

3717-1-01 State of Ohio Uniform Food Safety Code and definitions.

[Comment: For publication dates of the Code of Federal Regulations (C.F.R.) referenced in this rule, see paragraph (B)(15)(b) of rule 3717-1-01 of the Administrative Code.]

(A) "The State of Ohio Uniform Food Safety Code."

Chapter 3717-1 of the Administrative Code shall also be known as "The State of Ohio Uniform Food Safety Code."

(B) Definitions.

For the purposes of Chapter 3717-1 of the Administrative Code:

(1) Additive.

(a) "Color additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, section 201(t) (as amended on August 2, 2004) and 21 C.F.R. 70.3 (f).

(b) "Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, section 201(s) (as amended on August 2, 2004) and 21 C.F.R. 170.3 (e)(1).

(2) "Adulterated" has the meaning stated in section 3715.59 of the Revised Code.

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

(4) "Approved source" means a food is from:

(a) A processor that is inspected by a federal food safety regulatory agency or equivalent, the Ohio department of agriculture under Chapter 3715., 911., 913., 915., 917., 918. whether mandatory or voluntary, or 925. of the Revised Code, or other recognized food regulatory agency of another state responsible for food safety; or

(b) A cottage food production operation as defined in division (A) of section 3715.01 of the Revised Code, or an exempt processor of maple syrup, honey, or sorghum as specified in division (A) of section 3715.021 of the Revised Code; and that is in compliance with the provisions of Chapter 3715. of the Revised Code and any applicable rules adopted thereunder; or

(c) A food service operation or retail food establishment as defined and licensed in accordance with Chapter 3717. of the Revised Code provided the processing is not subject to regulation as stated in paragraphs (B)(4)(a) and (B)(4)(b) of this rule.

(d) The term "approved source" is not applicable to fresh unprocessed fruits and vegetables with the exception of mushrooms and sprouts.

(5) "ANSI" means the American national standards institute.

- (6) "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. It includes not showing symptoms because symptoms have resolved or subsided.
- (7) " 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 .
- (8) "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.
- (9) "Beverage" means a liquid for drinking, including water.
- (10) "Board of health" means the board of health of any city or general health district, or the authority having the duties of a board of health as authorized by section 3709.05 of the Revised Code.
- (11) "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.
- (12) "Bulk water machine" means a self-service device used for the filling of containers with water. The device includes a water treatment process, does not require replenishing after each use, and does not require prior payment by the user for activation of the machine.
- (13) "Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.
- (14) "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.
- (15) "C.F.R." means Code of Federal Regulations which is the compilation of the general and permanent rules published in the federal register by the executive departments and agencies of the federal government which:
 - (a) Is published annually by the United States government printing office;
 - (b) Contains FDA rules in 21 C.F.R. (as published on April 1, 2006), USDA rules in 7 C.F.R. and 9 C.F.R. (as published on January 1, 2006), EPA rules in 40 C.F.R. (as published on July 1, 2006), and wildlife and fisheries rules in 50 C.F.R. (as published on October 1, 2006); and
 - (c) Citations in this chapter to the C.F.R. refer sequentially to the title, part, and section numbers, such as 40 C.F.R. 180.194 refers to Title 40, Part 180, Section 194.
- (16) "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. "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.

(17) "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.

(18) "Comminuted":

- (a) Means reduced in size by methods including chopping, flaking, grinding, or mincing; and
- (b) 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 two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.

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

(20) "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.

(21) "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 service operation, retail food establishment or food processing plant, and does not offer the food for resale.

(22) "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.

(23) "Cottage food production operation" means a person who, in the person's home, produces food items that are not potentially hazardous foods, including bakery products, jams, jellies, candy, fruit butter, and similar products specified in rules adopted pursuant to section 3715.025 of the Revised Code.

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

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

(26) "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.

