

4626.0020 STATEMENT OF APPLICATION AND DEFINITIONS. 1-201.10

Subpart 1. **Applicability.** The terms used in this chapter have the meanings given them in this part.

Subp. 2. **Additive.**

A. "Food additive" has the meaning given in the Federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 321(s), and Code of Federal Regulations, title 21, section 170.3(e)(1).

B. "Color additive" has the meaning given in the Federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 321(t), and Code of Federal Regulations, title 21, section 70.3(f).

Subp. 3. **Adulterated.** "Adulterated" has the meaning given in Minnesota Statutes, section 34A.02, and the Federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 342.

Subp. 4. **Approved.** "Approved" means acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Subp. 4a. **Asymptomatic.**

A. "Asymptomatic" means without obvious symptoms or 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 were never manifested.

Subp. 5. **a_w.** "a_w" means water activity that 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 the pure water at the same temperature, and is indicated by the symbol a_w.

Subp. 5a. **Balut.** "Balut" means an embryo inside a fertile egg that has been incubated until the embryo reaches a specific stage of development and is then removed from incubation before hatching.

Subp. 6. **Beverage.** "Beverage" means a liquid for drinking, including water.

Subp. 7. **Bottled drinking water.** "Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

Subp. 8. **Bulk food.** "Bulk food" has the meaning given in Minnesota Statutes, section 31.80, subdivision 2.

Subp. 9. [Repealed, 43 SR 295]

Subp. 10. **Certification number.** "Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the National Shellfish Sanitation Program.

Subp. 10a. **Certified food protection manager or CFPM.** "Certified food protection manager" or "CFPM" means an individual who has a valid Minnesota food protection manager's certification under part 4626.0033 or an individual who is certified under Minnesota Rules 2015, parts 4626.2005 to 4626.2020.

Subp. 11. **CIP.**

A. "CIP" means cleaned in place.

B. A CIP system circulates cleaning, rinsing, and sanitizing solutions through a fixed system.

C. CIP does not include in-place, manual cleaning without the use of a CIP system for equipment such as band saws, slicers, or mixers.

Subp. 11a. [Repealed, 43 SR 295]

Subp. 12. [Repealed, 43 SR 295]

Subp. 12a. **Commingle.** "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.

Subp. 13. **Comminuted.**

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

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

Subp. 13a. **Commissioner.** "Commissioner" means the commissioner of health.

Subp. 14. [Repealed, 43 SR 295]

Subp. 14a. **Conditional employee.** "Conditional employee" means a potential food employee to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with the Americans with Disabilities Act, United States Code, title 42, chapter 126.

Subp. 15. **Confirmed disease outbreak.** "Confirmed disease outbreak" means a foodborne disease outbreak when laboratory analysis of appropriate specimens identifies a causative organism and epidemiological analysis implicates the food as the source of the illness.

Subp. 16. **Consumer.** "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.

Subp. 17. [Repealed, 43 SR 295]

Subp. 18. **Corrosion-resistant material.** "Corrosion-resistant material" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of food contact, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

Subp. 18a. **Counter-mounted equipment.** "Counter-mounted equipment" means equipment that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

Subp. 19. **Critical control point.** "Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

Subp. 19a. **Critical limit.** "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.

Subp. 19b. **Cross-contamination.** "Cross-contamination" is the movement or transfer of bacteria, microorganisms, or other harmful substances from one person, object, place, or food item to another.

Subp. 20. [Repealed, 43 SR 295]

Subp. 20a. **Cut leafy greens or leafy greens.** "Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. "Leafy greens" includes iceberg lettuce; romaine lettuce; leaf lettuce; butter lettuce; baby leaf lettuce such as immature lettuce or leafy greens; escarole; endive; spring mix; spinach; cabbage; kale; arugula; and chard. Leafy greens does not include herbs such as cilantro or parsley.

Subp. 20b. **Dealer.** "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.

Subp. 20c. **Disclosure.** "Disclosure" means a written statement that clearly identifies the animal-derived foods or items containing ingredients that contain animal-derived foods that are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens.

Subp. 21. **Drinking water.** "Drinking water" means water from a source that meets chapters 4720 and 4725 and Code of Federal Regulations, title 40, part 141.

Drinking water includes the term water except the terms boiler water, mop water, rainwater, wastewater, nondrinking water, and other terms that connote that the water is not potable.

