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## AFDO FOOD CODE

# A pocket guide for regulators (Based on the 2013 FDA Food Code)

### Table of Contents

Definitions	1
"Food establishment"	1
"Highly susceptible population"	
"Imminent Health Hazard"	
"Major Food Allergen"	
"Ready-to-eat food"	6
"Sanitization"	
"Time/temperature control for safety food"	
Demonstration of Knowledge	12
Handwashing	17
When to Wash Hands	17
Hand Antiseptics:	18
Time/Temperature Controls	20
Temperature	20
Raw Animal Foods	22
Microwave Cooking	28
Plant Food Cooking for Hot Holding	29
Non-Continuous Cooking of Raw Animal Foods	29
Parasite Destruction	31
Reheating for Hot Holding	33
Cooling	34

Time/Temperature Control for Safety Food, Hot and Cold Holding Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking Time as a Public Health Control	35 37
Variances	
Variance Requirement	45
Reduced Oxygen Packaging without a Variance, Criteria	47
Packaging and Identification	55
Shucked Shellfish	55
Shellstock Identification	56
Food Labels	59
Food Storage, Prohibited Areas	61
Use Limitation	62
Cast Iron, Use Limitation	62
Lead, Use Limitation	63
Copper, Use Limitation	64
Galvanized Metal, Use Limitation	64
Sponges, Use Limitation	64
Wood, Use Limitation	65
Wood, Use Limitation	
	66
Equipment and Utensil Cleaning	66
Equipment and Utensil Cleaning Manual Warewashing, Sink Compartment Requirements Mechanical Warewashing Equipment, Wash Solution Temperature	<b>66</b> 66 68
Equipment and Utensil Cleaning Manual Warewashing, Sink Compartment Requirements Mechanical Warewashing Equipment, Wash Solution	<b>66</b> 66 68

Mechanical Warewashing Equipment, Sanitization Pressure	
7 Manual and Mechanical Warewashing Equipment, Chemica Sanitization Temperature, pH, Concentration, and Hardness 7	al s
Equipment Food-Contact Surfaces and Utensils	73
Handwashing Sink, Installation7	'9
Light Intensity7	'9
Disposable Glove Use With Ready to Eat Foods8	80

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The concept of "Team Spirit" is still alive and well. This edition of the "Pocket Guide for Regulators" is continuing evidence of the benefits of coordinated group interaction.

Joseph Corby Executive Director AFDO Ellen Buchanan Chair AFDO Food Committee

# FOOD CODE

# A POCKET GUIDE FOR REGULATORS

### **Definitions**

### "Food establishment" means an operation that:

- (a) 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 bank; and
- (b) 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:

- (a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and
- (b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the premises; and regardless of whether there is a charge for the food.

### "Food establishment" does not include:

- (a) An establishment that offers only pre-packaged foods that are not time/temperature control for safety foods;
- (b) A produce stand that only offers whole, uncut fresh fruits and vegetables;
- (c) A food processing plant; including those that are located on the premises of a food establishment
- (d) A kitchen in a private home if only food that is not time/temperature control for safety food, is prepared

for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law and if the consumer is informed by a clearly visible placard at the sales or service location that the food is prepared in a kitchen that is not subject to regulation and inspection by the regulatory authority;

- (e) An area where food that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption;
- (f) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers food to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the consumer is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the food is prepared in a kitchen that is not regulated and inspected by the regulatory authority; or
- (g) A private home that receives catered or homedelivered food.

"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.

"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:

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

### "Major Food Allergen" means:

- (a) Milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or
- (b) A food ingredient that contains protein derived from a food, as specified in Subparagraph (1)(a) of this definition.

### "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).

### "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), § 3401.12, 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.

### "Ready-to-eat food" includes:

- (a) Raw animal food that is cooked as specified under § 3-401.11 or 3-401.12, or frozen as specified under § 3-402.11;
- (b) Raw fruits and vegetables that are washed as specified under § 3-302.15;
- (c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;

- (d) All 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

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

**"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.

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

### "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 garlicin-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 Aw and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

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

Aw	pH Values		
values	4.6 or less	> 4.6 -5.6	> 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

# Table B. Interaction of pH and Aw for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged

Aw	pH Values			
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

# "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 Aw value, or interaction of Aw 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,
  - 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.

### Demonstration of Knowledge

Based on the risks inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the regulatory authority knowledge of foodborne disease prevention, application of the hazard analysis and critical control point principles, and the requirements of this code. The person in charge shall demonstrate this knowledge by:

- (A) Complying with this Code by having no violations of priority items during the current inspection;
- (B) Being a certified food protection manager who has shown proficiency of required information through

passing a test that is part of an accredited program; or

- (C) Responding correctly to the inspector's questions as they relate to the specific food operation. The areas of knowledge include:
  - Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;
  - (2) Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;
  - (3) Describing the symptoms associated with the diseases that are transmissible through food;
  - (4) Explaining the significance of the relationship between maintaining the time and temperature of time/temperature control for safety food and the prevention of foodborne illness;
  - (5) Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish;

- (6) Stating the required food temperatures and times for safe cooking of time/temperature control for safety food including meat, poultry, eggs, and fish;
- (7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of time/temperature control for safety food
- (8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:
  - (a) Cross contamination,
  - (b) Hand contact with ready-to-eat foods,
  - (c) Handwashing, and
  - (d) Maintaining the food establishment in a clean condition and in good repair;
- (9) Describing foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction.

