



Public Health
Prevent. Promote. Protect.

Lincoln County Food Service Sanitation Regulations 2011

Lincoln County, MO Lincoln
County Health Department Office
of Environmental Sanitation
5 Health Department Dr.
Troy, MO 63379
(636) 528-6117
www.lchdmo.org

ORDINANCE NUMBER 10-18-2011
Lincoln County, Missouri
Food Service Sanitation Ordinance

An ordinance adopting the 2009 Edition of the "Food & Drug Administration Model Food Code" regulating the retail sale, commercial and institutional service, and vending of food; defining permit holder, person in charge, employee, food, potentially hazardous food, food establishment, safe material, sanitization, and other terms; and providing standards for employee food safety, knowledge, health, and practices; food sources, preparation, holding temperatures, and protection; equipment design, construction, installation, cleaning, and sanitization; water, and liquid and solid wastes; facilities construction and maintenance, and storage and use of poisonous and toxic materials, requiring a permit to operate a food establishment; and providing for the restriction or exclusion of employees, the examination and condemnation of food, and the enforcement of this code, including the setting of fees and penalties.

Section 1. Authority

Section 192.300, RSMo. The county commissions and county health boards of the several counties may make and promulgate orders, ordinances, rules or regulations, respectively as will tend to enhance the public health and prevent the entrance of infectious, contagious, communicable or dangerous diseases into such county, but any orders, ordinances, rules or regulations shall not be in conflict with any rules or regulations authorized and made by the Department of Health in accordance with this chapter or by the Department of Social Services under chapter 198, RSMo.

Section 2. Adoption of Food Code

That a certain document, a reference copy of which is on file in the County Clerk's Office located in the Lincoln County Courthouse in Troy, Missouri being marked and designated as the Food Code, 2009 *Recommendations of the United States Public Health Service/Food and Drug Administration* as published by the US Department of Health and Human Services, Public Health Service, Food and Drug Administration, is hereby adopted as the Food Service Sanitation Code of Lincoln County, Missouri, for regulating the design, construction,

management and operation of food establishments and provided for plan submission and approval and the issuance of permits and collection of fees therefore. A copy of this document is available upon request after payment of the appropriate copy fee as established by the County Clerk's Office. A reference copy containing the regulatory section of the Adopted Code (Chapters 1-9) and this Ordinance is on file in the County Clerk's Office located in the Lincoln County Courthouse in Troy, Missouri being marked and designated as *Lincoln County Food Service Sanitation Regulations*. A copy of this document is available after payment at current cost of publication from the Lincoln County Office of Environmental Sanitation, 5 Health Department Dr., Troy, MO 63379.

Section 3. Applicability

This Ordinance shall apply to any *Food Establishment* (as defined in Part 1-201.10 (30) Food Establishment of the Adopted Code, (1) "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. (2) "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. (3) "*Food establishment*" does not include: (a) An establishment that offers only

prePACKAGED FOODS that are not POTENTIALLY HAZARDOUS (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 POTENTIALLY HAZARDOUS (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 18, 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 home-delivered FOOD.

Section 4. Definitions

In addition to the "Definition" Section of the Adopted Code contained in Part 1-201.10, unless the context otherwise requires, the following terms shall mean:

4.1 "Adopted Code" means the Food Code 2009 Recommendations of the United States Public Health Service/Food and Drug Administration as published by the US Department of health and Human Services, Food and Drug Administration.

4.2 "Agent" any person authorized in a written and signature statement by the property owner to execute the interests of the property owner in matters related to this Ordinance.

4.3 "Regulatory Authority" defined in Part 1-102.10 means the local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment. For the purpose of this ordinance, the Lincoln County office of Environmental

Sanitation shall be designated the Regulatory Authority and shall apply this Ordinance and Adopted Code to promote its underlying purpose of safeguarding public health and assuring that food is safe, unadulterated, and honestly presented when offered to the consumer.

Section 5. Permits

Subsequent to passage of this Ordinance, any construction, modification, or operation of a Food Establishment shall require the owner or the agent of the legal ownership to obtain a "Permit to Operate a Food Establishment," and pay the appropriate fees, if established, to the Lincoln County Office of Environmental Sanitation, 5 Health Department Dr, Troy, Missouri 63379 (636) 528-6117. Regulatory requirements detailing Permits are contained in Chapter 9 of the Adopted Code.

Section 6. Inspection

Regulatory requirements detailing Inspections are contained in Part 8-4 and Annex 1 of the Adopted Code.

Section 7. Compliance and Enforcement.

Regulatory requirements detailing Compliance and Enforcement are contained in Part 8-4 and in Annex 1 of the Adopted Code.

Section 8. Violation Notices.

Regulatory requirements detailing Violation Notices, Exclusion Orders, Hold Orders, or Summary Suspension are contained in Part 8-406, 8-801.20, 8-903, and 8-904 in Annex 1 of the Adopted Code.

Section 9 Hearings.

Regulatory requirements detailing Hearings Administration are contained in Part 8-905 of Annex 1 of the Adopted Code.

Section 10. Penalties

Regulatory requirements detailing Penalties are contained in Part 8-911.10 (B) of Annex 1 of the Adopted Code and shall read as follows: A person who violates a provision of this Code shall be guilty of a misdemeanor, punishable by: (1) A fine of not more than \$1,000 (one-thousand dollars), or by

imprisonment not exceeding 1 year (one year), or both the fine and imprisonment; of (3) If the person has been convicted once of violating the Code or if there is an intent to defraud or mislead, a fine not exceeding \$2,500 (two-thousand-five hundred dollars) and 2 (two) years imprisonment or both. In addition, Federal law provide under the *Criminal Fine Enforcement Act of 1984* , 18 U.S.C. § 3571 for a fine up to \$100,000 (one-hundred-thousand dollars) for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine up to \$250,000 (two-hundred-fifty-thousand dollars) for individuals and \$500,000 (five-hundred-thousand dollars) for corporations.

Section 11. Inconsistent Codes Repealed.

The Order entitled “Article 1: Food Service Sanitation” that provided for the inspection and licensing of all Food Establishments in Lincoln County and all other codes or portions of codes in conflict herewith are hereby repealed.

Section 12. Conflict With Other Laws.

The provisions of any law or regulation of Lincoln County, Missouri or of any municipality, the State of Missouri, or Federal Agency establishing standards affording greater protection to the public health and/or safety of the citizens of Lincoln County shall prevail within the respective jurisdictions over the provisions of this Ordinance adopted hereunder.

Section 13. Severability

If any portion of this Ordinance and Adopted Code is for any reason held invalid or unconstitutional by any court of competent jurisdiction, that portion shall be deemed a separate, distinct, and independent provision and that holdings shall not affect the validity of the remaining portion of this Ordinance and Adopted Code.

Section 14. Revisions and Amendments

The Lincoln County Commission may convene a hearing and enter into this Ordinance any necessary revisions of amendments for the administration of this Ordinance. Such revisions or amendments shall represent a separate, distinct and independent entity of the Ordinance and may be accomplished by court order or any other method allowed by law. The Lincoln County Office of Environmental Sanitation shall be responsible for informing the Lincoln County Commission of the changes in Food Service Sanitation requirements/regulations and other issues that may necessitate revisions and/or amendments to this Ordinance and Adopted Code.

Section 15. Immunity.

The Lincoln County Office of Environmental Sanitation shall not be liable for damages resulting from approval by the Lincoln County Office of Environmental Sanitation for the construction, modification, or operation of a Food Establishment. The safe and sanitary day-to-day operation of a Food Establishment in compliance with this Ordinance and the Adopted Code shall be the legal responsibility of the permit holder and/or his agent.


Section 16. Schedule of Fees.

The Lincoln County Commission may adopt a schedule of fees associated with the administration of the Ordinance and Adopted Code. The schedule of fees shall be recorded as a court order effective the 1st day of January of each year, beginning January 1, 1999, and such fees shall not exceed the sum of \$1000.

Section 17. Effective Date.

This Ordinance shall become effective on the date that this ordinance is acted upon and ordered by the Lincoln County Commission.