- (27) "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.
- (28) "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.
- (29) "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.
- (30) "Drinking water" means water that meets criteria as specified in 40 C.F.R. 141.
"Drinking water" is traditionally known as "potable water."
"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.
- (31) "Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not time/temperature controlled for safety and dry goods such as single-service items.
- (32) "Easily cleanable":
- (a) Means a characteristic of a surface that:
 - (i) Allows effective removal of soil by normal cleaning methods;
 - (ii) Is dependent on the material, design, construction, and installation of the surface; and
 - (iii) 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) Includes a tiered application of the criteria that qualify the surface as easily cleanable as specified under paragraph (B)(32)(a) of this rule to different situations in which varying degrees of cleanability are required such as:
 - (i) 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

- (ii) 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.

(33) "Easily movable" means:

- (a) Portable, weighing thirty pounds (fourteen kilograms) or less; mounted on casters, gliders, or rollers; or provided with a mechanical means requiring no more than thirty pounds (fourteen kilograms) 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.

(34) "Egg" means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratites or turkey. It does not include a balut; the egg of reptile species such as alligator; or an egg product.

(35) "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. It does not include food which contains eggs only in a relatively small proportion such as cake mixes.

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

(37) "EPA" means the United States environmental protection agency.

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

(39) "Exclude" means to prevent a person from working as an employee in a food service operation or retail food establishment, or entering a food service operation or retail food establishment as an employee.

(40) "FDA" means the United States food and drug administration.

(41) "Fish":

- (a) 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.
- (b) Includes an edible human food product derived in whole or in part from fish,

including fish that have been processed in any manner.

- (42) "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.
- (43) "Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.
- (44) "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:
 - (i) Into a food; or
 - (ii) Onto a surface normally in contact with food.
- (45) "Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.
- (46) "Food processing plant" means a commercial business or that portion of a business that manufactures, packages, labels, or stores food for human consumption, and is under regulation of the federal government or the Ohio department of agriculture under Chapter 3715., 911., 913., 915., 917., 918., or 925. of the Revised Code.
- (47) "Food service operation":
 - (a) Means a place, location, site, or separate area where food intended to be served in individual portions is prepared or served for a charge or required donation. As used in this definition, "served" means a response made to an order for one or more individual portions of food in a form that is edible without washing, cooking, or additional preparation and "prepared" means any action that affects a food other than receiving or maintaining it at the temperature at which it was received;
 - (b) Includes a catering food service operation, a food delivery sales operation, a mobile food service operation, temporary food service operation, seasonal food service operation, and a vending machine location; and
 - (c) Does not include those operations exempted in section 3717.42 of the Revised Code.
- (48) "Food service operation sales volume" means the annual sales, minus sales tax, for individual portions of food that are prepared or served by the operation for on premise consumption or individual portions of food served for carry-out or delivery and that are edible without further washing, cooking, or additional preparation.
- (49) "Game animal":
 - (a) Means an animal, the products of which are food, that is not classified as

cattle, sheep, swine, goat, horse, mule or other equine in 9 C.F.R. 301.2, or as poultry, or fish.

- (b) 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) Does not include ratites.
- (50) "General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 C.F.R. 152.175.
- (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.
- (52) "HACCP plan" means a written document that delineates the formal procedures for following the hazard analysis and critical control point (HACCP) principles developed by the national advisory committee on microbiological criteria for foods.
- (53) "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. The term includes an automatic handwashing facility.
- (54) "Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.
- (55) "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.
- (56) "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.
- (57) "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."
- (58) "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 such liquid or puree. Juice includes juice as a whole beverage, an ingredient of a beverage and a puree as an ingredient of a beverage.

