND ENFORCEMENT.

- (1) Applicability.
 - (a) Public Health Protection. In enforcing the provisions of this chapter, the commissioner shall assess existing facilities or equipment that were in use before the effective date of this chapter 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 0080-04-09-.04(1)(a);
 3. Whether the capacities of cooling, heating, and holding equipment are sufficient to comply with 0080-04-09-.04(3)(a)1; and
 4. The existence of a documented agreement with the permit holder that the facilities or equipment will be replaced as specified under 0080-04-09-.08(3)(i)6.
 - (b) Preventing Health Hazards, Provision for Conditions Not Addressed.
 1. If necessary to protect against public health hazards or nuisances, the commissioner may impose specific requirements in addition to the requirements contained in this chapter that are authorized by law.
 2. The commissioner 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 commissioner's file for the food establishment.
 - (c) Variances.
 1. Modifications and Waivers. The commissioner may grant a variance by modifying or waiving the requirements of this chapter if in the opinion of the commissioner a health hazard or nuisance will not result from the variance. If a variance is granted, the commissioner shall retain the information specified under part 2 of this subparagraph in its records for the food establishment. Variance requests shall be submitted to a committee including a food scientist and representatives from industry and state and local public health agencies appointed by the department.
 2. Documentation of Proposed Variance and Justification. Before a variance from a requirement of this chapter is approved, the information that shall be provided by the person requesting the variance and retained in the commissioner's file on the food establishment includes:
 - (i) A statement of the proposed variance of the chapter requirement citing relevant chapter section numbers;
 - (ii) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant chapter sections will be alternatively addressed by the proposal; and

(Rule 0080-04-09-.08, continued)

- (iii) A HACCP plan if required as specified under 0080-04-09-.08(2)(c) that includes the information specified under 0080-04-09-.08(2)(d) as it is relevant to the variance requested.
- 3. Conformance with Approved Procedures. If the commissioner grants a variance as specified in 0080-04-09-.08(1)(c), or a HACCP plan is otherwise required as specified under 0080-04-09-.08(2)(c), the permit holder shall:
 - (i) Comply with the HACCP plans and procedures that are submitted as specified under 0080-04-09-.08(2)(d) and approved as a basis for the modification or waiver; (P) and
 - (ii) Maintain and provide to the commissioner, upon request, records specified under 0080-04-09-.08(2)(d)4 and 5 that demonstrate that the following are routinely employed:
 - (I) Procedures for monitoring the critical control points,
 - (II) Monitoring of the critical control points,
 - (III) Verification of the effectiveness of the operation or process, and
 - (IV) Necessary corrective actions if there is failure at a critical control point.
- (2) Plan Submission and Approval.
 - (a) When Plans Are Required. Plans drawn to scale for food establishments shall be submitted for review and approval to the department. A permit applicant or permit holder shall submit to the commissioner properly prepared plans and specifications for review and approval before:
 - 1. The construction of a food establishment;
 - 2. The conversion of an existing structure for use as a food establishment; or
 - 3. The remodeling of a food establishment or a change of type of food establishment or food operation as specified under 0080-04-09-.08(3)(e)3 if the commissioner determines that plans and specifications are necessary to ensure compliance with this chapter.
 - (b) Contents of the Plans and Specifications. The plans and specifications for a food establishment, including a food establishment specified under 0080-04-09-.08(2)(c), shall include, as required by the commissioner based on the type of operation, type of food preparation, and foods prepared, the following information to demonstrate conformance with chapter provisions:
 - 1. Intended menu and plans to be reviewed;
 - 2. Anticipated volume of food to be stored, prepared, and sold or served;
 - 3. Proposed layout, mechanical schematics, construction materials, and finish schedules;
 - 4. Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;

(Rule 0080-04-09-.08, continued)