PRESIDING COMMISSIONER


ASSOCIATE COMMISSIONER DISTRICT 1

Commissioner Bass abstained from vote
ASSOCIATE COMMISSIONER DISTRICT 2



CHANGES IN THE LINCOLN COUNTY FOOD CODE-2011

The following table provides a synopsis of the textual changes from the 1997 Lincoln County Food Code to the adoption of the 2009 FDA Food Code. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. *This record should not be relied upon as an absolute comparison that identifies each and every change.*

1997 Lincoln County Food Code to 2009 FDA Food Code	
<u>Chapter 1: Purpose and Definitions</u>	
Addition: 1-201.10 Accredited Program	Changed: 1-201.10: General use pesticide
Addition: 1-201.10: Asymptomatic	Retained from Lincoln County Ordinance-not located in 2009 FDA Food Code: Section 1-201-10: Group Residence
Addition: 1-201.10: Balut	Addition: 1-201.10: Handwashing sink
Addition: 1-201.10: Casing	Addition: 1-201.10: Health practitioner
Addition: 1-201.10: Commingle	Changed: 1-201.10: Highly susceptible population
Addition: 1-201.10: Conditional employee	Changed: 1-201.10: Injected
Addition: 1-201.10: Core Item	Addition: 1-201.10: Juice
Addition: 1-201.10: Counter –mounted equipment	Addition: 1-201.10: Major food allergen
Deleted: 1-201-10: Critical Item	Addition: 1-201.10: Mechanically tenderized
Addition: 1-201.10: Cut leafy greens	Addition: 1-201.10: Non-continuous cooking
Addition: 1-201.10: Dealer	Changed: 1-201.10: Potentially hazardous food
Addition: 1-201.10: Disclosure	Changed: 1-201.10: Poultry
Changed: 1-201-10: Dry storage area	Addition: 1-201.10: Priority item
Changed: 1-201-10: Easily movable	Addition: 1-201.10: Priority foundation item
Addition: 1-201.10: Egg	Addition: 1-201.10: Ratite
Addition: 1-201.10: Enterohemorrhagic <i>Escherichia coli</i>	Changed: 1-201.10: Ready-to-eat food
Addition: 1-201.10: Exclude	Changed: 1-201.10: Reduced oxygen packaging
Addition: 1-201.10: FDA	Addition: 1-201.10: Reminder
Changed: 1-201.10: Foodborne disease outbreak	Addition: 1-201.10: Re-service
Changed: 1-201.10: Food establishment	Addition: 1-201.10: Restrict
Changed: 1-201.10: Food processing plant	Addition: 1-201.10: Restricted egg
Changed: 1-201.10: Game animal	Addition: 1-201.10: Risk
Changed: 1-201.10: Servicing area	Addition: 1-201.10: Service animal
Addition: 1-201.10: Shiga toxin-producing <i>Escherichia coli</i> (STEC)	Changed: 1-201.10: Utensil

Changed: 1-201.10: Single-service articles	Addition: 1-201.10: Variance
Changed: 1-201.10: Slacking	Changed: 1-201.10: Vending machine
Deleted: 1-201.10: Support animal	Changed: 1-201.10: Warewashing
Deleted: 1-201.10: Table-mounted equipment	Addition: 1-201.10: Whole-muscle, intact beef
Addition: 1-201.10: Safe material	
<u>Chapter 2: Management and Personnel</u>	
Changed: 2-101.11: Assignment	Changed Entire Section 2-2 Employee Health
Changed: Entire Section 2-102.11 Demonstration	Changed: Entire Section 2-3 Personal Cleanliness
Changed: Entire Section 2-102.20 Food Protection Manager Certification	Changed: 2-402.11 Effectiveness
Changed: 2-103.11 Person in Charge	Changed: 2-403.11 Handling Prohibition
<u>Chapter 3: Food</u>	
Addition: 3-201.11 (E-G)	Changed: Entire Section 3-304.11 Food Contact with Equipment and Utensils.
Changed: 3-201.17 Game Animals (2)	Changed: Entire Section 3-304.12 In-Use Utensils, Between-Use Storage.
Changed: Entire Section 3-202.11 Temperature.	Changed: Entire Section 3-304.14 Wiping Cloths, Use Limitation.
Changed: Entire Section 3-202.12 Additives	Changed: 3-304.16 Using Clean Tableware for Second Portions and Refills. (A)
Changed: Entire Section 3-202.13 Eggs	Changed: Entire Section 3-304.17 Refilling Returnables
Changed: Entire Section 3-202.14 Eggs and Milk Products, Pasteurized.	Changed: 3-305.13 Vended Potentially Hazardous Food
Changed: Entire Section 3-202.17 Shucked Shellfish, Packaging and Identification.	Changed: 3-306.13 Consumer Self-Service Operations. (A)
Changed: Entire Section 3-202.18 Shellstock Identification.	Changed: Entire Section 3-306.14 Returned Food and Re-Service of Food
Addition: 3-202.110 Juice	Changed: Entire Section Cooking: 3-401.11 Raw Animal Foods.
Changed: Entire Section 3-203.11 Molluscan Shellfish, Original Container.	Changed: Entire Section 3-401.13 Plant Food Cooking for Hot Holding
Changed: Entire Section 3-203.12 Shellstock, Maintaining Identification.	Addition: 3-401.14 Non-Continuous Cooking of Raw Animal Foods.

Changed: 3-301.11 Preventing Contamination From Hands (B)	Changed: Entire Section Freezing 3-402.11 & 3-402.12
Addition: 3-301.11 Preventing Contamination From Hands (D)	Changed: Entire Section Reheating: 3-403.11
Addition: 3-302.11 Packaged and Unpackaged Food-Separation, Packaging, and Segregation (A)(1)(c) , (4)	Addition: 3-404.11 Other methods: Treating Juice
Changed: 3-302.11 Packaged and Unpackaged Food-Separation, Packaging, and Segregation (4)	Changed: Entire Section 3-501 Temperature and Time Control
Changed: Entire Section 3-302.12 Food Storage Containers, identified with Common Name of Food	Changed: Entire Section 3-502 Specialized Processing Methods
Changed : Entire Section 3-302.13 Pasteurized Eggs, Substitute for Raw Eggs for Certain Recipes.	Changed: Entire Section 3-602.11 Food Labels
Changed: 3-302.14 Protection from Unapproved Additives (A2) AND (B)	Addition: 3-602.12 Other forms of Information
Changed: 3-302.15 Washing Fruits and Vegetables (A)	Changed: Entire Section 3-603.11 Consumption of Raw or Undercooked Animal Foods
Changed: 3-303.12 Storage or Display of Food in Contact with Water or Ice. (D)	Changed: 3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food. (A)
	Changed: Entire Section 3-8 Special Requirements for Highly Susceptible Populations
<u>Chapter 4-Equipment, Utensils, and Linen</u>	
Changed: Entire Section 4-101.13 Lead, Use Limitation	
Deleted: Entire Sections 4-101.17 & 4-101.18 Lead	Changed: 4-402.11 (B) Fixed Equipment, Spacing or Sealing
Addition: 4-201-11 Food-Contact Surfaces	Changed: 4-402.12 Fixed Equipment, Elevation or Sealing.(D) & (E)
Changed: 4-202.13 "V" Threads, Use Limitation	Changed: 4-501.16 Warewashing Sinks, Use Limitation.(A)
Changed: 4-202.17 Kick Plates, Removable.(A)	Changed Entire Section: 4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.
Changed: Entire section 4-203.12 Temperature Measuring Devices, Ambient Air and Water.	Changed Entire Section: 4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.
Addition: 4-201.13 Dispensing Equipment, Protection of Equipment and Food (E)	Changed: Entire Section 4-602.11 Equipment Food-Contact Surfaces and Utensils.
Addition: 4-204.14 Vending Machine, Vending Stage Closure.	Addition: 4-603.11 Dry Cleaning Section (A)
Changed: Entire Section 4-204.16 Beverage Tubing, Separation	Addition: 4-603.17 Returnables, Cleaning for Refilling Section (B)