- (10) Explaining the relationship between food safety and providing equipment that is:
  - (a) Sufficient in number and capacity, and
  - Properly designed, constructed, located, installed, operated, maintained, and cleaned;
- (11) Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;
- (12) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;
- (13) Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;

- (14) Identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code.
- (15) Explaining the details of how the person in charge and food employees comply with the HACCP plan if a plan is required by the law, this code, or an agreement between the regulatory authority and the food establishment
- (16) Explaining the responsibilities, rights, and authorities assigned by this Code to the:
  - (a) Food Employee
  - (b) Conditional Employee
  - (c) Person in Charge
  - (d) Regulatory Authority
- (17) Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and exclusion or restriction of food

### Handwashing

### When to Wash Hands

Food employees shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped singleservice and singleuse articles and:

- (a) After touching bare human body parts other than clean hands and clean, exposed portions of arms;
- (b) After using the toilet room;
- (c) After caring for or handling service animals or aquatic animals as specified in ¶ 2-403.11(B);
- (d) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
- (e) After handling soiled equipment or utensils;
- (f) During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;

- (g) When switching between working with raw food and working with ready-to-eat food;
- (h) Before donning gloves to initiate a task that involves working with food;
- (i) After engaging in other activities that contaminate the hands.

### Hand Antiseptics:

- (A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:
  - (1) Comply with one of the following:
    - (a) Be an approved drug that is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness
    - (b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash

- (2) Consist only of components which the intended use of each complies with one of the following:
  - (a) A threshold of regulation exemption under 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles
  - (b) 21 CFR 178 -Indirect food additives: adjuvants, production aids, and sanitizers as regulated for use as a food additive with conditions of safe use
  - (c) A determination of generally recognized as safe (GRAS). Partial listings of substances with food uses that are GRAS may be found in 21 CFR 182 -Substances Generally Recognized as Safe, 21 CFR 184 -Direct food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 – Indirect food Substances Affirmed as Generally Recognized as Safe for use in contact with food, and in FDA's Inventory of GRAS Notices
  - (d) A prior sanction listed under 21 CFR 181 Prior Sanctioned Food Ingredients

- (e) a Food Contact Notification that is effective
- (3) Be applied only to hands that are cleaned as specified under § 2-301.12.
- (B) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:
  - Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves
  - (2) Limited to situations that involve no direct contact with food by the bare hands.
- (C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 MG/L chlorine.

### Time/Temperature Controls

### Temperature

 (A) Except as specified in ¶ (B) of this section, refrigerated, time/temperature control for safety food shall be at a temperature of 5° C (41° F) or below when received.

- (B) If a temperature other than 5°C (41°F) for a time/temperature control for safety food is specified in law governing its distribution, such as laws governing milk and molluscan shellfish, the food may be received at the specified temperature.
- (C) Raw eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 7° C (45° F) or less.
- (D) Time/temperature control for safety food that is cooked to a temperature and for a time specified under §§ 3-401.11 3-401.13 and received hot shall be at a temperature of 57° C (135° F) or above.
- (E) A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen.
- (F) Upon receipt, time/temperature control for safety food shall be free of evidence of previous temperature abuse.

### **Raw Animal Foods**

- (A) Except as specified under ¶ (B) and in ¶¶ (C) and (D) of this section, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:
  - (1)  $63^{\circ}$  C (145° F) or above for 15 seconds for:
    - Raw eggs that are broken and prepared in response to a consumer's order and for immediate service
    - (b) Except as specified under Subparagraphs (A)(2) and (A)(3) and ¶ (B), and in ¶ (C) of this section, fish and meat including game animals commercially raised for food as specified under Subparagraph 3-201.17(A)(1) and game animals under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2)
  - (2) 68° C (155° F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites,

mechanically tenderized, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under Subparagraph 3-201.17(A)(1), and game animals under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); and raw eggs that are not prepared as specified under Subparagraph (A)(1)(a) of this section:

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

- (3) 74° C (165° F) or above for 15 seconds for poultry, baluts, wild game animals as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry, or ratites.
- (B) Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

 In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:

#### **Oven Temperature Based on Roast Weight**

Oven Type	Roast Weight Less than 4.5 kg (10 lbs)	4.5 kg (10 lbs) or More
Still Dry	177°C (350°F) or	121°C (250°F) or
	more	more
Convection	163°C (325°F) or	121°C (250°F) or
	more	more
1 High	121°C (250°F) or	121°C (250°F) or
Humidity*	less	less