5. Evidence that standard procedures that ensure compliance with the requirements of this chapter are developed or are being developed; and
 6. Other information that may be required by the commissioner for the proper review of the proposed construction, conversion or modification, and procedures for operating a food establishment.
- (c) When a HACCP Plan is Required.
1. Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the commissioner for approval a properly prepared HACCP plan as specified under 0080-04-09-.08(2)(d) and the relevant provisions of this chapter if:
 - (i) Submission of a HACCP plan is required according to law;
 - (ii) A variance is required as specified under 0080-04-09-.03(4)(a)1(iv)(IV), 0080-04-09-.03(5)(b)1, or 0080-04-09-.04(2)(d)8(ii);
 - (iii) The commissioner determines that a food preparation or processing method requires a variance based on a plan submittal specified under 0080-04-09-.08(2)(b), an inspectional finding, or a variance request.
 2. A permit applicant or permit holder shall have a properly prepared HACCP plan as specified under 0080-04-09-.03(5)(b)2.
- (d) Contents of a HACCP Plan. For a food establishment that is required under 0080-04-09-.08(2)(c) to have a HACCP plan, the plan and specifications shall indicate:
1. A categorization of the types of 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 commissioner;
 2. A flow diagram by specific or category type identifying critical control points and providing information on the following:
 - (i) Ingredients, materials, and equipment used in the preparation of that food, and
 - (ii) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
 3. Food employee and supervisory training plan that addresses the food safety issues of concern;
 4. A statement of standard operating procedures for the plan under consideration including clearly identifying:
 - (i) Each critical control point,
 - (ii) The critical limits for each critical control point,
 - (iii) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge,

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- (iv) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points,
 - (v) Action to be taken by the person in charge if the critical limits for each critical control point are not met, and
 - (vi) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed; and
 - 5. Additional scientific data or other information, as required by the commissioner, supporting the determination that food safety is not compromised by the proposal.
 - (e) Preoperational Inspections. The commissioner may 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 0080-04-09-.08(2)(b)5, and is in compliance with law and this chapter.
- (3) Permit to Operate.
- (a) Prerequisite for Operation. A person shall not operate a food establishment without a valid permit to operate issued by the commissioner.
 - (b) 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.
 - (c) Form of Submission. A person desiring to operate a food establishment shall submit to the commissioner a written application for a permit on a form provided by the commissioner.
 - (d) To qualify for a permit, an applicant shall:
 - 1. Be an owner of the food establishment or an officer of the legal ownership;
 - 2. Comply with the requirements of this chapter;
 - 3. As specified under 0080-04-09-.08(4)(b)1, agree to allow access to the food establishment and to provide required information; and
 - 4. Pay the applicable permit fees at the time the application is submitted.
 - (e) Contents of the Application. The application shall include:
 - 1. 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;
 - 2. Information specifying whether the food establishment is owned by an association, corporation, individual, partnership, or other legal entity;
 - 3. A statement specifying whether the food establishment:
 - (i) Is mobile or stationary and temporary or permanent, and

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- (ii) Is an operation that includes one or more of the following:
 - (I) Prepares, offers for sale, or serves 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 0080-04-09-.03(5)(a)9,
 - (II) Prepares time/temperature control for safety food in advance using a food preparation method that involves two or more steps which may include combining time/temperature control for safety food ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,
 - (III) Prepares food as specified under item 3(ii)(II) of this subparagraph for delivery to and consumption at a location off the premises of the food establishment where it is prepared,
 - (IV) Prepares food as specified under item 3(ii)(II) of this subparagraph for service to a highly susceptible population,
 - (V) Prepares only food that is not time/temperature control of safety food, or
 - (VI) Does not prepare, but offers for sale only prepackaged food that is not time/temperature control for safety food;
- 4. The name, title, address, and telephone number of the person directly responsible for the food establishment;
- 5. The names, titles, and addresses of:
 - (i) The persons comprising the legal ownership as specified under part 2 of this subparagraph including the owners and officers, and
 - (ii) The local resident agent if one is required based on the type of legal ownership;
- 6. A statement signed by the applicant that attests to the accuracy of the information provided in the application.
- 7. Other information required by the commissioner.
- (f) New, Converted, or Remodeled Establishments. For food establishments that are required to submit plans as specified under 0080-04-09-.08(2)(a), the commissioner shall issue a permit to the applicant after:
 - 1. A properly completed application is submitted;

(Rule 0080-04-09-.08, continued)