Addition: 4-204.111 Vending Machines, Automatic Shutoff. Section (A)	Changed: 4-703.11 Hot Water and Chemicals (B) and (C)
Changed: Entire Section 4-204.111 Vending Machines, Automatic Shutoff.	Changed: 4-801.11 Frequency (B) and (D)
Addition: 4-204.112 Temperature Measuring Devices. Section (B)	Changed: 4-901.11 Equipment and Utensils, Air-Drying Required. (A)
Changed: Entire Section: 4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.	Changed: Entire Section 4-902.11 Food-Contact Surfaces.
Addition: 4-301.12 Manual Warewashing Sink Compartment Requirements Section (D)	Changed: 4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles. (D)
Changed: Entire Section 4-302.12 Food Temperature Measuring Devices	Changed: Entire Section 4-904.13 Preset Tableware
Addition: 4-904.14 Rinsing Equipment and Utensils after Cleaning and Sanitizing.	
<u>Chapter 5-Water, Plumbing, and Waste</u>	
Deleted: 5-102.12-Nondrinking water (B) “and irrigation”	Changed: 5-204.11 and 5-205.11 “lavatory” to “sink”
Changed Entire Section: 5-103.11 Capacity	Add: 5-205.11 Using a Handwashing Lavatory, (C)
Deleted: 5-103.13 Hot Water	Changed: Entire Section 5-205.12 Prohibiting a Cross Connection
Changed: 5-202.11-Approved System and Cleanable Fixtures (B)- “lavatory” to “SINK”	Changed: Entire Section 5-402.11 Backflow Prevention
Changed: Entire Section 5-202.12-Handwashing Lavatory, Water Temperature, and Flow	Changed: Entire Section 5-501.14 Receptacles in Vending Machines
Added: 5-203.13 Service Sink Section (B)	Changed: 5-501.116 Cleaning Receptacles “5-402.14” to 5-402.13
Changed: Entire Section 5-203.15 Backflow Prevention Device, Carbonator	
<u>Chapter 6: Physical Facilities</u>	
Changed: Entire chapter “lavatories” to “sinks”	Addition: 6-301.14 Handwashing Signage
Removed: 6-101.11 (B) “suitable”	Changed: 6-303.11 Intensity (A) and (B)
Reworded: 6-201.11 Floors, Walls, and Ceilings	Addition: 6-306.10 Availability “5-302.13(A)”
Reworded: 6-201.18 Walls and Ceilings, Studs, Joists, and Rafters	Changed: Entire Section 6-501.12 Cleaning, Frequency and Restrictions.
Changed: Entire Section 6-202.14 Toilet Rooms, Enclosed	Changed: Entire Section 6-501.18 Maintaining and Using Handwashing

	Lavatories
Changed: Entire Section 6-202.15 Outer Openings, Protected	Changed: Entire Section 6-501.19 Closing Toilet Room Doors
Reworded: 6-201.17 Outdoor Food Vending Areas, Overhead Protection	Changed: Entire Section 6-501.111 Controlling Pests
Reworded: 6-201.18 Outdoor Food Servicing Areas, Overhead Protection	Changed: Entire Section 6-501.115 Prohibiting Animals
Changed: Entire Section 6-301.12 Hand Drying Provision	
<u>Chapter 7-Poisonous or Toxic Materials</u>	
Changed: 7-202.12 Conditions of Use “restricted use pesticide	Changed: Entire Section 7-206.13 Tracking Powders, Pest Control and Monitoring
Changed: Entire Section 7-204.11 Sanitizers, Criteria	Changed: Entire Section 7-207.11 Restriction and Storage
Changed: Entire Section 7-204.12 Criteria for Washing Fruits and Vegetables, Criteria	
<u>Chapter 8 Compliance and Enforcement</u>	
Deleted: 8-101.10 Public Health Protection	Addition: 8-402.10 Competency of Inspectors
Changed: Entire Section 8-201.12 Contents of the Plans and Specifications (E) & (E)	Changed: Entire Section 8-403.10 Documenting Information and Observations
Deleted: 8-201.12 Contents of the Plans and Specifications (G)	Changed: Entire Section 8-405.11 Timely Correction
Changed: Entire Section 8-201.13 When a HACCP Plan is Required	Changed: Entire Section 8-405.20 Verification and Documentation of Correction
Changed: Entire Section 8-201.14 Contents of a HACCP Plan	Changed: Entire Section 8-406.11 Time Frame for Correction
Changed: 8-302.14 Contents of the Application	Changed: Entire Section 8-501.30 Restriction or Exclusion Oder: Warning or Hearing not Required, Information Required in Order
Changed: Entire Section 8-304.11 Responsibilities of the Permit Holder	Changed: Entire Section 8-501.40 Release of Employee from Restriction or Exclusion
Changed: 8-401.10 Establishing Inspection Interval (C)	Changed: 8-501.10 “ FOOD EMPLOYEE”
Changed: Entire Section 8-401 Performance- and Risk-Based	
<u>Chapter 9: Permits, Fees, and Exemptions</u>	ADDED SECTION

CONTENTS

PREFACE		P1
CHAPTER 1	PURPOSE AND DEFINITIONS	1
CHAPTER 2	MANAGEMENT AND PERSONNEL	22
CHAPTER 3	FOOD	43
CHAPTER 4	EQUIPMENT, UTENSILS, AND LINENS	85
CHAPTER 5	WATER, PLUMBING, AND WASTER	119
CHAPTER 6	PHYSICAL FACILITIES	135
CHAPTER 7	POISONOUS OR TOXIC MATERIALS	148
CHAPTER 8	COMPLIANCE AND ENFORCEMENT	155
CHAPTER 9	PERMITS, FEES, AND EXEMPTIONS	171
INDEX		173
ANNEX LIST	END OF CONTENTS PAGES	

CHAPTER 1 PURPOSE AND DEFINITIONS

1-1 TITLE, INTENT, SCOPE

	1-101	Title	1
	1-102	Intent	1
	1-103	Scope	1

1-2 DEFINITIONS

	1-201	Applicability and Terms Defined	1
--	--------------	--	----------

CHAPTER 2 MANAGEMENT AND PERSONNEL

2-1 SUPERVISION

	2-101	Responsibility	22
	2-102	Knowledge	24
	2-103	Duties	25

2-2 EMPLOYEE HEALTH

	2-201	Disease or Medical Condition	26
--	--------------	-------------------------------------	-----------

2-3 PERSONAL CLEANLINESS

	2-301	Hands and Arms	37
	2-302	Fingernails	39
	2-303	Jewelry	40
	2-304	Outer Clothing	40

2-4 HYGENIC PRACTICES

	2-401	Food Contamination Prevention	40
	2-402	Hair Restraints	41
	2-403	Animals	41

CHAPTER 3 FOOD

3-1 CHARACTERISTICS

	3-101	Condition	43
--	--------------	------------------	-----------

3-2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS

	3-201	Sources	43
	3-202	Specifications for Receiving	47
	3-203	Original Containers and Records	50

3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING

	3-301	Preventing Contamination by Employees	52
	3-302	Preventing Food and Ingredient Contamination	54
	3-303	Preventing Contamination from Ice Used as a Coolant	56
	3-304	Preventing Contamination from Equipment, Utensils, and Linens	56
	3-305	Preventing Contamination from the Premises	59
	3-306	Preventing Contamination by Consumers	60
	3-307	Preventing Contamination from Other Sources	61

3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN

	3-401	Cooking	61
	3-402	Freezing	65
	3-403	Reheating	66

3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

	3-501	Temperature and Time Control	67
	3-502	Specialized Processing Methods	74

3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING

	3-601	Accurate Representation	78
	3-602	Labeling	78
	3-603	Consumer Advisory	80

3-7 CONTAMINATED FOOD

	3-701	Disposition	80
--	--------------	--------------------	-----------

3-8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

	3-801	Additional Safeguards	81
--	--------------	------------------------------	-----------

CHAPTER 4 EQUIPMENT, UTENSILS, AND LINENS

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR

	4-101	Multiuse	85
	4-102	Single-Service and Single-Use	88

4-2 DESIGN AND CONSTRUCTION

	4-201	Durability and Strength	88
	4-202	Cleanability	88
	4-203	Accuracy	90
	4-204	Functionality	91
	4-205	Acceptability	97

4-3 NUMBERS AND CAPACITIES

	4-301	Equipment	97
	4-302	Utensils, Temperature Measuring Devices, and Testing Devices	99

4-4 LOCATION AND INSTALLATION

	4-401	Location	99
	4-402	Installation	100

4-5 MAINTENANCE AND OPERATION

	4-501	Equipment	101
	4-502	Utensils and Temperature and Pressure Measuring Devices	105