\*Relative humidity greater than 90% for at least 2 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

(2) As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature:

Temperature °C (°F)	Time <sup>1</sup> in Minutes
54.4 (130)	112
55.0 (131)	89
56.1 (133)	56
57.2 (135)	36
57.8 (136)	28
58.9 (138)	18
60.0 (140)	12
61.1 (142)	8
62.2 (144)	5
62.8 (145)	4

Temperature °C (°F)	Time <sup>1</sup> in Seconds
63.9 (147)	134
65.0 (149)	85
66.1 (151)	54
67.2 (153)	34
68.3 (155)	22
69.4 (157)	14
70.0 (158)	0

Holding time may include post oven heat rise.

- (C) A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a readyto-eat form if:
  - (1) The food establishment serves a population that is not a highly susceptible population
  - (2) The steak is labeled to indicate that it meets the definition of "whole-muscle, intact beef" as specified under ¶ 3-201.11(E)
  - (3) The steak is cooked on both the top and bottom to a surface temperature of 63° C (145° F) or above and a cooked color change is achieved on all external surfaces.
- (D) A raw animal food such as raw egg, raw fish, rawmarinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in ¶ (C) of this section, may be served or offered for sale upon consumer request or selection in a readyto-eat form if:
  - As specified under ¶¶ 3-801.11(C)(1) and (2), the food establishment serves a population that is not a highly susceptible population;

- (2) The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat; and
- (3) the consumer is informed as specified under § 3-603.11 that to ensure its safety, the food should be cooked as specified under ¶ (A) or (B) of this section; or
- (4) The regulatory authority grants a variance from

   ¶ (A) or (B) of this section as specified in § 8- 103.10 based on a HACCP plan that:
  - (a) Is submitted by the permit holder and approved as specified under § 8-103.11,
  - (b) Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food, and
  - (c) Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions of the variance.

### **Microwave Cooking**

Raw animal foods cooked in a microwave oven shall be:

- (A) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;
- (B) Covered to retain surface moisture;
- (C) Heated to a temperature of at least 74° C (165° F) in all parts of the food; and
- (D) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

### Plant Food Cooking for Hot Holding

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of  $57^{\circ}$  C ( $135^{\circ}$  F).

### Non-Continuous Cooking of Raw Animal Foods

Raw animal foods that are cooked using a noncontinuous cooking process shall be:

- (A) Subject to an initial heating process that is no longer than sixty minutes in duration
- (B) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked time/temperature control for safety food under ¶ 3501.14(A)
- (C) After cooling, held frozen or cold, as specified for time/temperature control for safety food under ¶ 3501.16(A)(2)
- (D) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C)

- (E) Cooled according to the time and temperature parameters specified for cooked time /temperature control for safety food under ¶ 3-501.14(A) if not either hot held as specified under ¶3-501.16(A), served immediately, or held using time as a public health control as specified under §3-501.19 after complete cooking
- (F) Prepared and stored according to written procedures that:
  - (1) Have obtained prior approval from the regulatory authority
  - (2) Are maintained in the food establishment and are available to the regulatory authority upon request
  - (3) Describe how the requirements specified under ¶ (A)-(E) of this Section are to be monitored and documented by the permit holder and the corrective actions to be taken if the requirements are not met

- (4) Describe how the foods, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as foods that must be cooked as specified under ¶ (D) of this section prior to being offered for sale or service
- (5) Describe how the foods, after initial heating but prior to cooking as specified under ¶(D) of this section, are to be separated from ready-to-eat foods as specified under ¶3-302.11 (A).

### Parasite Destruction

- (A) Except as specified in ¶ (B) of this section, before service or sale in ready-to-eat form, raw, rawmarinated, partially cooked, or marinated-partially cooked fish shall be:
  - (1) Frozen and stored at a temperature of -20°C (-4°F) or below for a minimum of 168 hours (7 days) in a freezer
  - (2) Frozen at -35°C (-31°F) or below until solid and stored at -35°C (-31°F) or below for a minimum of 15 hours

- (3) Frozen at -35°C (-31°F) or below until solid and stored at -20°C (-4°F) or below for a minimum of 24 hours.
- (B) Paragraph (A) of this section does not apply to:
  - (1) Molluscan shellfish;
  - A scallop product consisting only of the shucked adductor muscle;
  - (3) Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern)
  - (4) Aquacultured fish, such as salmon, that:
    - (a) If raised in open water, are raised in netpens, or
    - (b) Are raised in land-based operations such as ponds or tanks, and
    - (c) Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish.

(5) Fish eggs that have been removed from the skein and rinsed.