Subp. 22. **Dry storage area.** "Dry storage area" means a room or area designated for the storage of packaged or containerized food that is not time/temperature control for safety food, and dry goods such as single-service items.

Subp. 23. **Easily cleanable.** "Easily cleanable" means a characteristic of a surface that:

- A. allows effective removal of soil by normal cleaning methods; and
- B. is dependent on the material, design, construction, and installation of the surface.

Subp. 24. **Easily movable.** "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.

Subp. 24a. **Egg.**

A. "Egg" means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratite, or turkey.

B. Egg does not include:

- (1) a balut;
- (2) the egg of reptile species such as alligator; or
- (3) an egg product.

Subp. 24b. **Egg product.**

A. "Egg product" means all, or a portion of, the contents found inside eggs separated from the shell in a food processing plant, and processed to be free of viable *Salmonella* microorganisms.

B. Egg product does not include food that contains eggs only in a relatively small proportion such as cake mixes.

Subp. 25. **Employee.** "Employee" means a licensee, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food establishment.

Subp. 26. **Equipment.**

A. "Equipment" means an article that is used in the operation of a food establishment such as a freezer, grinder, hood, ice maker, mixer, oven, reach-in refrigerator, sink, slicer, stove, table, vending machine, warewashing machine, grill, and fryer.

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.

Subp. 26a. **Exclude.** "Exclude" means to prevent a person from working as an employee in a food establishment or entering a food establishment as an employee.

Subp. 27. [Repealed, 43 SR 295]

Subp. 28. [Repealed, 43 SR 295]

Subp. 28a. **FDA.** "FDA" means the U.S. Food and Drug Administration.

Subp. 29. **Fish.**

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

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.

Subp. 30. **Food.** "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.

Subp. 31. **Foodborne disease outbreak.**

A. "Foodborne disease outbreak" means an incident, except as specified in item B, when:

(1) two or more persons experience a similar illness after ingestion of a common food;
and

(2) epidemiological analysis implicates the food as the source of the illness.

B. Foodborne disease outbreak includes a single case of illness from botulism or chemical poisoning.

Subp. 32. **Food cart.** "Food cart" has the meaning given in Minnesota Statutes, section 157.15, subdivision 6. A food cart must be a single self-contained unit.

Subp. 32a. **Food catering.** "Food catering" means food that is prepared for service in support of an event with a predetermined guest list such as a reception, party, luncheon, conference, ceremony, or trade show. A food establishment doing catering is responsible for maintaining control of and ensuring the safety of the food from preparation to service to the consumer.

Subp. 33. **Food-contact surface.** "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.

Subp. 34. **Food employee.** "Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

Subp. 35. **Food establishment.**

A. "Food establishment" means an operation that stores, prepares, packages, serves, vends, caters, delivers, or otherwise provides food for human consumption, where consumption is on or off the premises and regardless of whether there is a charge for the food, and relinquishes possession either directly or indirectly to a consumer.

Food establishment includes:

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

(2) retail operations located within the following establishments:

(a) wholesale food processors, wholesale food handlers, food manufacturers, or food brokers as classified in Minnesota Statutes, section 28A.05, paragraphs (b), (c), and (d);

(b) custom processors as defined in Minnesota Statutes, section 28A.03, subdivision 8, or custom processing as defined in Minnesota Statutes, section 31A.02, subdivision 5; or

(c) animal food manufacturers as defined in Minnesota Statutes, section 31A.02, subdivision 8; and

(d) those food service operations within a hospital, nursing home, or boarding care home licensed under Minnesota Statutes, sections 144.50 to 144.56, that are not limited to patient or resident care.

B. Food establishment does not include:

(1) an establishment excluded from licensure under Minnesota Statutes, sections 28A.15, 28A.151, and 28A.152, or 31.56;

(2) an establishment exempted under Minnesota Statutes, section 157.22;

(3) a private home or other location that receives catered or home-delivered food when only invited guests are present; or

(4) a food service limited to patient or resident care within a hospital, nursing home, boarding care home, or supervised living facility licensed under Minnesota Statutes, sections 144.50 to 144.56, except for those operations subject to the rules and laws administered by the Minnesota Department of Agriculture.

Subp. 36. **Food processing plant.** "Food processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption and provides food for sale or distribution only to other business entities such as food processing plants or food establishments.