- (59) "Kitchenware" means food preparation and storage utensils.
- (60) "Law" means applicable local, state, and federal statutes, regulations, and ordinances.
- (61) "License" means the document issued by the licensor that authorizes a person to operate a food service operation or retail food establishment.
- (62) "License holder" means the entity that:
- (a) Is legally responsible for the operation of the food service operation or retail food establishment such as the owner, the owner's agent, or other person; and
 - (b) Possesses a valid license to operate a food service operation or retail food establishment.
- (63) "Licensor" means one of the following:
- (a) A board of health or the authority having the duties of a board of health approved under section 3717.11 of the Revised Code;
 - (b) The director of agriculture acting under section 3717.11 of the Revised Code or 3717.111 of the Revised Code with respect to licensing retail food establishments; or
 - (c) The director of health acting under section 3717.11 of the Revised Code or 3717.111 of the Revised Code with respect to licensing food service operations.
- (64) "Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.
- (65) "Major food allergen" means:
- (a) Milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or
 - (b) A food ingredient that contains protein derived from a food, as specified in paragraph (B)(65)(a) of this rule.
 - (c) The term does not include:
 - (i) Any highly refined oil derived from a food specified in paragraph (B)(65)(a) of this rule and any ingredient derived from such highly refined oil; or
 - (ii) 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).
- (66) "Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish and poultry.
- (67) "Mechanically tenderized"

- (a) 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) Does not include processes by which solutions are injected into meat.
- (68) "mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).
- (69) "Micro market" means a retail food establishment that offers for sale food items that are allowable in a risk level one operation in displays not more than two hundred and fifty linear feet. All commercially prepackaged refrigerated or frozen time/temperature controlled for safety foods shall be stored in equipment that complies with paragraph (H) of rule 3717-1-03.4, paragraphs (LL) and (MM) of rule 3717-1-04.1 of the Administrative Code.
- (70) "Mobile food service operation" means a food service operation that is operated from a movable vehicle, portable structure, or watercraft and that routinely changes location, except that if the operation remains at any one location for more than forty consecutive days, the operation is no longer a mobile food service operation. "Mobile food service operation" includes a food service operation that does not remain at any one location for more than forty consecutive days and serves, in a manner consistent with division (F) of section 3717.01 of the Revised Code.
- (71) "Mobile retail food establishment" means a retail food establishment that is operated from a movable vehicle or other portable structure, and that routinely changes location, except that if the establishment operates from any one location for more than forty consecutive days, the establishment is no longer a mobile retail food establishment.
- (72) "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.
- (73) "Non-continuous cooking":
- (a) Means the cooking of food in a food service operation or retail 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) Does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.
- (74) "NSF" means the national sanitation foundation or NSF international which contains standard 61, "Drinking Water System Components - Health Effects" (as published on June 10, 2011).
- (75) "Packaged":
- (a) Means bottled, canned, cartoned, securely bagged, or wrapped, whether packaged in a food service operation, retail food establishment or a food processing plant; and

- (b) Does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.
- (76) "Person" means an association, corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.
- (77) "Person in charge" means the individual present at a food service operation or retail food establishment who is responsible for the operation at the time of inspection.
- (78) "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. Personal care items include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.
- (79) "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. Values between zero and seven indicate acidity and values between seven and fourteen indicate alkalinity. The value for pure distilled water is seven, which is considered neutral.
- (80) "Physical facilities" means the structure and interior surfaces of a food service operation or retail food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.
- (81) "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.
- (82) "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.
- (83) "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;
 - (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.

(84) "Potentially hazardous food" means time/temperature controlled for safety food as defined in paragraph (B)(122) of this rule.

(85) "Poultry" means:

- (a) Any domesticated bird (chickens, ducks, geese, guineas, ratites, squabs or turkeys), whether live or dead, as defined in 9 C.F.R. 381.1; and
- (b) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 C.F.R. 362.1.

(86) "Premises" means:

- (a) The physical facility, its contents, and the contiguous land or property under the control of the license holder; or
- (b) The physical facility, its contents, and the land or property not described under paragraph (B)(86)(a) of this rule if its facilities and contents are under the control of the license holder and may impact food service operation or retail food establishment personnel, facilities, or operations, and a food service operation or retail food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

(87) "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.

(88) "Public water system" has the meaning stated in Chapter 3745-81 of the Administrative Code.