## **Reheating for Hot Holding**

- (A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, time/temperature control for safety food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74° C (165° F) for 15 seconds.
- (B) Except as specified under ¶ (C) of this section, time/temperature control for safety food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74° C (165° F) and the food is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.
- (C) Ready-to-eat time/temperature control for safety food that has been commercially processed and packaged in a food processing plant that is inspected by the regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least 57° C (135° F) when being reheated for hot holding

- (D) Reheating for hot holding as specified under ¶¶ (A) -(C) of this section shall be done rapidly and the time the food is between 5° C (41° F) and the temperatures specified under ¶¶ (A) -(C) of this section may not exceed 2 hours.
- (E) Remaining unsliced portions of meat roasts that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).

# Cooling

- (A) Cooked time/temperature control for safety food shall be cooled:
  - Within 2 hours from 57°C (135° F) to 21° C (70° F)
  - (2) Within a total of 6 hours from 57° C (135° F) to 5° C (41° F) or less.

- (B) Time/temperature control for safety food shall be cooled within 4 hours to 5° C (41° F) or less if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.
- (C) Except as specified under ¶ (D) of this section, a time/temperature control for safety food received in compliance with laws allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less.
- (D) Raw eggs shall be received as specified under ¶ 3-202.11(c) and immediately placed in refrigerated equipment that maintains an ambient air temperature of 7° C (45° F) or less.

# Time/Temperature Control for Safety Food, Hot and Cold Holding

(A) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under §3-501.19, and except as specified under ¶ (B) and in ¶ (C) of this section, time/temperature control for safety food shall be maintained:

- (1) At 57° C (135° F) or above, except that roasts cooked to a temperature and for a time specified in ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54° C (130° F) or above or
- (2) At 5° C (41° F) or less.
- (B) Eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of 7° C (45° F) or less.
- (C) Time/temperature control for safety food in a homogenous liquid form may be maintained outside of the temperature control requirements, as specified under ¶ (A) of this section, while contained within specially designed equipment that complies with the design and construction requirements as specified under ¶ 4-204.13(E).

# Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking

- (A) Except when packaging food using a reduced oxygen packaging method as specified under § 3-502.12, and except as specified in ¶¶ (E) and (F) of this section, refrigerated, ready-to -eat, time/temperature control for safety food prepared and held in a food establishment for more than 24 hours shall be clearly marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded when held at a temperature of 5° C (41° F) or less for a maximum of 7 days. The day of preparation shall be counted as Day 1.
- (B) Except as specified in ¶¶ (E) -(G) of this section, refrigerated, ready-to-eat time/temperature control for safety food prepared and packaged by a food processing plant shall be clearly marked, at the time the original container is opened in a food establishment and if the food is held for more than 24 hours, to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in ¶ (A) of this section and:

- The day the original container is opened in the food establishment shall be counted as Day 1 and
- (2) The day or date marked by the food establishment may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on food safety.
- (C) A refrigerated, ready-to-eat time/temperature control for safety food ingredient or a portion of a refrigerated, ready-to-eat, time/temperature control for safety food that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest-prepared or firstprepared ingredient.
- (D) A date marking system that meets the criteria stated in ¶¶ (A) and (B) of this section may include:
  - Using a method approved by the regulatory authority for refrigerated, ready-to-eat time/temperature control for safety food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;

- (2) Marking the date or day of preparation, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under ¶ (A) of this section;
- (3) Marking the date or day the original container is opened in a food establishment, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under ¶ (B) of this section; or
- (4) Using calendar dates, days of the week, colorcoded marks, or other effective marking methods, provided that the marking system is disclosed to the regulatory authority upon request.
- (E) Paragraphs (A) and (B) of this section do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.
- (F) Paragraphs (A) and (B) of this section do not apply to shellstock.

- (G) Paragraph (B) of this section does not apply to the following foods prepared and packaged by a food processing plant inspected by a regulatory authority:
  - Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR 110 Current good manufacturing practice in manufacturing, packing, or holding human food;
  - (2) Hard cheeses containing not more than 39% moisture as defined in 21 CFR 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;
  - (3) Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;
  - (4) Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as yogurt, sour cream, and buttermilk;
  - (5) Preserved fish products, such as pickled herring and dried or salted cod, and other

acidified fish products defined in 21 CFR 114 Acidified foods;

- (6) Shelf stable, dry fermented sausages, such as pepperoni and Genoa; and
- (7) Shelf stable salt-cured products such as prosciutto and Parma (ham).