Subp. 37. **Game animal.**

A. "Game animal" means an animal, the products of which are food.

B. Game animals include (1) big and small game as defined in Minnesota Statutes, section 97A.015, subdivisions 3 and 45; and (2) game birds as defined in Minnesota Statutes, section 97A.015, subdivision 24.

C. Game animal does not include animals classified as livestock in Code of Federal Regulations, title 9, section 301.2, or as animals as defined in Minnesota Statutes, section 31A.02, subdivision 4, or poultry or fish; or animals raised as livestock, Cervidae, Ratitae, or llama as defined in Minnesota Statutes, sections 17.452, 17.453, and 17.455.

Subp. 38. **General use pesticide.** "General use pesticide" means a pesticide that is not classified by the U.S. Environmental Protection Agency for restricted use as specified in Code of Federal Regulations, title 40, section 152.175.

Subp. 38a. **Grade A standards.** "Grade A standards" means the requirements found in "Grade A Pasteurized Milk Ordinance" produced with guidance from the U.S. Public Health Service and the FDA, and with which certain fluid and dry milk and milk products must comply. This publication is incorporated by reference, is subject to frequent change, and is available through the FDA website at www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM513508.pdf.

Subp. 39. [Repealed, 43 SR 295]

Subp. 40. **HACCP plan.** "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. This publication is incorporated by reference, is subject to infrequent change, and is available at www.fsis.usda.gov.

Subp. 40a. **Handwashing sink.**

A. "Handwashing sink" means a lavatory, a basin, or a vessel for washing; a wash basin; or a plumbing fixture dedicated to handwashing.

B. Handwashing sink includes an automatic handwashing facility.

Subp. 41. **Hazard.** "Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

Subp. 42. **Hermetically sealed container.** "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.

Subp. 42a. **Highly susceptible population.** "Highly susceptible population" means persons who are more likely than others in the general population to experience foodborne disease because they are immunocompromised, preschool-age children, or older adults and they are obtaining food at a facility that provides services such as custodial care, health care, or nutritional or socialization services.

Subp. 43. **Imminent health hazard.** "Imminent health hazard" means a significant threat or danger to health that exists when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

- A. the number of potential injuries; and
- B. the nature, severity, and duration of the anticipated injury.

Subp. 44. **Injected.** "Injected" means manipulating meat by introducing a solution into its interior by processes referred to as "injecting," "pump marinating," or "stitch pumping."

Subp. 44a. **Juice.**

A. "Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of the liquid or puree.

B. For purposes of HACCP, juice does not include liquids, purees, or concentrates that are not used as beverages or ingredients of beverages.

Subp. 45. **Kitchenware.** "Kitchenware" means food preparation and storage utensils.

Subp. 46. **License.** "License" means the authorization issued by the regulatory authority to a person to operate a food establishment.

Subp. 47. **Licensee.** "Licensee" means the person licensed by the regulatory authority who:

A. is the owner, the owner's agent, or other person legally responsible for the operation of the food establishment; and

B. possesses a valid license to operate a food establishment according to Minnesota Statutes, chapter 28A or 157.

Subp. 48. **Linens.** "Linens" means fabric items such as cloth hampers, cloth napkins, tablecloths, wiping cloths, cloth gloves, and other work garments.

Subp. 48a. **Major food allergen.**

A. "Major food allergen" means:

(1) milk; egg; fish, such as bass, flounder, or cod; crustacean shellfish, including 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 subitem (1).

B. Major food allergen does not include:

(1) any highly refined oil derived from a food specified in item A, subitem (1), and any ingredient derived from the 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.

Subp. 49. [Repealed, 43 SR 295]

Subp. 50. **Meat.**

A. "Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals.

B. Meat does not include fish, poultry, and wild animals as defined in Minnesota Statutes, section 97A.015, subdivision 55, and as specified in part 4626.0160, item C.

Subp. 50a. **Mechanically tenderized.**

A. "Mechanically tenderized" means manipulating meat with deep penetration by processes such 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.

Subp. 51. **mg/L.** "mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

Subp. 52. **Molluscan shellfish.** "Molluscan shellfish" means an 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.

Subp. 52a. [Repealed, 43 SR 295]

Subp. 52b. **Mushrooms.**

A. "Mushrooms, wild" means edible species of mushrooms that have been harvested from their naturally occurring environment where no human intervention occurred to support their growth.

B. "Mushrooms, cultivated" means edible species of mushrooms that have been grown by a person or persons under controlled conditions, outdoors or indoors, on natural or artificial substrate.