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

(90) "Ready-to-eat food":

- (a) Means food that:
 - (i) Is in a form that is edible without additional preparation to achieve food safety, as specified under one of the following paragraphs (A)(1) or (A)(4), (B), or (E) of rule 3717-1-03.3 of the Administrative Code or as specified in paragraph (A)(2) of rule 3717-1-03.3 of the Administrative Code; or
 - (ii) Is a raw or partially cooked animal food and the consumer is advised as specified under paragraphs (A)(3)(a) and (A)(3)(b) of rule 3717-1-03.3 of the Administrative Code; or
 - (iii) Is prepared in accordance with a variance that is granted as specified under paragraph (A)(3)(c) of rule 3717-1-03.3 of the Administrative Code; and
 - (iv) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

- (b) Includes:
- (i) Raw animal food that is cooked as specified under paragraph (A) or (B) or frozen as specified under paragraph (E) of rule 3717-1-03.3 of the Administrative Code;
 - (ii) Raw, fruits and vegetables that are washed as specified under paragraph (G) of rule 3717-1-03.2 of the Administrative Code;
 - (iii) Fruits and vegetables that are cooked for hot holding, as specified under paragraph (C) of rule 3717-1-03.3 of the Administrative Code;
 - (iv) All time/temperature controlled for safety food that is cooked to the temperature and time required for the specific food under paragraphs (A) to (D) of rule 3717-1-03.3 of the Administrative Code and cooled as specified in paragraph (D) of rule 3717-1-03.4 of the Administrative Code;
 - (v) 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;
 - (vi) Substances derived from plants such as spices, seasonings, and sugar;
 - (vii) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;
 - (viii) 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
 - (ix) Foods manufactured as specified in 21 C.F.R. 113, thermally processed low-acid foods packaged in hermetically sealed containers.

(91) "Reduced oxygen packaging":

- (a) Means the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding atmosphere, which is approximately twenty-one per cent at sea level; and
- (b) Is a process as specified in paragraph (B)(91)(a) of this rule that involves a food for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form.
- (c) Includes:
 - (i) 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;

- (ii) 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;
 - (iii) 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;
 - (iv) Cook chill packaging, in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or
 - (v) 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 psychrotrophic pathogens.
- (92) "Refuse" means solid waste not carried by water through the sewage system.
- (93) "Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the process or facility.
- (94) "Reminder" means a written statement concerning the health risk of consuming animal foods raw, undercooked, or without otherwise being processed to eliminate pathogens.
- (95) "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.
- (96) "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.
- (97) "Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 7 C.F.R. 57.1.
- (98) "Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 C.F.R. 152.175 and that is limited to use by or under the direct supervision of a certified applicator.
- (99) "Retail food establishment" means a premises or part of a premises where food is stored, processed, prepared, manufactured, or otherwise held or handled for retail sale. Except when expressly provided otherwise, retail food establishment includes a mobile retail food establishment, seasonal retail food establishment and temporary retail food establishment. It does not include those operations

exempted in section 3717.22 of the Revised Code.

As used in this definition:

- (a) "Retail" means the sale of food to a person who is the ultimate consumer of the food.
 - (b) "Prepared" means any action that affects a food, including receiving and maintaining it at the temperature at which it was received.
- (100) "Retail food establishment sales volume" means the annual sales, minus sales tax, for food, that is sold in bulk or multiple portions by the establishment for off premise consumption that may require further washing, cooking, or additional preparation; or in individual portions that are not consumed on the premise and that either require further washing, cooking or additional preparation before consumption or are ingredient labeled for self service.
- (101) "Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.
- (102) "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 section 409 of the Federal Food, Drug, and Cosmetic Act (as amended on November 21, 1997) or section 706 of the Federal Food, Drug, and Cosmetic Act (as amended on August 13, 1993); or
 - (c) Other materials that are not additives and that are used in conformity with applicable regulations of the food and drug administration.
- (103) "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 five logs, which is equal to a 99.999 per cent reduction, of representative disease microorganisms of public health importance.
- (104) "Sealed" means free of cracks or other openings that allow the entry or passage of moisture.
- (105) "Seasonal food service operation" means a food service operation, other than a mobile food service operation, that is operated for not more than six months in a licensing period.
- (106) "Seasonal retail food establishment" means a retail food establishment, other than a mobile retail food establishment, that is operated for not more than six months in a licensing period.
- (107) "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.
- (108) "Servicing area" means an operating base location to which a mobile food

service operation, mobile retail 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.