4-6 CLEANING OF EQUIPMENT AND UTENSILS

	4-601	Objective	106
	4-602	Frequency	108
	4-603	Methods	109

4-7 SANITATION OF EQUIPMENT AND UTENSILS

	4-701	Objective	111
	4-702	Frequency	112
	4-703	Methods	112

4-8 LAUNDERING

	4-801	Objective	112
	4-802	Frequency	113
	4-803	Methods	113

4-9 PROTECTION OF CLEAN ITEMS

	4-901	Drying	114
	4-902	Lubricating and Reassembling	114
	4-903	Storing	115
	4-904	Handling	116

CHAPTER 5 WATER, PLUMBING, AND WASTE

5-1 WATER

	5-101	Source	119
	5-102	Quality	120
	5-103	Quantity and Availability	120
	5-104	Distribution, Delivery, and Retention	121

5-2 PLUMBING SYSTEM

	5-201	Materials	121
	5-202	Design, Construction, and Installation	122
	5-203	Numbers and Capacities	123
	5-204	Location and Placement	124
	5-205	Operation and Maintenance	124

5-3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT WATER TANK

	5-301	Materials	125
	5-302	Design, Construction, and Installation	126
	5-303	Numbers and Capacities	127
	5-304	Operation and Maintenance	128

5-4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER

	5-401	Mobile Holding Tank	128
	5-402	Retention, Drainage, and Delivery	129
	5-403	Disposal Facility	130

5-5 REFUSE, RECYCLABLES, AND RETURNABLES

	5-501	Facilities and Premises	130
	5-502	Removal	133
	5-503	Facilities for Disposal and Recycling	134

CHAPTER 6 PHYSICAL FACILITIES

6-1 MATERIALS FOR CONSTRUCTION AND REPAIR

	6-101	Indoor Areas	135
	6-102	Outdoor Areas	136

6-2 DESIGN, CONSTRUCTION, AND INSTALLATION

	6-201	Cleanability	136
	6-202	Functionality	138

6-3 NUMBERS AND CAPACITIES

	6-301	Handwashing Lavatories	140
	6-302	Toilets and Urinals	141
	6-303	Lighting	142
	6-304	Ventilation	142
	6-305	Dressing Areas and Lockers	142
	6-306	Service Sinks	142

6-4 LOCATION AND PLACEMENT

	6-401	Handwashing Lavatories	143
	6-402	Toilet Rooms	143
	6-403	Employee Accommodations	143
	6-404	Distressed Merchandise	143
	6-405	Refuse, Recyclables, and Returnables	143

6-5 MAINTENANCE AND OPERATION

	6-501	Premises, Structures, Attachments, and Fixtures- Methods	144
--	--------------	---	------------

CHAPTER 7 POISONOUS OR TOXIC MATERIALS

7-1 LABELING AND IDENTIFICATION

	7-101	Original Containers	148
	7-102	Working Containers	148

7-2 OPERATIONAL SUPPLIES AND APPLICATIONS

	7-201	Storage	148
	7-202	Presence and Use	149
	7-203	Container Prohibitions	150
	7-204	Chemicals	150
	7-205	Lubricants	151
	7-206	Pesticides	151
	7-207	Medicines	152
	7-208	First Aid Supplies	152
	7-209	Other Personal Care Items	152

7-3 STOCK AND RETAIL SALE

	7-301	Storage and Display	153
--	--------------	----------------------------	------------

CHAPTER 8 COMPLIANCE AND ENFORCEMENT

8-1 CODE APPLICABILITY

	8-101	Use for Intended Purposes	155
	8-102	Additional Requirements	156
	8-103	Variances	156

8-2 PLAN SUBMISSION AND APPROVAL

	8-201	Facility and Operating Plans	157
	8-202	Confidentiality	159
	8-203	Construction Inspection and Approval	159

8-3 PERMIT TO OPERATE

	8-301	Requirement	159
	8-302	Application Procedure	160
	8-303	Issuance	162
	8-304	Conditions and Retention	163

8-4 INSPECTION AND CORRECTION OF VIOLATIONS

	8-401	Frequency	164
	8-402	Access	165
	8-403	Report of Findings	166
	8-404	Imminent Health Hazard	168
	8-405	Critical Violation	168
	8-406	Noncritical Violation	169

8-5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

	8-501	Investigation and Control	169
--	--------------	----------------------------------	------------

CHAPTER 9 PERMITS, FEES, AND EXEMPTIONS

9-1 PERMIT YEAR, FEES, AND EXEMPTIONS

	9-101	Permit year, fees, and exemptions	171
--	--------------	--	------------

ANNEX LISTING

Annex 1: Compliance and Enforcement

Annex 2: References

Annex 3: Public Health Reasons/Guides

Annex 4: Management of Food Safety

**Practices-Achieving Active Managerial Control of
Food-borne Illness Risk Factors**

Annex 5: Conducting Risk-Based Inspections

Annex 6: Food Processing Criteria

Annex 7: Model/Forms/Guides/Other Aids

For Annex information, please visit:

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/>

FDA Food Code 2009: Joint Introduction to the 2009 Food Code

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) and the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA) are pleased to release the 2009 edition of the Food Code. The Food Code is a model code and reference document for state, city, county and tribal agencies that regulate restaurants, retail food stores, vending operations and foodservice operations in institutions such as schools, hospitals, nursing homes and child care centers.

The Food Code establishes practical, science-based guidance and enforceable provisions for mitigating risk factors known to cause foodborne illness. Food safety is a priority for HHS and USDA, and we strongly encourage the adoption and implementation of the 2009 Food Code at all levels of government.

Among the key findings of the Food Safety Working Group created by President Obama was the need to modernize statutes that require effective sanitation and preventive controls in food establishments. An increasingly globalized food supply chain, the aging of our population, increases in the number of immunocompromised and immunosuppressed individuals, and the trend toward greater consumption of foods prepared outside the home demand sustained vigilance by industry and the regulatory community to promote food safety in retail and foodservice establishments.

Implementation of the Food Code also supports many of the food safety objectives of Healthy People 2010, the comprehensive, nationwide set of health promotion and disease prevention objectives designed to serve as a 10-year strategy for improving health in the United States. Healthy People 2010 objectives include reducing infections caused by foodborne pathogens, reducing outbreaks of foodborne illness, and improving food employee behaviors and food preparation practices that directly relate to foodborne illness in retail food establishments. Similar objectives are planned for the next generation of the initiative, Healthy People 2020.

Food Code adoption and implementation is important for achieving uniform national food safety standards and for enhancing the efficiency and effectiveness of our nation's food safety system. As of January 2009, 49 of 50 states and 3 of 6 territories of the United States report having retail codes patterned after prior editions of the Food Code. Many federal agencies and tribal governments have adopted the Code as well. We commend these jurisdictions and agencies and urge all to update their existing codes and initiate rule-making that is consistent with the 2009 Food Code.

The federal government is committed to enhanced coordination of food safety efforts with state, local, and tribal agencies, and the food industry to protect our food supply. Establishing uniform and enforceable standards of food safety in retail and foodservice establishments is an important part of strengthening our nation's food protection system. HHS and USDA will continue to take progressive steps to partner with all who have a stake in food safety and are committed to reducing the incidence of foodborne illness in the United States.

Margaret A. Hamburg, M.D. Commissioner Food and Drug Administration U.S. Department of Health and Human Services	Alfred V. Almanza Administrator Food Safety and Inspection Service U.S. Department of Agriculture	Thomas R. Frieden, M.D., M.P.H Director Centers for Disease Control and Prevention U.S. Department of Health and Human Services
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Preface

1. Foodborne Illness Estimates, Risk Factors, and Interventions

Foodborne illness in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. Meade et. al. (1999) estimated that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.

For many victims, foodborne illness results only in discomfort or lost time from the job. For some, especially preschool age children, older adults in health care facilities, and those with impaired immune systems, foodborne illness is more serious and may be life threatening.

The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs are estimated to be \$10 - \$83 billion. As stated by Meade et. al., the nature of food and foodborne illness has changed dramatically in the United States over the last century. While technological advances such as pasteurization and proper canning have all but eliminated some disease, new causes of foodborne illness have been identified. Surveillance of foodborne illness is complicated by several factors. The first is underreporting. Although foodborne illnesses can be severe or even fatal, milder cases are often not detected through routine surveillance. Second, many pathogens transmitted through food are also spread through water or from person to person, thus obscuring the role of foodborne transmission. Finally, pathogens or agents that have not yet been identified and thus cannot be diagnosed cause some proportion of foodborne illness.