Subp. 52c. **Neighborhood kitchen.** "Neighborhood kitchen" means a satellite or auxiliary kitchen in residential buildings for adults age 55 or older that is secondary to the primary approved commercial kitchen where most of the food is received, stored, and prepared.

Subp. 52d. **Noncontinuous cooking.**

A. "Noncontinuous 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. Noncontinuous cooking does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

Subp. 52e. **Nonpublic water system.** "Nonpublic water system" means any water system that does not meet the definition of a public water system as defined in subpart 66.

Subp. 53. **Packaged.**

A. "Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant.

B. Packaged does not include food delivered to a consumer by a food employee, upon consumer request, that is wrapped or placed in a carry-out container to protect the food during delivery to the consumer.

Subp. 54. **Person.** "Person" means an association, corporation, individual, partnership, government, or governmental subdivision or agency.

Subp. 55. **Person in charge.** "Person in charge" means the individual present at a food establishment who is responsible for the operation at the time of inspection.

Subp. 56. **Personal care item.** "Personal care item" means an item or substance that may be poisonous, toxic, or a source of contamination and is used to maintain or enhance a person's health, hygiene, or appearance.

Subp. 57. **pH.** "pH" is 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.

Subp. 58. **Physical facility.** "Physical facility" 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.

Subp. 59. **Plumbing fixture.** "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.

Subp. 60. **Plumbing system.** "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.

Subp. 61. **Poisonous or toxic material.** "Poisonous or toxic material" means a substance that is not intended for ingestion and is included in one of the following 4 categories:

- A. cleaners and sanitizers, such as cleaning and sanitizing agents and other chemicals such as caustics, acids, drying agents, and polishes;
- B. pesticides, except sanitizers, including substances such as insecticides and rodenticides;
- C. substances necessary for the operation and maintenance of the establishment, such as non-food-grade lubricants and personal care items that may be deleterious to health; or
- 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.

Subp. 62. **Potentially hazardous food.**

A. "Potentially hazardous food" means a food that is natural or synthetic and is in a form capable of supporting:

- (1) the rapid and progressive growth of infectious or toxigenic microorganisms;
- (2) the growth and toxic production of *Clostridium botulinum*; or
- (3) in raw shell eggs, the growth of *Salmonella enteritidis*.

B. Potentially hazardous food includes a food of animal origin that is raw or heat-treated, a food of plant origin that is heat-treated or consists of raw seed sprouts, cut melons, and garlic and oil mixtures that are not acidified or otherwise modified at a food processing plant in a way that results in mixtures that do not support growth as specified in item A.

C. Potentially hazardous food does not include:

- (1) an air-cooled hard-boiled egg with shell intact;
- (2) a food with an a_w value of 0.85 or less;
- (3) a food with a pH level of 4.6 or below when measured at 24 degrees C (75 degrees F);
- (4) a food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;
- (5) a food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious and toxigenic microorganisms or the growth of *Salmonella enteritidis* in eggs or *Clostridium botulinum* cannot occur, including a food that has an a_w and a pH that are above the levels specified in subitem (2) or (3) and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or

(6) a food that may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness, but that does not support the growth of microorganisms as specified in item A.

Subp. 63. **Poultry.** "Poultry" means:

A. any domesticated bird, such as chickens, turkeys, ducks, geese, guineas, ratites, or squabs, whether live or dead, as defined in Code of Federal Regulations, title 9, part 381.1; and

B. any migratory waterfowl or game bird, whether live or dead, as defined in Code of Federal Regulations, title 9, part 362.1, including pheasant, partridge, quail, grouse, or pigeon.

Subp. 64. **Premises.** "Premises" means:

A. the physical facility, its contents, and the contiguous land or property under the control of the licensee; or

B. the physical facility, its contents, and the land or property not described in item A, if its facilities and contents that are under the control of the licensee and may impact food establishment personnel, facilities, or operations, and a food establishment is only 1 component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

Subp. 64a. **Prepare.** "Prepare" means to process food by means such as heating, cooking, canning, extracting, fermenting, distilling, pickling, freezing, baking, drying, smoking, grinding, cutting, mixing, coating, stuffing, packing, bottling, packaging, or any other treatment or preservation process.

Subp. 65. **Primal cut.** "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.