#### Time as a Public Health Control

- (A) Except as specified under ¶ (D) of this section, if time without temperature control is used as the public health control for a working supply of time/temperature control for safety food before cooking, or for ready-to-eat time/temperature control for safety food that is displayed or held for sale or service:
  - Written procedures shall be prepared in advance, maintained in the food establishment and made available to the regulatory authority upon request that specify:

- (a) Methods of compliance with Subparagraphs (B)(1)-(3) or C)(1) (5) of this section; and
- (b) Methods of compliance with § 3-501.14 for food that is prepared, cooked, and refrigerated before time is used as a public health control.
- (B) If time without temperature control is used as the public health control up to a maximum of 4 hours:
  - The food shall have an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control;

- (2) The food shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the food is removed from temperature control;
- (3) The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control; and
- (4) The food in unmarked containers or packages, or marked to exceed a 4-hour limit shall be discarded.
- (C) If time without temperature control is used as the public health control up to a maximum of 6 hours:
  - The food shall have an initial temperature of 5°C (41°F) or less when removed from temperature control and the food temperature may not exceed 21°C (70°F) within a maximum time period of 6 hours;
  - (2) The food shall be monitored to ensure the warmest portion of the food does not exceed 21°C (70°F) during the 6-hour period, unless an ambient air temperature is maintained that

ensures the food does not exceed 21°C (70°F) during the 6-hour holding period;

- (3) The food shall be marked or otherwise identified to indicate:
  - (a) The time when the food is removed from 5°C (41°F) or less cold holding temperature control, and
  - (b) The time that is 6 hours past the point in time when the food is removed from cold holding temperature control;
- (4) The food shall be:
  - (a) Discarded if the temperature of the food exceeds 21°C (70°F), or
  - (b) Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of 6 hours from the point in time when the food is removed from 5°C (41°F) or less cold holding temperature control; and

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

(D) A food establishment that serves a highly susceptible population may not use time as specified under  $\P\P$  (A), (B) or (C) of this section as the public health control for raw eggs.

## Variances

### Variance Requirement

A food establishment shall obtain a variance from the regulatory authority as specified in § 8-103.10 and under § 8-103.11 before:

- (A) Smoking food as a method of food preservation rather than as a method of flavor enhancement;
- (B) Curing food;
- (C) Using food additives or adding components such as vinegar:
  - (1) As a method of food preservation rather than as a method of flavor enhancement, or

- To render a food so that it is not time/temperature control of safety food;
- (D) Packaging time/temperature control for safety food using a reduced oxygen packaging method except where the growth of and toxin formation by Clostridium botulinum and the growth of Listeria monocytogenes are controlled as specified under § 3-502.12;
- (E) Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption;
- (F) Custom processing animals that are for personal use as food and not for sale or service in a food establishment;
- (G) Preparing food by another method that is determined by the regulatory authority to require a variance; or
- (H) Sprouting seeds or beans.

## Reduced Oxygen Packaging without a Variance, Criteria

- (A) Except for a food establishment that obtains a variance as specified under § 3-502.11, a food establishment that packages time/temperature control for safety food using a reduced oxygen packaging method shall control the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes.
- (B) Except as specified under ¶ (F) of this section, a food establishment that packages time/temperature control for safety food using a reduced oxygen packaging method shall implement a HACCP plan that contains the information specified under ¶¶ 8-201.14 (B) and (D) and that:
  - (1) Identifies the food to be packaged;
  - (2) Except as specified under ¶¶ (C) -(E) of this section, requires that the packaged food shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria:
    - (a) Has an AW of 0.91 or less,
    - (b) Has a PH of 4.6 or less,

- (c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact package, or
- (d) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables;
- (3) Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
  - (a) Maintain the food at 5° C (41° F) or below, and
  - (b) Discard the food if within 30 calendar days of its packaging if it is not served for onpremises consumption, or consumed if served or sold for off-premises consumption;

- (4) Limits the refrigerated shelf life to no more than 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;
- (5) Includes operational procedures that:
  - (a) Prohibit contacting ready-to-eat food with bare hands as specified under ¶ 3-301.11(B),
  - (b) Identify a designated work area and the method by which:
    - Physical barriers or methods of separation of raw foods and ready-toeat foods minimize cross contamination, and
    - Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, and

- (c) Delineate cleaning and sanitization procedures for food-contact surfaces; and
- (6) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:
  - (a) Concepts required for a safe operation,
  - (b) Equipment and facilities, and
  - (c) Procedures specified under Subparagraph
     (B)(5) of this section and ¶¶ 8-201.14 (B) and (D).
- Is provided to the regulatory authority prior to implementation as specified under ¶ 8-201.13(B).
- (C) Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a p reduced oxygen packaging method.
- (D) Except as specified under ¶ (C) and ¶ (F) of this section, a food establishment that packages time/temperature control for safety food using a cook-chill or sous vide process shall:

- Provide to the regulatory authority prior to implementation, a HACCP plan that contains the information as specified under ¶¶ 8-201.14 (B) and (D);
- (2) Ensure the food is:
  - (a) Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer,
  - (b) Cooked to heat all parts of the food to a temperature and for a time as specified under ¶¶ 3-401.11 (A), (B), and (C),
  - (c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,
  - (d) Placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below 57°C (135°F),