Epidemiological outbreak data repeatedly identify five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness:

- Improper holding temperatures,
- Inadequate cooking, such as undercooking raw shell eggs,
- Contaminated equipment,
- Food from unsafe sources, and
- Poor personal hygiene

The Food Code addresses controls for risk factors and further establishes 5 key public health interventions to protect consumer health. Specifically, these interventions are: demonstration of knowledge, employee health controls, controlling hands as a vehicle of contamination, time and temperature parameters for controlling pathogens, and the consumer advisory. The first two interventions are found in Chapter 2 and the last three in Chapter 3.

Healthy People 2010 and Healthy People 2020 are national initiatives that work through the cooperative federal-state-private sector and which establish 10-year objectives to improve the health of all Americans through prevention. Food Safety Objective 10-6 in Healthy People 2010 is: *Improve food employee behaviors and food preparation practices that directly relate to foodborne illness in retail food establishments*. This includes food operations such as retail food stores, food service establishments, health care facilities, schools and other "food establishments" as defined in the Food Code. In 2010, the Healthy People 2020 objectives will be released along with guidance for achieving the new 10-year targets.

The Food and Drug Administration (FDA) endeavors to assist the approximately 75 state and territorial agencies and more than 3,000 local departments that assume primary responsibility for preventing

foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. This industry segment consists of more than one million establishments and employs a work force of over 16 million.

2. PHS Model Codes History, Purpose, and Authority

(A) History and Purpose

U.S. Public Health Service (PHS) activities in the area of food protection began at the turn of the 20th century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective disease prevention requires the application of comprehensive food sanitation measures from production to consumption. Additional studies identified and evaluated measures which would most effectively control disease, including work which led to improved processes for pasteurization.

Next, model codes were developed to assist state and local governments in initiating and maintaining effective programs for prevention of foodborne illness. The first of these, which is now titled *Grade A Pasteurized Milk Ordinance – Recommendations of the PHS/FDA*¹, was initially published in 1924. Subsequently, the PHS published recommended model food codes that address the various components of the retail segment of the food industry. These code editions are listed chronologically on pp. iii and iv. Through the years all states, hundreds of local jurisdictions, and many federal agencies have adopted some edition of model food codes recommended by the PHS.

Today, FDA's purpose in maintaining an updated model food code is to assist food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail segment of the food industry. The retail segment includes those establishments or locations in the food distribution chain where the consumer takes possession of the food.

The model Food Code is neither federal law nor federal regulation and is not preemptive. Rather, it represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. Although not federal requirements (until adopted by federal bodies for use within federal jurisdictions), the model Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government. A *list of jurisdictions that have reported to FDA their status in adopting the Food Code*² is available on the FDA CFSAN web site. The list is self-reported and FDA has not yet evaluated whether all the adopted codes are equivalent to the model Food Code.

Providing model food codes and model code interpretations and opinions is the mechanism through which FDA, as a lead federal food control agency, promotes uniform implementation of national food regulatory policy among the several thousand federal, state, and local agencies and tribes that have primary responsibility for the regulation or oversight of retail level food operations.

(B) Authority

PHS authority for providing assistance to state and local governments is derived from the Public Health Service Act [42 USC 243]. Section 311(a) states in part:

"... The Secretary shall ... assist states and their political subdivisions in the prevention and suppression of communicable diseases, and with respect to other public health matters, shall cooperate with and aid state and local authorities in the enforcement of their ... health regulations and shall advise the several states on

matters relating to the preservation and improvement of the public health." Responsibility for carrying out the provisions of the Act relative to food protection was delegated within the PHS to the Commissioner of Food and Drugs in 1968 [21 CFR 5.10(a)(2) and (3)].

Under authority of the Economy Act, June 30, 1932 as amended [31 USC 1535], FDA provides assistance to federal agencies.

Assistance provided to local, state, and federal governmental bodies is also based on FDA's authorities and responsibilities under the Federal Food, Drug, and Cosmetic Act [21 USC 301].

3. Public Health and Consumer Expectations

It is a shared responsibility of the food industry and the government to ensure that food provided to the consumer is safe and does not become a vehicle in a disease outbreak or in the transmission of communicable disease. This shared responsibility extends to ensuring that consumer expectations are met and that food is unadulterated, prepared in a clean environment, and honestly presented.

Under FDA's 2009 Mission Statement the agency is responsible for:

Protecting the public health by assuring the safety and security of our nation's food supply... and for advancing the public health by helping to make foods safer and more affordable; and helping the public get the accurate, science-based information they need about foods to improve their health.

Accordingly, the provisions of the Food Code provide a system of prevention and overlapping safeguards designed to minimize foodborne illness; ensure employee health, industry manager knowledge, safe food, nontoxic and cleanable equipment, and acceptable levels of sanitation on food establishment premises; and promote fair dealings with the consumer.

4. Advantage of Uniform Standards

The advantages of well-written, scientifically sound, and up-to-date model codes have long been recognized by industry and government officials.

Industry conformance with acceptable procedures and practices is far more likely where regulatory officials "speak with one voice" about what is required to protect the public health, why it is important, and which alternatives for compliance may be accepted.

Model codes provide a guide for use in establishing what is required. They are useful to business in that they provide accepted standards that can be applied in training and quality assurance programs. They are helpful to local, state, and federal governmental bodies that are developing or updating their own codes.

The model Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations with years of experience using earlier model code editions. It embraces the concept that our quality of life, state of health, and the public welfare are directly affected by how we collectively provide and protect our food.

The model Food Code provisions are consistent with, and where appropriate incorporate, federal performance standards for the same products and processes. Federal performance standards in effect

define public food safety expectations for the product, usually in terms of lethality to a pathogenic microorganism of particular concern. Use of performance standards as the measure of regulatory compliance means establishments are free to use innovative approaches in producing safe products, in lieu of adherence to traditional processing approaches, such as specified cooking times and temperatures, that achieve the same end. Federally inspected establishments demonstrate compliance with performance standards by showing that their process adheres to an appropriately designed, validated HACCP plan.

Retail processors may be given the same opportunity as federally-regulated establishments to use innovative techniques in the production of safe foods. Retail establishments may apply to the regulatory authority for a variance to use a specific federal food safety performance standard for a product or a process in lieu of compliance with otherwise applicable specifications in the Food Code. However, to show compliance with the federal performance standard, the retail processor must, like a federally inspected establishment, show that processing controls are in place to ensure that the standard is being met. Thus, a request for a variance based on a federal performance standard must be supported by a validated HACCP plan with record keeping and documented verification being made available to the regulatory authority.

5. Modifications and Improvements in This Edition

The revisions contained in this edition reflect changes, additions, deletions, and format modifications listed in the Supplement to the 2005 FDA Food Code and recommendations developed during the 2008 Biennial meeting of the Conference for Food Protection. The revisions also reflect input provided by those who have been intimately involved with studying, teaching, and using the earlier editions. Most of these enhancements involve added clarification or new information. Some reflect evolving regulatory policy contained in new or revised federal regulations.

The needed clarifications and missing Code provisions were identified by FDA and others during standardization and certification activities, State Training Team courses, regional food protection seminars, the deliberations of food equipment standards organizations, and the verbal and written requests for clarification received by FDA field and headquarters components.

Changes in provisions related to federal laws and regulations administered by other federal agencies such as the United States Department of Agriculture were jointly developed with those agencies.

New to the 2009 Food Code is a revised designation system for Code provisions. The former use of "critical" or "non-critical" has been changed in recognition that there is a need for better identifying risk-based controls contained within the Code's provisions.

A Summary of Changes is provided at the end of the Food Code. General enhancements include:

- (1) Added and improved definitions that are more precise and more consistent with terminology and definitions found in related laws and regulations;
- (2) Modified provisions to make them more consistent with national requirements and standards administered by other federal agencies and international bodies; more flexible without compromising public health; and more internally consistent with other Food Code provisions;
- (3) Clarified other provisions regarding their intent, thereby reducing confusion and the potential for inconsistent application;

(4) Improved user aids contained in the Annexes such as added references and updated public health reasons, model forms, guides, and lists; and

(5) Expanded the Index with additional terms to assist a broader base of users in finding topics of interest.