Subp. 65a. **Priority 1 item or p₁.**

A. "Priority 1 item" or "p₁" means a provision in this Code whose application contributes directly to the elimination, prevention, or reduction to an acceptable level of hazards associated with foodborne illness or injury, and there is no other provision that more directly controls the hazard. This is the same as the FDA's "priority designation."

B. A priority 1 item includes an item with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, and handwashing.

Subp. 65b. **Priority 2 item or p₂.**

A. "Priority 2 item" or "p₂" means a provision in this Code whose application supports, facilitates, or enables one or more priority 1 items. This is the same as the FDA's "priority foundation designation."

B. A priority 2 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, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling.

Subp. 65c. **Priority 3 item.**

A. "Priority 3 item" means a provision in this Code that is not designated as a priority 1 item or a priority 2 item. This is the same as the FDA's "core designation."

B. A priority 3 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.

C. Items not designated with a p_1 or p_2 are priority 3 items.

Subp. 66. **Public water system.** "Public water system" has the meaning given in Code of Federal Regulations, title 40, part 141.2.

Subp. 66a. **Ratite.** "Ratite" or "Ratitae" means a flightless bird such as an emu, ostrich, or rhea.

Subp. 67. **Ready-to-eat food.**

A. "Ready-to-eat food" means food that:

(1) is in a form that is edible without additional preparation to achieve food safety as specified in part 4626.0340 or 4626.0350;

(2) is a raw or partially cooked animal food and the consumer is advised as specified in part 4626.0340, item D, subitem (3); or

(3) is prepared according to a variance that is granted under part 4626.0340, item D, subitem (4); and

(4) may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

B. Ready-to-eat food includes:

(1) raw animal food that is cooked as specified under part 4626.0340 or 4626.0345, or frozen as specified under part 4626.0350;

(2) raw fruits and vegetables that are washed as specified under part 4626.0255;

(3) fruits and vegetables that are cooked for hot holding, as specified in part 4626.0347;

(4) 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;

(5) all TCS food as defined in subpart 90a that is cooked to the temperature and time required for the specific food under parts 4626.0340 to 4626.0349 and cooled as specified in part 4626.0385;

(6) substances derived from plants such as spices, seasonings, and sugar;

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

(8) products that are produced according to USDA guidelines and have received a lethality treatment for pathogens; and

(9) food manufactured as specified in Code of Federal Regulations, title 21, part 113.

Subp. 68. 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, which is approximately 21 percent at sea level; and

(2) the process in subitem (1) 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 packaging in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;

(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 psychotropic pathogens; or

(5) sous-vide packaging in which raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychotropic pathogens.

Subp. 69. Refuse. "Refuse" means solid waste not carried by water through the sewage system.

Subp. 70. Regulatory authority. "Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment.

Subp. 70a. **Reminder.** "Reminder" means a written statement concerning the health risk of consuming animal foods raw, undercooked, or without otherwise being processed to eliminate pathogens.

Subp. 70b. **Re-service.** "Re-service" means food that is served or sold to a consumer who then returns the unused food, which is then transferred by means of serving or selling to another person.

Subp. 70c. **Restrict.** "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 or handle clean equipment, utensils, linens, or unwrapped single-service or single-use articles.

Subp. 70d. **Restricted egg.** "Restricted egg" means any egg as defined in Code of Federal Regulations, title 9, section 590.5, that is a check, incubator reject, inedible, leaker, loss, or dirty egg.

Subp. 71. **Restricted use pesticide.** "Restricted use pesticide" means a pesticide product that contains the active ingredients specified in Code of Federal Regulations, title 40, section 152.175, and that is limited to use by a licensed applicator.

Subp. 72. [Repealed, 43 SR 295]

Subp. 73. **Retail food vehicle, portable structure, or cart.** "Retail food vehicle, portable structure, or cart" means a food establishment licensed under Minnesota Statutes, sections 28A.06 and 28A.07, that is a motor vehicle, portable structure, or nonmotorized cart where food and food products are:

- A. offered to the consumer;
- B. intended for off-premises consumption; and
- C. not subject to on-site preparation.

Subp. 73a. **Risk.** "Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

Subp. 74. **Safe material.** "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 the Federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 348 or 379e; or

C. any other material that is not an additive and that is used in conformity with applicable regulations of the Food and Drug Administration.

Subp. 75. **Sanitization.** "Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, yields within 1 minute a reduction

of 5 logs, which is equal to a 99.999 percent reduction, of representative disease microorganisms of public health importance.