2. The required fee is submitted;
 3. The required plans, specifications, and information are reviewed and approved; and
 4. A preoperational inspection as specified in 0080-04-09-.08(2)(e) 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 chapter.
- (g) Existing Establishments and Change of Ownership. As applicable, the commissioner may issue a permit to a new owner of an existing food establishment after an application is submitted, reviewed, and approved, and an inspection shows that the establishment is in compliance with this chapter.
- (h) Denial of Application for Permit, Notice. If an application for a permit to operate is denied, the commissioner shall provide the applicant with a notice that includes:
1. The specific reasons and chapter citations for the permit denial;
 2. The actions, if any, that the applicant must take to qualify for a permit; and
 3. Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in law.
- (i) Responsibilities of the Permit Holder. Upon acceptance of the permit issued by the commissioner, the permit holder in order to retain the permit shall:
1. Comply with the provisions of this chapter including the conditions of a granted variance as specified under 0080-04-09-.08(1)(c)3, and approved plans as specified under 0080-04-09-.08(2)(b);
 2. If a food establishment is required under 0080-04-09-.08(2)(c) to operate under a HACCP plan, comply with the plan as specified under 0080-04-09-.08(1)(c)3;
 3. Immediately contact the commissioner to report an illness of a food employee or conditional employee as specified under 0080-04-09-.02(2)(a)2;
 4. Immediately discontinue operations and notify the commissioner if an imminent health hazard may exist as specified under 0080-04-09-.08(4)(d)1;
 5. Allow representatives of the commissioner access to the food establishment as specified under 0080-04-09-.08(4)(b)1;
 6. Replace existing facilities and equipment specified in 0080-04-09-.08(1)(a) with facilities and equipment that comply with this chapter if:
 - (i) The commissioner directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted,
 - (ii) The commissioner directs the replacement of the facilities and equipment because of a change of ownership, or
 - (iii) The facilities and equipment are replaced in the normal course of operation;

(Rule 0080-04-09-.08, continued)

7. Comply with directives of the commissioner including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the commissioner in regard to the permit holder's food establishment or in response to community emergencies;
 8. Accept notices issued and served by the commissioner according to law; and
 9. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this chapter or a directive of the commissioner, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.
- (j) A permit shall 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 0080-04-09-.08(3)(e)3 and the change in operation is not approved.
- (4) Inspection and Correction of Violations.
- (a) Frequency.
1. Establishing Inspection Interval. Except as specified in parts 2 and 3 of this subparagraph, the commissioner may inspect a food establishment at least once every six months.
 2. The commissioner may increase the interval between inspections beyond six months if:
 - (i) The food establishment is fully operating under an approved and validated HACCP plan as specified under 0080-04-09-.08(2)(d) and 0080-04-09-.08(1)(c) 3(i) and (ii);
 - (ii) The food establishment is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every six months the establishment is contacted by telephone or other means by the commissioner to ensure that the establishment manager and the nature of food operation are not changed, or
 - (iii) The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not time/temperature control for safety food such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.
 3. The commissioner may periodically inspect throughout its permit period a temporary food establishment that prepares, sells, or services unpackaged time/temperature control for safety food and that:
 - (i) Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or
 - (ii) Has inexperienced food employees.

(Rule 0080-04-09-.08, continued)

4. Performance and Risk-Based. Within the parameters specified in subparagraph (a) of this paragraph, the commissioner shall prioritize and conduct more frequent inspections based upon its assessment of a food establishment's history of compliance with this chapter and the establishment's potential as a vector of foodborne illness by evaluating:
 - (i) Past performance, for nonconformance with this chapter or HACCP plan requirements that are priority items or priority foundation items;
 - (ii) Past performance, for numerous or repeat violations of this chapter or HACCP plan requirements that are core items;
 - (iii) Past performance, for complaints investigated and found to be valid;
 - (iv) The hazards associated with the particular foods that are prepared, stored, or served;
 - (v) The type of operation including the methods and extent of food storage, preparation, and service;
 - (vi) The number of people served; and
 - (vii) Whether the population served is a highly susceptible population.
- (b) Access.
1. Allowed at Reasonable Times after Due Notice. After the commissioner presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the commissioner to determine if the food establishment is in compliance with this chapter by allowing access to the establishment, allowing inspection, and providing information and records specified in this chapter and to which the commissioner is entitled according to law, during the food establishment's hours of operation and other reasonable times.
 2. Refusal, Notification of Right to Access, and Final Request for Access. If a person denies access
 - (i) The permit holder shall allow access to the commissioner as specified under 0080-04-09-.08(4)(b)1;
 - (ii) Access is a condition of the acceptance and retention of a food establishment permit to operate as specified under 0080-04-09-.08(3)(i)5;
 - (iii) If access is denied, an administrative warrant may be obtained according to law; and
 - (iv) A final request for access will be made.
 3. Refusal, Reporting. If after the commissioner presents credentials and provides notice as specified under 0080-04-09-.08(4)(c)1, explains the authority upon which access is requested, and makes a final request for access as specified in 0080-04-09-.08(4)(b)2, the person in charge continues to refuse access, the commissioner shall provide details of the denial of access on an inspection report form.
- (c) Report of Findings.