6. Discussion of the Food Code as a HACCP Model and the Intention to Incorporate Other Models

It is important to note that preapproval of HACCP plans for food establishments operating pursuant to a variance is provided for under the Food Code, but such plan preapproval is not a part of another HACCP regulatory model, the Fish and Fishery Products regulation 21 CFR 123, effective December 18, 1997 (a Third Edition issued June 2001). Additionally, there are differences between the two models in the required content of the HACCP plan. For example, the HACCP plans mandated by the Food Code must include flow diagrams, product formulations, training plans, and a corrective action plan. Flow diagrams and product formulations are suggested but not mandated components of the Fish and Fishery Products regulation.

These differences are necessitated by differences in the nature of the regulations and the regulatory structure set up to enforce them. HACCP plans developed under the Food Code variance process are provided to the regulatory authority to enable the regulatory authority to assess whether the establishment has designed a system of controls sufficient to ensure the safety of the product. The plans will be reviewed outside the food establishment and, in most cases, in the absence of any historical performance information for the product at that establishment. Therefore, the plan must contain sufficient detail to allow the regulator to fully understand the operations and the intended controls. Products requiring a variance are those which are deemed to be potentially hazardous (time/temperature control for safety) and for which retail production would otherwise be prohibited.

To assist food establishments in applying HACCP principles at retail, FDA has issued a document entitled: *Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level*³.

Under the Fish and Fishery Products regulation, every seafood processor is required to perform a hazard analysis, and must have and implement a written HACCP Plan whenever a hazard analysis reveals a food safety hazard that is reasonably likely to occur. HACCP plans developed pursuant to the Fish and Fishery Products regulation are for all products in the class and are not for products for which production is presently prohibited. Plans will be reviewed on site, with records available to judge, among other things, the adequacy of past corrective actions.

It is intended that the Food Code will be amended to incorporate federal HACCP regulations and guidelines by inclusion in the text of the Food Code, by reference, or through the issuance of interpretations. This will provide alternatives to the preapproval of HACCP plans, such as simplified HACCP plans in line with the Fish and Fishery Products model, if the product is produced under a HACCP plan developed in conformance with such regulation or guideline. In so doing, the need for preapproved plans under the more intensive regimen of the Food Code will be significantly reduced.

HACCP plans are key to the use of performance standards as measures of regulatory compliance. Performance standards issued by the Food Safety and Inspection Service are applicable to a broad range of meat, poultry, and egg products. Federal performance standards are acceptable, equivalent alternatives to the command-and-control provisions that now provide specific times and temperatures for processing

various products. Federal performance standards may be used to determine the safety of a product or process under the Food Code if authorized under a variance granted in accord with the Code's variance provisions, and demonstrated by adherence to a validated HACCP plan, consistent with the Code's HACCP provisions.

7. Code Adoption/Certified Copies

The model Food Code is provided for use by food regulatory jurisdictions at all levels of government. At the state and local levels the model may be:

- (A) Enacted into statute as an act of the state legislative body;
- (B) Promulgated as a regulation, if the state legislative body has delegated rule-making authority to a governmental administrative agency; or
- (C) Adopted as an ordinance, if the local legislative body has been delegated rule-making authority or regulatory powers.

Typically, code adoption bodies publish a notice of their intent to adopt a code, make copies available for public inspection, and provide an opportunity for public input prior to adoption. This is usually done in one of two ways.

The recommended method is the "short form" or "adoption by reference" approach where a simple statement is published stating that certified copies of the proposed code are on file for public review. This approach may be used by governmental bodies located in states that have enabling laws authorizing the adoption of codes by reference. An advantage to this approach is a substantial reduction in the cost of publishing and printing.

Certified copies of the Food Code for use in adopting the model by reference are available through the FDA Retail Food Protection Team, HFS-320, 5100 Paint Branch Parkway, College Park, MD 20740-3835. Refer to item 2. (A) of this Preface to access a listing of jurisdictions' adoptions.

The alternative method is the "long form" or "section-by-section" approach where the proposed code is published in its entirety.

Both methods of adoption allow for the modification of specific provisions to accommodate existing law, administrative procedure, or regulatory policy. Annex 7 contains model adoption forms for use by governmental bodies who wish to use either of these methods.

8. Information to Assist the User

Many of the improvements contained in the model Food Code, as listed under item 5 of this Preface, are provided to make the document easier to use. Other characteristics of the new edition, if they are understood by the user, make it easier to follow and apply. These include structure, nomenclature, and methodology.

Food Code provisions address essentially four areas: personnel (Chapter 2), food (Chapter 3), equipment/facilities/supplies (Chapters 4, 5, 6, 7), and compliance and enforcement (Chapter 8). A new user will find it helpful to review the Table of Contents together with the Code Reference Sheet (Annex 7,

Guide 3-B) in order to quickly gain an understanding of the scope and sequence of subjects included within these four areas. The structural nomenclature of the document is as follows:

Chapter	9
Part	9-1
Subpart	9-101
Section (§)	9-101.11
Paragraph (¶)	9-101.11(A)
Subparagraph	9-101.11(A)(1)

Code provisions are either appropriate for citing and debiting on an inspection report or they are not. Those not intended for citing/debiting are identified by the digits following the decimal point in the numbering system. These "nondebitable" provisions fall into two categories, those that end with two digits after the decimal point and the last digit is a zero, e.g., § 1-201.10; and those that end with three digits after the decimal point and the last 2 digits are zeros, e.g., § 8-805.100.

Two types of internal cross referencing are widely used throughout the Code to eliminate the need for restating provisions.

- A. The first type of cross reference uses phrases that contain the word "under", e.g., "as specified **under** ... (followed by the relevant portion of the Code)."

The purpose of this type of cross reference is to:

- 1) Alert the reader to relevant information, and
- 2) Provide a system by which each violation is recorded under the one most appropriate provision. This type of cross reference signals to the reader the provision of the Code under which a certain violation is properly cited/debited.

- B. The second type of cross reference uses phrases that contain the word "in," e.g., "as specified **in**... (followed by the relevant portion of the Code)."

The purpose of this type of cross reference is to:

- 1) Indicate the specific provisions of a separate document such as a federal regulation that are being incorporated by reference in the requirement of the Code, e.g., ¶ 3-201.11(C);
or
- 2) Refer the reader to a nondebitable provision of the Code which provides further information for consideration, such as provision for an exception or for an allowance to comply via an alternative method.

For example, ¶ 3-201.16 (A) begins with "Except as specified in ¶ (B)..." and ¶ (B) states the relevant exceptions to ¶ (A). Paragraph 3-201.11(E) states in part, "... as specified in ¶ 3-401.11(C)" and ¶ 3-401.11(C) provides for an allowance to serve or sell raw or undercooked, whole-meat, intact beef steaks in a ready-to-eat form.

If you review the exception in ¶ 3-201.16(B) and the allowance in ¶ 3-401.11(C), you will see that exceptions and allowances often contain conditions of compliance, i.e., conditions that must be met in order for the exception or allowance to convey.

Based on the violation being cited, the substance of the text being referred to, and the context in which the reference is made, users of the Code must infer the intent of the cross reference. That is, the user must determine if the cross reference simply alerts the user to additional information about the requirement or if the cross reference:

- sends (via the word "under") the citing/debiting to another Code provision;

or

- incorporates (via the word "in") the referenced requirements into the Code provision.

The Food Code presents requirements by principle rather than by subject. For example, equipment requirements are presented under headings such as Materials, Design and Construction, Numbers and Capacities, Location and Installation, and Maintenance and Operation rather than by refrigerators, sinks, and thermometers. In this way provisions need be stated only once rather than repeated for each piece or category of equipment. Where there are special requirements for certain equipment, the requirement is delineated under the appropriate principle (e.g., Design and Construction) and listed separately in the index.

Portions of some sections are written in *italics*. These provisions are not requirements, but are provided to convey relevant information about specific exceptions and alternative means for compliance. Italics are pursuant to a preceding provision that states a requirement, to which the italics offer an exception or another possibility. Italicized sections usually involve the words "except for," "may", "need not" or "does not apply." See ¶ 3-202.18(D).

