

2022

# Food Code

U.S. Food and Drug Administration



U.S. Department of Health and Human Services  
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**Annexes**

# Chapter 1 Purpose and Definitions

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## 1-1 Title, Intent, Scope

### 1-101 Title

#### 1-101.10 Food Code.

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

### 1-102 Intent

#### 1-102.10 Food Safety, Illness Prevention, and Honest Presentation.

The purpose of this Code is to safeguard public health and provide to CONSUMERS FOOD that is safe, UNADULTERATED, and honestly presented.

### 1-103 Scope

#### 1-103.10 Statement.

This Code establishes definitions; sets standards for management and personnel, FOOD operations, and EQUIPMENT and facilities; and provides for FOOD ESTABLISHMENT plan review, PERMIT issuance, inspection, EMPLOYEE RESTRICTION, and PERMIT suspension.

## 1-2 Definitions

### 1-201 Applicability and Terms Defined

#### 1-201.10 Statement of Application and Listing of Terms.

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

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

##### Accredited Program.

(1) "**Accredited program**" means a food protection manager certification program that has been evaluated and listed by an

accrediting agency as conforming to national standards for organizations that certify individuals.

(2) **"Accredited program"** refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(3) **"Accredited program"** does not refer to training functions or educational programs.

#### **Additive.**

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

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

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

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

#### **Asymptomatic.**

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

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

**" $a_w$ "** means water activity which is a measure of the free moisture in a FOOD, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol  $A_w$ .

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

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

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

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

**"Certification number"** means the unique identification number issued by the SHELLFISH CONTROL AUTHORITY to each dealer for each location. Each certification number shall consist to a one-to-five digit Arabic number preceded by the two letter State abbreviation and followed by a two-letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this provision of the National Shellfish Sanitation Program using the terms in the following tables:

**Table A. Certifications**

ACRONYM	TERM
SP	Shucker Packer
RP	Repacker
SS	SHELLSTOCK Shipper
RS	Reshipper
DP	Depuration

**Table B. Permits**

ACRONYM	TERM
PHP	Post-Harvest Processing
AQ	Aquaculture
WS	Wet Storage

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

**CIP.**

(1) **"CIP"** means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and SANITIZING solution onto or over EQUIPMENT surfaces that require cleaning, such as the method used, in part, to clean and SANITIZE a frozen dessert machine.

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

**"Commingle"** means the act of combining different lots of shellfish.

**Comminuted.**

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

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

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

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

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

#### **Core Item.**

(1) **"Core item"** means a provision in this Code that is not designated as a PRIORITY ITEM or a PRIORITY FOUNDATION ITEM.

(2) **"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.

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

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

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

**"Critical 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.

**"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.

**"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.

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

### **Drinking Water.**

- (1) **"Drinking water"** means water that meets criteria as specified in 40 CFR 141 National Primary Drinking Water Regulations.
- (2) **"Drinking water"** is traditionally known as "potable water."
- (3) **"Drinking water"** includes the term "water" *except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.*

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

### **Easily Cleanable.**

- (1) **"Easily cleanable"** means a characteristic of a surface that:
  - (a) Allows effective removal of soil by normal cleaning methods;
  - (b) Is dependent on the material, design, construction, and installation of the surface; and
  - (c) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into FOOD based on the surface's APPROVED placement, purpose, and use.
- (2) **"Easily cleanable"** includes a tiered application of the criteria that qualify the surface as EASILY CLEANABLE as specified in Subparagraph (1) of this definition to different situations in which varying degrees of cleanability are required such as:
  - (a) The appropriateness of stainless steel for a FOOD preparation surface as opposed to the lack of need for

stainless steel to be used for floors or for tables used for CONSUMER dining; or

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

**"Easily movable"** means:

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

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

**Egg.**

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

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

(a) A balut;

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

(c) An egg product.

**Egg Product.**

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

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

**"Employee"** means the PERMIT HOLDER, PERSON IN CHARGE, FOOD EMPLOYEE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT.

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

**Equipment.**

(1) **"Equipment"** means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.

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

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

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

**Fish.**

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

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

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

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

**"Food-contact surface"** means:

(1) A surface of EQUIPMENT or a UTENSIL with which FOOD normally comes into contact; or

(2) A surface of EQUIPMENT or a UTENSIL from which FOOD may drain, drip, or splash:

(a) Into a FOOD, or

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

**"Food Employee" or "Food Handler"** means an individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES. "Food employee" or "food handler" does not include temporary food establishments or unpaid volunteers in a food establishment, whether permanent or temporary.