(Rule 0080-04-09-.08, continued)

1. Documenting Information and Observations. The commissioner shall document on an inspection report:
 - (i) Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation as specified under 0080-04-09-.08(3)(e)3, 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
 - (ii) Specific factual observations of violative conditions or other deviations from this chapter that require correction by the permit holder including:
 - (I) Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this chapter as specified under 0080-04-09-.02(1)(b),
 - (II) Failure of food employees, conditional employees, and the person in charge to report a disease or medical condition as specified under 0080-04-09-.02(2)(a)2 and 4,
 - (III) Nonconformance with priority items or priority foundation items of this chapter,
 - (IV) Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the commissioner as specified under 0080-04-09-.08(1)(c)3,
 - (V) Failure of the person in charge to provide records required by the commissioner for determining conformance with a HACCP plan as specified under 0080-04-09-.08(2)(d)4(vi), and
 - (VI) Nonconformance with critical limits of a HACCP plan.
2. Specifying Time Frame for Corrections. The commissioner shall specify on the inspection report form the time frame for correction of the violations as specified under 0080-04-09-.08(4)(d) and 0080-04-09-.08(4)(e)1.
3. Issuing Report and Obtaining Acknowledgment of Receipt. At the conclusion of the inspection and according to law, the commissioner shall provide a copy of the completed inspection report and the notice to correct violations to the permit holder or to the person in charge, and request a signed acknowledgment of receipt.
4. Refusal to Sign Acknowledgment. The commissioner shall:
 - (i) Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in 0080-04-09-.08(4)(c)3 that:
 - (I) An acknowledgment of receipt is not an agreement with findings,
 - (II) Refusal to sign an acknowledgment of receipt will not affect the permit holder's obligation to correct the violations noted in the inspection report within the time frames specified, and

(Rule 0080-04-09-.08, continued)

- (III) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the commissioner's historical record for the food establishment; and
 - (ii) Make a final request that the person in charge sign an acknowledgment receipt of inspectional findings.
 - (d) Imminent Health Hazard.
 - 1. Ceasing Operations and Reporting.
 - (i) Except as specified in subpart (ii) of this part, 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.
 - (ii) A permit holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.
 - 2. Resumption of Operations. If operations are discontinued as specified under part (d)1 of this paragraph or otherwise according to law, the permit holder shall obtain approval from the commissioner before resuming operations.
 - (e) Violation of Priority Item or Priority Foundation Item.
 - 1. Timely Correction.
 - (i) Except as specified in subpart (ii) of this part, a permit holder shall at the time of inspection correct a violation of a priority item or priority foundation item of this chapter and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.
 - (ii) Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the commissioner 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 priority item or priority foundation item or HACCP plan deviations.
 - 2. Verification and Documentation of Correction.
 - (i) After observing at the time of inspection a correction of a violation of a priority item or priority foundation item or a HACCP plan deviation, the commissioner shall enter the violation and information about the corrective action on the inspection report.
 - (ii) As specified under 0080-04-09-.08(4)(e)1(ii), after receiving notification that the permit holder has corrected a violation of a priority item or priority foundation item or HACCP plan deviation, or at the end of the specified period of time, the commissioner may verify correction of the violation.
 - (f) Core Violation.

(Rule 0080-04-09-.08, continued)

1. Except as specified in part 2 of this subparagraph, the permit holder shall correct core items by a date and time agreed to or specified by the commissioner but no later than 90 calendar days after the inspection.
2. The commissioner may approve a compliance schedule that extends beyond the time limits specified under part 1 of this subparagraph 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.

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