- (e) Cooled to 5°C (41°F) in the sealed package or bag as specified under § 3-501.14 and:
  - Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of packaging;
  - (ii) Held at 5°C (41°F) or less for no more than 7 days at which time the food must be consumed or discarded; or
  - (iii) Held frozen with no shelf life restriction while frozen until consumed or used.
- (f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,
- (g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to

ensure that times and temperatures are monitored during transportation, and

- (h) Labeled with the product name and the date packaged; and
- (3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan and:
  - (a) Make such records available to the regulatory authority upon request, and
  - (b) Hold such records for at least 6 months; and
- (4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.
- (E) Except as specified under ¶ (F) of this section, a food establishment that packages cheese using a reduced oxygen packaging method shall:

- Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;
- (2) Have a HACCP plan that contains the information specified under ¶¶ 8-201.14 (B) and (D) and as specified under ¶¶ (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;
- (3) Labels the package on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and
- (4) Discards the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.
- (F) A HACCP plan is not required when a food establishment uses a reduced oxygen packaging

method to package time/temperature control for safety food that is always:

- (1) Labeled with the production time and date,
- (2) Held at 5°C (41°F) or less during refrigerated storage, and
- (3) Removed from its package in the food establishment within 48 hours after packaging.

### Packaging and Identification

#### Shucked Shellfish

- (A) Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the:
  - Name, address, and certification number of the shucker, packer or repacker of the molluscan shellfish; and
  - (2) The "sell by" or "best if used by" date for packages with a capacity of less than 1.89 L (one-half gallon) or the date shucked for packages with a capacity of 1.89 L (one-half gallon) or more.

(B) A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified under ¶ (a) of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D -Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d) Molluscan shellfish.

## Shellstock Identification

- (A) Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list:
  - Except as specified under ¶ (C) of this section, on the harvester's tag or label, the following information in the following order:
    - (a) The harvester's identification number that is assigned by the Shellfish Control Authority,

- (b) The date of harvesting,
- (c) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the Shellfish Control Authority and including the abbreviation of the name of the state or country in which the shellfish are harvested,
- (d) The type and quantity of shellfish, and
- (e) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"; and
- (2) Except as specified in ¶ (D) of this section, on each dealer's tag or label, the following information in the following order:
  - (a) The dealer's name and address, and the certification number assigned by the Shellfish Control Authority,
  - (b) The original shipper's certification number including the abbreviation of the name of

the state or country in which the shellfish are harvested,

- (c) The same information as specified for a harvester's tag under Subparagraphs
   (A)(1)(b)-(d) of this section, and
- (d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days."
- (B) A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D -Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).
- (C) If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first.
- (D) If the harvester's tag or label is designed to accommodate each dealer's identification as specified under Subparagraphs (A)(2)(a) and (b) of

this section, individual dealer tags or labels need not be provided.

#### Food Labels

- (A) Food packaged in a food establishment, shall be labeled as specified in law, including 21 CFR 101 -Food labeling, and 9 CFR 317 Labeling, marking devices, and containers.
- (B) Label information shall include:
  - the common name of the food, or absent a common name, an adequately descriptive identity statement;
  - (2) If made from two or more ingredients, a list of ingredients and sub-ingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the food;
  - An accurate declaration of the net quantity of contents;
  - (4) The name and place of business of the manufacturer, packer, or distributor; and

- (5) The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient.
- (6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(q)(3) -(5), nutrition labeling as specified in 21 CFR 101 -Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.
- (7) For any salmonid fish containing canthaxanthin or astaxanthin as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.
- (C) Bulk food that is available for consumer selfdispensing shall be prominently labeled with the following information in plain view of the consumer:
  - (1) The manufacturer's or processor's label that was provided with the food; or

- (2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (6) of this section.
- (D) Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:
  - A health, nutrient content, or other claim is not made;
  - (2) There are no state or local laws requiring labeling; and
  - (3) The food is manufactured or prepared on the premises of the food establishment or at another food establishment or a food processing plant that is owned by the same person and is regulated by the food regulatory agency that has jurisdiction.

## Food Storage, Prohibited Areas

Food may not be stored:

(A) In locker rooms;

- (B) In toilet rooms;
- (C) In dressing rooms;
- (D) In garbage rooms;
- (E) In mechanical rooms;
- (F) Under sewer lines that are not shielded to intercept potential drips;
- (G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
- (H) Under open stairwells; or
- (I) Under other sources of contamination.

#### **Use Limitation**

#### Cast Iron, Use Limitation

- (A) Except as specified in ¶¶ (B) and (C) of this section, cast iron may not be used for utensils or foodcontact surfaces of equipment.
- (B) Cast iron may be used as a surface for cooking.

(C) Cast iron may be used in utensils for serving food if the utensils are used only as part of an uninterrupted process from cooking through service.

## Lead, Use Limitation

(A) Ceramic, china, and crystal utensils, and decorative utensils such as hand painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories:

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

- (B) Pewter alloys containing lead in excess of 0.05% may not be used as a food-contact surface.
- (C) Solder and flux containing lead in excess of 0.2% may not be used as a food-contact surface.