- (109) "Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.
- (110) "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.
- (111) "Shellstock" means raw, in-shell molluscan shellfish.
- (112) "Shiga toxin-producing Escherichia coli" or STEC means any E. coli capable of producing Shiga toxins (also called verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild non-bloody diarrhea, to hemorrhagic colitis (i.e., bloody diarrhea), to hemolytic uremic syndrome (HUS - a type of kidney failure). Examples of serotypes of STEC include: E. coli O157:H7; E.coli O157: NM; E.coli O26:H11; E. coli O145:NM; E. coli O103:H2; and E. coli O111:NM. STEC are sometimes referred to as verocytotoxigenic E. colie (VTEC) or as Enterohemorrhagic E. coli (EHEC). EHEC are a subset of STEC which can cause hemorrhagic colitis or HUS.
- (113) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.
- (114) "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.
- (115) "Single-use articles":
- (a) Means utensils and bulk food containers designed and constructed to be used once and discarded; and
 - (b) Includes, but are not limited to, 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 ten cans which do not meet the materials, durability, strength, and cleanability specifications under paragraph (A) of rule 3717-1-04 of the Administrative Code, and paragraphs (A) and (C) of rule 3717-1-04.1 of the Administrative Code for multiuse utensils.
- (116) "Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of minus ten degrees Fahrenheit (minus twenty-three degrees Celsius) to twenty-five degrees Fahrenheit (minus four degrees Celsius) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food.
- (117) "Smooth" means:
- (a) A food-contact surface having a surface free of pits and inclusions with a

cleanability equal to or exceeding that of (one hundred grit) number three 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; or
- (c) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

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

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

(120) "Temporary food service operation" means a food service operation that is operated at an event for no more than five consecutive days, except when operated for more than five consecutive days under division (E)(2) of section 3717.43 of the Revised Code.

(121) "Temporary retail food establishment" means a retail food establishment that is operated at an event for not more than five consecutive days, except when operated for more than five consecutive days pursuant to division (E)(2) of section 3717.23 of the Revised Code.

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

- (a) TCS food includes:
 - (i) 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
 - (ii) Except as specified in paragraph (B)(122)(b)(iv) of this rule, 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 rule.

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.

	pH 4.6 or less	pH greater than 4.6 to 5.6	pH greater than 5.6
a_w less than or equal to 0.92	non-TCS food	non-TCS food	non-TCS food

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 greater than 0.92 to 0.95	non-TCS food	non-TCS food	PA
a_w greater than 0.95	non-TCS food	PA	PA

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.

	pH less than 4.2	pH 4.2 to 4.6	pH greater than 4.6 to 5.0	pH greater than 5.0
a_w less than 0.88	non-TCS food	non-TCS food	non-TCS food	non-TCS food
a_w 0.88 to 0.90	non-TCS food	non-TCS food	non-TCS food	PA
a_w greater than 0.90 to 0.92	non-TCS food	non-TCS food	PA	PA
a_w greater than 0.92	non-TCS food	PA	PA	PA

(b) TCS 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 paragraph (B)(122)(a) of this rule;
- (iv) A food that is designated as product assessment required (PA) in table A or B of paragraph (B)(122)(a) of this rule 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

- (v) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with either paragraph (B)(122)(b)(i), (B)(122)(b)(ii), (B)(122)(b)(iii), or (B)(123)(b)(iv) of this rule even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

(123) "USDA" means the United States department of agriculture.

(124) "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.

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

(126) "Vending machine" means a self-service device that automatically dispenses on the insertion of currency, tokens, or similar means a predetermined unit serving of food, either in bulk or in package, without having to be replenished after each use.

(127) "Vending machine location" means an area or room where one or more vending machines are installed and operated, except that if the machines within an area are separated by more than one hundred fifty feet, each area separated by that distance constitutes a separate vending machine location.

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

(129) "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.

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