**"Food Establishment"** means an operation that:  
stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption, such as a restaurant, satellite or catered feeding location, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people, market, vending location, conveyance used to transport people, institution or food pantry; and  
relinquishes possession of food to a consumer directly, or indirectly, through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

**"Food establishment"** includes:  
an element of the operation, such as a transportation vehicle or a central preparation facility, that supplies a vending location or satellite feeding location, unless the vending or feeding location is permitted by the regulatory authority; and an operation that is conducted in a mobile, stationary, temporary or permanent facility or location. This inclusion applies regardless of whether consumption is on or off the premises and whether there is a charge for the food.

**"Food establishment"** does not include:

- an establishment that offers only prepackaged foods that are not time/temperature control for safety foods;
- a produce stand that only offers whole, uncut fresh fruits and vegetables;
- a food processing plant, including those located on the premises of a food establishment;
- a kitchen in a private home, such as a small family daycare provider or a bed and breakfast operation, as defined in the Bed and Breakfast Act, that prepares and offers food to guests;
- a private home that receives catered or home delivered food;
- a closed family function where food is prepared or served for individual family consumption; or
- a cottage food operation.

**Food Processing Plant.**

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

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

**Game Animal.**

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

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

(3) **"Game animal"** does not include ratites.

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

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

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

**Handwashing Sink.**

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

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

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

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

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

**"Highly susceptible population"** means PERSONS who are more likely than other people in the general population to experience foodborne disease because they are:

- (1) Immunocompromised; preschool age children, or older adults; and
- (2) Obtaining FOOD at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

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

- (1) The number of potential injuries, and
- (2) The nature, severity, and duration of the anticipated injury.

**"Injected"** means manipulating MEAT to which a solution has been introduced into its interior by processes that are referred to as "injecting," "pump marinating," or "stitch pumping".

**"In-Shell Product"** means non-living, processed shellfish with one or both shells present.

**"Intact Meat"** means a cut of whole muscle(s) MEAT that has not undergone COMMINATION, MECHANICAL TENDERIZATION, vacuum tumbling with solutions, reconstruction, cubing or pounding.

#### **Juice.**

(1) **"Juice"** means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée.

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

**"Kitchenware"** means FOOD preparation and storage UTENSILS.

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

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

**Major Food Allergen.**

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

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

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

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

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

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

**"Meat"** means the flesh of animals used as FOOD including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, *except FISH, POULTRY, and wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4).*

**"Mechanically Tenderized"** means manipulating meat by piercing with a set of needles, pins, blades or any mechanical device, which breaks up muscle fiber and tough connective tissue, to increase tenderness. This includes INJECTION, scoring, and processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," or "needling".

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

**"Molluscan shellfish"** means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, *except when the scallop product consists only of the shucked adductor muscle.* MOLLUSCAN SHELLFISH includes SHELLSTOCK, SHUCKED SHELLFISH and IN-SHELL PRODUCTS.

**Non-Continuous Cooking.**

(1) **"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.

(2) **"Non-continuous cooking"** does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

**Packaged.**

(1) **"Packaged"** means bottled, canned, cartoned, bagged, or wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.

(2) **"Packaged"** 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.

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

**"Permit holder"** means the entity that:

(1) Is legally responsible for the operation of the FOOD ESTABLISHMENT such as the owner, the owner's agent, or other PERSON; and

(2) Possesses a valid PERMIT to operate a FOOD ESTABLISHMENT.

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

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

**Personal Care Items.**

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

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

**"pH"** means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

**"Physical facilities"** means the structure and interior surfaces of a FOOD ESTABLISHMENT including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

**"Plumbing fixture"** means a receptacle or device that:



- (1) Is permanently or temporarily connected to the water distribution system of the PREMISES and demands a supply of water from the system; or
- (2) Discharges used water, waste materials, or SEWAGE directly or indirectly to the drainage system of the PREMISES.

**"Plumbing system"** means the water supply and distribution pipes; PLUMBING FIXTURES and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the PREMISES; and water-treating EQUIPMENT.

**"Poisonous or toxic materials"** means substances that are not intended for ingestion and are included in 5 categories:

- (1) Cleaners and SANITIZERS, which include cleaning and SANITIZING agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
- (2) Pesticides, *except* SANITIZERS, which include substances such as insecticides and rodenticides;
- (3) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and PERSONAL CARE ITEMS that may be deleterious to health; and
- (4) Substances that are not necessary for the operation and maintenance of the establishment and are on the PREMISES for retail sale, such as petroleum products and paints.
- (5) 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.

**"Poultry" means:**

- (1) Any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR 381.1 Poultry Products Inspection Regulations Definitions, Poultry; and
- (2) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1 Voluntary Poultry Inspection Regulations, Definitions.