## Copper, Use Limitation

- (A) Except as specified in ¶ (B) of this section, copper and copper alloys such as brass may not be used in contact with a food that has a pH below 6 such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.
- (B) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the pre-fermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

## Galvanized Metal, Use Limitation

Galvanized metal may not be used for utensils or food contact surfaces of equipment that are used in contact with acidic food.

#### Sponges, Use Limitation

Sponges may not be used in contact with cleaned and sanitized or in-use food-contact surfaces.

## Wood, Use Limitation

- (A) Except as specified in ¶¶ (B), (C), and (D) of this section, wood and wood wicker may not be used as a food-contact surface.
- (B) Hard maple or an equivalently hard, close-grained wood may be used for:
  - Cutting boards; cutting blocks; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and
  - (2) Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110° C (230° F) or above.
- (C) Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.
- (D) If the nature of the food requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw food may be kept in:
  - (1) Untreated wood containers; or

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

## Equipment and Utensil Cleaning

# Manual Warewashing, Sink Compartment Requirements

- (A) Except as specified in ¶ (C) of this section, a sink with at least 3 compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.
- (B) Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in ¶ (C) of this section shall be used.
- (C) Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. alternative manual warewashing equipment may include:

- (1) High-pressure detergent sprayers;
- (2) Low-or line-pressure spray detergent foamers;
- (3) Other task-specific cleaning equipment;
- (4) Brushes or other implements;
- (5) 2-compartment sinks as specified under ¶¶ (D) and (E) of this section; or
- (6) Receptacles that substitute for the compartments of a multicompartment sink.
- (D) Before a 2-compartment sink is used:
  - The permit holder shall have its use approved; and
  - (2) The permit holder shall limit the number of kitchenw are items cleaned and sanitized in the 2-compartment sink, and shall limit warewashing to batch operations for cleaning kitchenw are such as between cutting one type of raw meat and another or cleanup at the end of a shift, and shall:

- Make up the cleaning and sanitizing solutions immediately before use and drain them immediately after use, and
- (b) Use a detergent-sanitizer in accordance with the manufacturer's label instructions and as specified under § 4-501.115, or
- (c) Use a hot water sanitization immersion step as specified under ¶ 4-603.16(C).
- (E) A 2-compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchen are or tableware in an ongoing warewashing process.

# Mechanical Warewashing Equipment, Wash Solution Temperature

- (A) The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than:
  - For a stationary rack, single temperature machine, 74° C (165° F);

- (2) For a stationary rack, dual temperature machine, 66° C (150° F);
- (3) For a single tank, conveyor, dual temperature machine, 71° C (160° F); or
- (4) For a multi-tank, conveyor, multi-temperature machine, 66° C (150° F).
- (B) The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than 49° C (120° F)

# Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures

- (A) Except as specified in ¶ (B) of this section, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than 90° C (194° F), or less than:
  - For a stationary rack, single temperature machine, 74° C (165° F); or
  - (2) For all other machines, 82° C (180° F).
- (B) The maximum temperature specified under ¶ (A) of this section, does not apply to the high pressure and

temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.

# Mechanical Warewashing Equipment, Sanitization Pressure

The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine, as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control value, shall be within the range specified on the machine manufacturer's data plate and may not be less than 35 kilopascals (5 pounds per square inch) or more than 200 kilopascals (30 pounds per square inch).

#### Manual and Mechanical Warewashing Equipment, Chemical Sanitization Temperature, pH, Concentration, and Hardness

A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified under ¶4-703.11(C) shall meet the criteria specified under §7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows:

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

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

- (B) An iodine solution shall have a:
  - (1) Minimum temperature of 20°C (68°F),
  - (2) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, and
  - (3) Concentration between 12.5 MG/L and 25 MG/L;
- (C) A quaternary ammonium compound solution shall:
  - (1) Have a minimum temperature of 24° C (75° F),
  - (2) Have a concentration as specified under § 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and

- (3) Be used only in water with 500 MG/L hardness or less or in water having a hardness no greater than specified by the EPA-registered label use instructions;
- (D) If another solution of a chemical specified under ¶¶

   (A) (C) of this section is used, the permit holder shall demonstrate to the regulatory authority that the solution achieves sanitization and the use of the solution shall be approved;
- (E) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions; and
- (F) If a chemical sanitizer is generated by a device located on-site at the food establishment it shall be used as specified in ¶¶(A) -(D) of this section and shall be produced by a device that:
  - Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),
  - (2) Complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements,

- (3) Displays the EPA device manufacturing facility registration number on the device, and
- (4) Is operated and maintained in accordance with manufacturer's instructions.