Subp. 76. **Sealed.** "Sealed" means free of cracks or other openings that allow the entry or passage of moisture.

Subp. 76a. **Service animal.** "Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to a person with a disability.

Subp. 77. **Servicing area.** "Servicing area" means an operating base location to which a food cart, special event food stand, temporary food establishment, retail food vehicle, portable structure, cart, or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes or refilling water tanks and ice bins, and loading food.

Subp. 78. **Sewage.** "Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

Subp. 78a. [Repealed, 43 SR 295]

Subp. 78b. **Shellfish control authority.** "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.

Subp. 79. **Shellstock.** "Shellstock" means raw, in-shell molluscan shellfish.

Subp. 79a. **Shiga toxin-producing *Escherichia coli* or STEC.** "Shiga toxin-producing *Escherichia coli* " or "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*.

Subp. 80. **Shucked shellfish.** "Shucked shellfish" means molluscan shellfish that have 1 or both shells removed.

Subp. 81. **Single-service articles.** "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 to be used 1 time by 1 person, after which they are intended to be discarded.

Subp. 82. **Single-use article.**

A. "Single-use article" means a utensil or bulk food container designed and constructed to be used once and discarded.

B. Single-use article 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, number 10 cans, and other items that do not meet the materials, durability, strength, and cleanability specifications contained in parts 4626.0450, 4626.0505, and 4626.0515 for multiuse utensils.

Subp. 83. **Slacking.** "Slacking" means the process of moderating the temperature of a food, such as allowing a food to gradually increase from a temperature of -10 degrees F (-23 degrees C) to 25 degrees F (-4 degrees C) in preparation for deep-fat frying or for even heat penetration during the cooking of previously block-frozen food such as shrimp.

Subp. 84. **Smooth.** "Smooth" means:

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

B. a non-food-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; or

C. a floor, wall, or ceiling having an even or level surface with no roughness or projections that render the surface difficult to clean.

Subp. 85. **Special event food stand.** "Special event food stand" has the meaning given in Minnesota Statutes, section 157.15, subdivision 14.

Subp. 86. [Repealed, 43 SR 295]

Subp. 87. [Repealed, 43 SR 295]

Subp. 88. [Repealed, 43 SR 295]

Subp. 89. **Temperature measuring device.** "Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

Subp. 90. **Temporary food establishment.** "Temporary food establishment" means a food establishment that is a mobile food unit, seasonal permanent food stand, or seasonal temporary food stand, as those terms are defined in Minnesota Statutes, section 157.15, subdivisions 9, 12a, and 13.

Subp. 90a. **Time/temperature control for safety food (TCS).**

A. "Time/temperature control for safety food (TCS)" means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

B. TCS 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 item C, subitem (4), a food that because of the interaction of its a_w and pH values is designated as product assessment (PA) required in Table A or B:

TABLE A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged			
a_w values	pH values		
	4.6 or less	> 4.6 up to 5.6	> 5.6
≤ 0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 up to 0.95	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			

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				

C. TCS does not include:

(1) 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*;

(2) a food in an unopened, hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

(3) 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 item B, Table A or B;

(4) a food that is designated as product assessment (PA) required in item B, Table A or B, 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:

(a) intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

(b) 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

(c) a combination of intrinsic and extrinsic factors; or

(5) a food that does not support the growth or toxin formation of pathogenic microorganisms according to subitems (1) to (4) even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

Subp. 90b. **USDA.** "USDA" means the U.S. Department of Agriculture.

Subp. 91. **Utensil.** "Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, including 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.

Subp. 92. **Vending machine.** "Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

Subp. 93. **Vending machine location.** "Vending machine location" means the room, enclosure, space, or area where one or more vending machines are installed and operated and includes the storage areas and areas on the premises that are used to service and maintain the vending machines.

Subp. 94. **Warewashing.** "Warewashing" means the cleaning and sanitizing of utensils and food-contact surfaces of equipment.

Subp. 94a. **Whole-muscle, intact beef.** "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.

Subp. 95. [Repealed, 43 SR 295]

Subp. 96. [Repealed, 43 SR 295]

Subp. 97. [Repealed, 43 SR 295]

Subp. 98. [Repealed, 43 SR 295]

Statutory Authority: *MS s 31.101; 31.11; 144.05; 144.07; 144.08; 144.12; 157.011*

History: *23 SR 519; L 2005 1Sp1 art 1 s 97; 43 SR 295*

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