Requirements contained in the Food Code are presented as being in one of three categories of importance: ***priority item*** (i.e. 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); ***priority foundation item*** (i.e., a provision in this Code whose application supports, facilitates or enables one or more *priority items*); and, ***core item*** (i.e., a provision in this Code that is not designated as a *Priority Item* or a *Priority Foundation Item* and that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

A "P" or "Pf" designation after a paragraph or subparagraph indicates that the provision within that section is a priority item or *priority foundation item*. Any unmarked provisions within a section are *core items*.

The following conventions are used in the Food Code. "Shall" means the act is imperative, i.e., "shall" constitutes a command. "May not" means absolute prohibition. "May" is permissive and means the act is allowed. The term "means" is followed by a declared fact.

Defined words and terms are in "small caps" in the text of the Food Code chapters to alert the reader to the fact that there is a specific meaning assigned to those words and terms and that the meaning of a provision is to be interpreted in the defined context. A concerted effort was also made to place in "small caps" all forms and combinations of those defined words and terms that were intended to carry the weight of the definition.

The annexes located at the back of the document can provide tremendous assistance to those charged with applying Food Code provisions. No reference is made in the text of a provision to the annexes which support its requirements. This is necessary in order to keep future laws or other requirements based on the model Food Code "clean." However, the annexes are provided specifically to assist the regulatory authority apply the provisions uniformly and effectively.

It is, therefore, important for users to preview the subject and essence of each of the annexes before using the document. Some of the annexes (e.g., References, Public Health Reasons) are structured to present the information by the specific Food Code item number to which they apply. Other annexes provide information and materials intended to be helpful to the user such as model forms that can be used, a delineation of the principles of HACCP, guidelines for establishment inspection, and criteria for certain food processes for use in evaluating proposed HACCP plans.

9. The Code Revision Process

(A) Food Code Revision and Publication Cycles

FDA is issuing a new edition of the Food Code every 4 years. During the 4-year span of time between editions, FDA may issue supplements to an existing edition. Each new edition will incorporate the changes made in the supplement as well as any new revisions.

(B) Submission of Food Code Change Suggestions

FDA will continue to receive concerns and recommendations for modification of the Food Code from any individual or organization.

Given the purpose of the document as discussed in item 2. of this Preface, the Agency will be especially interested in addressing problems identified by those in government and industry who are responsible for implementing the Food Code. FDA will also be especially responsive to those needed policy and technical changes raised by an organization that uses a democratic process for addressing problems and concerns.

Included are organizations that provide a process that encourages representative participation in deliberations by government, industry, and academic and consumer interests, followed by public health ratification such as a state-by-state vote by officially designated delegates. The Conference for Food Protection (retail food issues), the National Conference on Interstate Milk Shipments (milk and dairy products issues), and the Interstate Shellfish Sanitation Conference (molluscan shellfish issues) are examples of such organizations. These organizations receive problems submitted by any interested individual, but specify the forms on which the issues must be detailed and provide specific time frames during which they may be submitted.

FDA encourages interested individuals to consider raising issues and suggesting solutions involving the federal-state cooperative programs based on FDA's model codes through these organizations.

10. Acknowledgements

Many individuals devoted considerable time and effort in addressing concerns and developing recommendations that are now reflected in the Food Code. These individuals represent a wide diversity of regulators, educators, industry leaders, and consumer representatives acting through their agencies,

companies, professional groups, or trade organizations. **It** is only through the dedicated efforts and contributions of experienced professionals that a scientifically sound, well focused, and up-to-date model code is possible. FDA acknowledges with gratitude the substantial assistance of those who contributed to public health and food safety in the development of the Food Code.

Chapter 1 - Purpose and Definitions

Parts

1-1 Title, Intent, Scope

1-2 Definitions

1-1 Title, Intent, Scope

Subparts

1-101 Title

1-102 Intent

1-103 Scope

Title

1-101.10 Food Code.

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

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.

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

Subpart

1-201 Applicability and Terms Defined

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 a unique combination of letters and numbers assigned by a SHELLFISH CONTROL AUTHORITY to a MOLLUSCAN SHELLFISH DEALER according to the provisions of the National Shellfish Sanitation Program.

"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:

(1) To combine SHELLSTOCK harvested on different days or from different growing areas as identified on the tag or label, or

(2) To combine SHUCKED SHELLFISH from containers with different container codes or different shucking dates.

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 POTENTIALLY HAZARDOUS (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.

"Enterohemorrhagic *Escherichia coli*" (EHEC) means *E. coli* which cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. The term is typically used in association with *E. coli* that have the capacity to produce Shiga toxins and to cause attaching and effacing lesions in the intestine. EHEC is a subset of STEC, whose members produce additional virulence factors. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Examples of serotypes of EHEC include: *E. coli* O157:H7; *E. coli* O157:NM; *E. coli* O26:H11; *E. coli* O145:NM; *E. coli* O103:H2; or *E. coli* O111:NM. Also see SHIGA TOXIN-PRODUCING *E. COLI*.

"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" means an individual working with UNPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.

Food Establishment.

(1) "**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.

(2) "**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.

(3) "**Food establishment**" *does not include*:

(a) *An establishment that offers only prePACKAGED FOODS that are not POTENTIALLY HAZARDOUS (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 POTENTIALLY HAZARDOUS (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 home-delivered FOOD.*

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".

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, and soybeans; 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.

(1) **"Mechanically tenderized"** means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using blades, pins, needles or any mechanical device.

(2) **"Mechanically tenderized"** does not include processes by which solutions are INJECTED into meat.

"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.*

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, securely bagged, or securely wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.

(2) *"Packaged" does not include a wrapper, carry-out box, or other nondurable container used to containerize FOOD with the purpose of facilitating FOOD protection during service and receipt of the FOOD by the CONSUMER.*

"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 4 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.

Potentially Hazardous Food (Time/Temperature Control for Safety Food).

(1) **"Potentially hazardous food (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) **"Potentially hazardous food (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 values			
	4.6 or less	> 4.6 - 5.6	> 5.6	
≤ 0.92	non-PHF*/non-TCS FOOD**	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD	
>0.92 - .95	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD	PA***	
>0.95	non-PHF/non-TCS FOOD	PA	PA	

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

Table B. Interaction of pH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED				
A_w values	pH values			
	<4.2	4.2 - 4.6	>4.6 - 5.0	>5.0
<0.88	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food
0.88 - 0.90	non-PHF/ non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
>0.90 - 0.92	non-PHF/ non-TCS food	non-PHF/non-TCS food	PA	PA
>0.92	non-PHF/ non-TCS food	PA	PA	PA

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

(3) "**Potentially hazardous food (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-PHF/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.*

"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-^P.

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 -^{Pf}.

"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) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;
- (d) All POTENTIALLY HAZARDOUS FOOD (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.

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 which have the air expelled and are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

(e) Sous vide PACKAGING, in which raw or partially cooked FOOD is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

"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 raw, in-shell MOLLUSCAN SHELLFISH.

"Shiga toxin-producing *Escherichia coli*" (STEC) means any *E. coli* capable of producing Shiga toxins (also called verocytotoxins or "Shiga-like" toxins). Examples of serotypes of STEC include both O157 and non-O157 *E. coli*. *Also see* ENTEROHEMORRHAGIC *ESCHERICHIA COLI*.

"Shucked shellfish" means MOLLUSCAN SHELLFISH that have one or 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 steel;

(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.

"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 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.

Chapter 2 - Management and Personnel

Parts

- 2-1 Supervision
- 2-2 Employee Health
- 2-3 Personal Cleanliness
- 2-4 Hygienic Practices

2-1 Supervision

Subparts

- 2-101 Responsibility
- 2-102 Knowledge
- 2-103 Duties

Responsibility

2-101.11 Assignment.

(A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall be the PERSON IN CHARGE or shall designate a PERSON IN CHARGE and shall ensure that a PERSON IN CHARGE is present at the FOOD ESTABLISHMENT during all hours of operation.^{Pf}

(B) In a FOOD ESTABLISHMENT with two or more separately PERMITTED departments that are the legal responsibility of the same PERMIT HOLDER and that are located on the same PREMISES, the PERMIT HOLDER may, during specific time periods when food is not being prepared, packaged, or served, designate a single PERSON IN CHARGE who is present on the PREMISES during all hours of operation, and who is responsible for each separately PERMITTED FOOD ESTABLISHMENT on the PREMISES.^{Pf}

Knowledge

2-102.11 Demonstration.