### **Equipment Food-Contact Surfaces and Utensils**

- (A) Equipment food-contact surfaces and utensils shall be cleaned:
  - Except as specified in ¶ (B) of this section, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry;
  - (2) Each time there is a change from working with raw foods to working with ready-to-eat foods;
  - Between uses with raw fruits and vegetables and with time/temperature control for safety food;
  - (4) Before using or storing a food temperature measuring device; and

- (5) At any time during the operation when contamination may have occurred.
- (B) Subparagraph (A)(1) of this section does not apply if the food-contact surface or utensil is in contact with a succession of different types of raw meat and poultry each requiring a higher cooking temperature as specified under § 3-401.11 than the previous type.
- (C) Except as specified in ¶ (D) of this section, if used with time/temperature control for safety food, equipment food contact surfaces and utensils shall be cleaned throughout the day at least every 4 hours.
- (D) Surfaces of utensils and equipment contacting time/temperature control for safety food may be cleaned less frequently than every 4 hours if:
  - In storage, containers of time/temperature control for safety food and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;

- (2) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:
  - (a) The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature; and

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C -7.2°C (>41°F -45°F)	20 hours
>7.2°C -10.0°C (>45°F -50°F)	16 hours
>10.0°C -12.8°C (>50°F - 55°F)	10 hours

- (b) The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment.
- (3) Containers in serving situations such as salad bars, delis, and cafeteria lines hold ready-to-eat time/temperature control for safety food that is maintained at the temperatures specified under Chapter 3, are intermittently combined with

additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours;

- (4) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under Chapter 3;
- (5) Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues;
- (6) The cleaning schedule is approved based on consideration of:
  - (a) Characteristics of the equipment and its use,
  - (b) The type of food involved,
  - (c) The amount of food residue accumulation, and

- (d) The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or
- (7) In-use utensils are intermittently stored in a container of water in which the water is maintained at 57° C (135° F) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.
- (E) Except when dry cleaning methods are used as specified under § 4-603.11, surfaces of utensils and equipment contacting food that is not time/temperature control for safety food shall be cleaned:
  - (1) At any time when contamination may have occurred;
  - (2) At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles;

- (3) Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers; and
- (4) In equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment:
  - (a) At a frequency specified by the manufacturer, or
  - (b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

### **Cooking and Baking Equipment**

(A) The food-contact surfaces of cooking and baking equipment shall be cleaned at least every 24 hours. this section does not apply to hot oil cooking and filtering equipment if it is cleaned as specified in Subparagraph 4-602.11(D)(6). (B) The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

### Handwashing Sink, Installation

- (A) A handwashing sink shall be equipped to provide water at a temperature of at least 38° C (100° F) through a mixing valve or combination faucet.
- (B) A steam mixing valve may not be used at a handwashing sink.
- (C) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.
- (D) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

### Light Intensity

The light intensity shall be:

 (A) At least 108 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry food storage areas and in other areas and rooms during periods of cleaning;

- (B) At least 215 lux (20 foot candles):
  - At a surface where food is provided for consumer self-service such as buffets and salad bars or where fresh produce or packaged foods are sold or offered for consumption,
  - (2) Inside equipment such as reach-in and undercounter refrigerators; and
  - (3) At a distance of 75 cm (30 inches) above the floor in areas used for handwashing, warewashing, and equipment and utensil storage, and in toilet rooms; and
- (C) At least 540 lux (50 foot candles) at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders, or saws where employee safety is a factor.

#### **Disposable Glove Use With Ready to Eat Foods**

Fecal-oral route pathogens like bacteria and viruses are most often spread from feces-to-hand-to-mouth. Studies have shown that a three-step barrier approach to preventing FBI via the fecal-oral route is most effective. This three-step barrier approach includes:

- (1) Preventing ill employees from handing food;
- (2) Frequent and proper hand washing;
- (3) Preventing the bare hand contact of ready-toeat foods.

The use of disposable gloves is only one method of preventing bare hand contact with ready-to-eat foods. Other effective methods include:

- (1) The use of tongs, spatulas;
- (2) Deli tissue paper;
- (3) Other dispensing utensils.

The use of gloves is never a substitute for frequent and proper hand washing.

When disposable gloves are used, they need to be utilized following the Food Code requirements for foodcontact utensils and changed when contaminated, torn, or if there is a task interruption. For example:

- (1) Change gloves after touching raw animal products;
- (2) Before touching ready-to-eat products;
- (3) After touching soiled utensils and equipment;
- (4) After coughing or sneezing.

Disposable gloves should never be worn for longer than one to two hours at a time. Always wash hands before putting on a new pair of gloves.

## About AFDO Publications

The Association of Food and Drug Officials (AFDO), established in 1896, successfully fosters uniformity in the adoption, implementation and enforcement of sciencebased food, drug, medical device, cosmetics and product safety laws, rules, and regulations.

AFDO and its six regional affiliates provide the mechanism and the forum where regional, national and international issues are deliberated and resolved to uniformly provide the best public health and consumer protection in the most expeditious and cost effective manner.

This handbook is one of several publications available through AFDO, many of which are model codes and guidelines AFDO has developed specifically for the food industry and regulators. For a complete listing and order form contact the AFDO office at (717) 757-2888, or download from the AFDO web site at www.afdo.org.

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