**"Premises" means:**

- (1) The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or
- (2) The PHYSICAL FACILITY, its contents, and the land or property not described in Subparagraph (1) of this definition if its facilities and

contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

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

#### **Priority Item.**

(1) **"Priority item"** means a provision in this Code 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.

(2) **"Priority item"** includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and

(3) **"Priority item"** is an item that is denoted in this Code with a superscript "P" (i.e., <sup>P</sup>).

#### **Priority Foundation Item.**

(1) **"Priority foundation item"** means a provision in this Code whose application supports, facilitates or enables one or more PRIORITY ITEMS.

(2) **"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, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and

(3) **"Priority foundation item"** is an item that is denoted in this Code with a superscript "Pf" (i.e., <sup>Pf</sup>).

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

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

#### **Ready-to-Eat Food.**

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

(a) Is in a form that is edible without additional preparation to achieve FOOD safety, as specified under one of the following:

¶ 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in ¶ 3-401.11(C); or

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

(c) Is prepared in accordance with a variance that is granted as specified in Subparagraph 3-401.11(D) (4); and

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

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

(a) Raw animal FOOD that is cooked as specified under § 3-401.11 or 3-401.12, or frozen as specified under § 3-402.11;

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

(c) Plant FOODS that are cooked for hot holding, as specified under § 3-401.13;

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

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

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

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

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

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

**(3) "Ready-to-eat food" does not include:**

(a) *Commercially PACKAGED FOOD that bears a manufacturer's cooking instructions; and*

(b) *FOOD for which the manufacturer has provided information that it has not been processed to control pathogens.*

### **Reduced Oxygen Packaging.**

(1) **"Reduced oxygen packaging"** means:

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

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

(2) **"Reduced oxygen packaging"** includes:

(a) Vacuum PACKAGING, in which air is removed from a PACKAGE of FOOD and the PACKAGE is HERMETICALLY SEALED so that a vacuum remains inside the PACKAGE;

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

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

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

(e) 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.

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

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

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

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

**"Restrict"** means to limit the activities of a FOOD EMPLOYEE so that there is no RISK of transmitting a disease that is transmissible through FOOD and the FOOD EMPLOYEE does not work with exposed FOOD, clean EQUIPMENT, UTENSILS, LINENS, or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

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

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

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

**"Safe material"** means:

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

**"Sanitization"** means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999%

reduction, of representative disease microorganisms of public health importance.

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

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

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

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

**"Shellfish control authority"** means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of MOLLUSCAN SHELLFISH harvesters and DEALERS for interstate commerce.

**"Shellstock"** means live MOLLUSCAN SHELLFISH in the shell.

**"Shiga toxin-producing *Escherichia coli*" (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 VTEC (verocytotoxigenic *E. coli*) or as EHEC (Enterohemorrhagic *E. coli*). EHEC are a subset of STEC which can cause hemorrhagic colitis or HUS.

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

**"Single-service articles"** means TABLEWARE, carry-out UTENSILS, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one PERSON use after which they are intended for discard.

#### **Single-Use Articles.**

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

(2) **"Single-use articles"** includes items such as wax paper, butcher paper, plastic wrap, formed aluminum FOOD containers,

jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse UTENSILS.

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

**"Smooth"** means:

- (1) A FOOD-CONTACT SURFACE having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless
- (2) A nonFOOD-CONTACT SURFACE of EQUIPMENT having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and
- (3) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

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

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

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

**Time/Temperature Control for Safety Food** (formerly "potentially hazardous food" (PHF)).

- (1) **"Time/temperature control for safety food"** means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
- (2) **"Time/temperature control for safety food"** includes:
  - (a) An animal FOOD that is raw or heat-treated; a plant FOOD that is heat-treated or consists of raw seed sprouts, cut melons, 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

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

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

$A_w$ VALUES	PH: 4.6 OR LESS	PH: > 4.6 - 5.6	PH: > 5.6
≤0.92	Non-TCS food*	non-TCS food	non-TCS food
> 0.92 - 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: < 4.2	PH: 4.2 - 4.6	PH: > 4.6 - 5.0	PH: > 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:

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

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

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



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

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

*(ii) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or*

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

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

**"Tobacco Product"** has the meaning stated in the Federal Food, Drug and Cosmetic Act §201(rr) (21 U.S.C. 321(rr)).

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

**"Utensil"** means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

**"Variance"** means a written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver.

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

**"Vending machine location"** means the room, enclosure, space, or area where one or more VENDING MACHINES are installed and operated and includes the storage areas and areas on the PREMISES that are used to service and maintain the VENDING MACHINES.

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

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