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;^{Pf}

(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;^{Pf} or

(C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:

- (1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE; ^{Pf}
- (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; ^{Pf}
- (3) Describing the symptoms associated with the diseases that are transmissible through FOOD; ^{Pf}
- (4) Explaining the significance of the relationship between maintaining the time and temperature of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) and the prevention of foodborne illness; ^{Pf}
- (5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH; ^{Pf}
- (6) Stating the required FOOD temperatures and times for safe cooking of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) including MEAT, POULTRY, EGGS, and FISH; ^{Pf}
- (7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD); ^{Pf}
- (8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:
 - (a) Cross contamination, ^{Pf}
 - (b) Hand contact with READY-TO-EAT FOODS, ^{Pf}
 - (c) Handwashing, ^{Pf} and
 - (d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair; ^{Pf}
- (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. ^{Pf}
- (10) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:
 - (a) Sufficient in number and capacity, ^{Pf} and
 - (b) Properly designed, constructed, located, installed, operated, maintained, and cleaned; ^{Pf}

(11) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT; ^{Pf}

(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; ^{Pf}

(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; ^{Pf}

(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; ^{Pf}

(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; ^{Pf}

(16) Explaining the responsibilities, rights, and authorities assigned by this Code to the:

(a) FOOD EMPLOYEE, ^{Pf}

(b) CONDITIONAL EMPLOYEE, ^{Pf}

(c) PERSON IN CHARGE, ^{Pf}

(d) REGULATORY AUTHORITY; ^{Pf} and

(17) Explaining how the PERSON IN CHARGE, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION or RESTRICTION of FOOD EMPLOYEES. ^{Pf}

2-102.20 Food Protection Manager Certification.

A PERSON IN CHARGE who demonstrates knowledge by being a FOOD protection manager that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs is deemed to comply with ¶ 2-102.11(B).

Duties

2-103.11 Person in Charge.

The PERSON IN CHARGE shall ensure that:

- (A) FOOD ESTABLISHMENT operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under § 6-202.111; ^{Pf}
- (B) PERSONS unnecessary to the FOOD ESTABLISHMENT operation are not allowed in the FOOD preparation, FOOD storage, or WAREWASHING areas, except that brief visits and tours may be authorized by the PERSON IN CHARGE if steps are taken to ensure that exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination; ^{Pf}
- (C) EMPLOYEES and other PERSONS such as delivery and maintenance PERSONS and pesticide applicators entering the FOOD preparation, FOOD storage, and WAREWASHING areas comply with this Code; ^{Pf}
- (D) EMPLOYEES are effectively cleaning their hands, by routinely monitoring the EMPLOYEES' handwashing; ^{Pf}
- (E) EMPLOYEES are visibly observing FOODS as they are received to determine that they are from APPROVED sources, delivered at the required temperatures, protected from contamination, UNADULTERED, and accurately presented, by routinely monitoring the EMPLOYEES' observations and periodically evaluating FOODS upon their receipt; ^{Pf}
- (F) EMPLOYEES are properly cooking POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD), being particularly careful in cooking those FOODS known to cause severe foodborne illness and death, such as EGGS and COMMINUTED MEATS, through daily oversight of the EMPLOYEES' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under § 4-203.11 and ¶ 4-502.11(B); ^{Pf}
- (G) EMPLOYEES are using proper methods to rapidly cool POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS) that are not held hot or are not for consumption within 4 hours, through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures during cooling; ^{Pf}
- (H) CONSUMERS who order raw; or partially cooked READY-TO-EAT FOODS of animal origin are informed as specified under § 3-603.11 that the FOOD is not cooked sufficiently to ensure its safety; ^{Pf}
- (I) EMPLOYEES are properly SANITIZING cleaned multiuse EQUIPMENT and UTENSILS before they are reused, through routine monitoring of solution temperature and exposure time for hot water SANITIZING, and chemical concentration, pH, temperature, and exposure time for chemical SANITIZING; ^{Pf}

(J) CONSUMERS are notified that clean TABLEWARE is to be used when they return to self-service areas such as salad bars and buffets as specified under § 3-304.16;^{Pf}

(K) Except when APPROVAL is obtained from the REGULATORY AUTHORITY as specified in ¶ 3-301.11(D), EMPLOYEES are preventing cross-contamination of READY-TO-EAT FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT;^{Pf}

(L) EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties;^{Pf} and

(M) FOOD EMPLOYEES and CONDITIONAL EMPLOYEES are informed of their responsibility to report in accordance with LAW, to the PERSON IN CHARGE, information about their health and activities as they relate to diseases that are transmissible through FOOD, as specified under ¶ 2-201.11(A).^{Pf}

2-2 Employee Health

Subpart

2-201 Responsibilities of Permit Holder, Person in Charge, Food Employees, and Conditional Employees

Responsibilities and Reporting Symptoms and Diagnosis

2-201.11 Responsibility of Permit Holder, Person in Charge, and Conditional Employees.

(A) The PERMIT HOLDER shall require FOOD EMPLOYEES and CONDITIONAL EMPLOYEES to report to the PERSON IN CHARGE information about their health and activities as they relate to diseases that are transmissible through FOOD. A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report the information in a manner that allows the PERSON IN CHARGE to reduce the RISK of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE:

Reportable symptoms: Has any of the following symptoms:

- (a) Vomiting,^P
- (b) Diarrhea,^P
- (c) Jaundice,^P
- (d) Sore throat with fever,^P or
- (e) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(i) On the hands or wrists, *unless an impermeable cover such as a finger cot or stall protects the lesion and a SINGLE-USE glove is worn over the impermeable cover,*^P

(ii) On exposed portions of the arms, *unless the lesion is protected by an impermeable cover,*^P or

(iii) On other parts of the body, *unless the lesion is covered by a dry, durable, tight-fitting bandage,*^{Pf}

Reportable diagnosis: Has an illness diagnosed by a HEALTH PRACTITIONER due to:

(a) Norovirus,^P

(b) Hepatitis A virus,^P

(c) *Shigella* spp.,^P

(d) ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*,^P or

(e) *Salmonella* Typhi;^P

Reportable past illness: Had a previous illness, diagnosed by a HEALTH PRACTITIONER, within the past 3 months due to *Salmonella* Typhi, without having received antibiotic therapy, as determined by a HEALTH PRACTITIONER;^P

Reportable history of exposure: Has been exposed to, or is the suspected source of, a CONFIRMED DISEASE OUTBREAK, because the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE consumed or prepared FOOD implicated in the outbreak, or consumed FOOD at an event prepared by a PERSON who is infected or ill with:

(a) Norovirus within the past 48 hours of the last exposure,^P

(b) ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*, or *Shigella* spp. within the past 3 days of the last exposure,^P

(c) *Salmonella* Typhi within the past 14 days of the last exposure,^P or

(d) Hepatitis A virus within the past 30 days of the last exposure;^P or

Reportable history of exposure: Has been exposed by attending or working in a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual who works or attends a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(a) Norovirus within the past 48 hours of the last exposure,^P

(b) ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*, or *Shigella* spp. within the past 3 days of the last exposure,^P

(c) *Salmonella* Typhi within the past 14 days of the last exposure,^P or

(d) Hepatitis A virus within the past 30 days of the last exposure.^P

Responsibility of person in charge to notify the regulatory authority

(B) The PERSON IN CHARGE shall notify the REGULATORY AUTHORITY when a FOOD EMPLOYEE is:

(1) Jaundiced,^{Pf} or

(2) Diagnosed with an illness due to a pathogen as specified under Subparagraphs (A)(2)(a) - (e) of this section.^{Pf}

Responsibility of the person in charge to prohibit a conditional employee from becoming a food employee

(C) The PERSON IN CHARGE shall ensure that a CONDITIONAL EMPLOYEE:

(1) Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under Subparagraphs (A)(1) - (3) of this section, is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria for the specific symptoms or diagnosed illness as specified under § 2-201.13;^P and

(2) Who will work as a FOOD EMPLOYEE in a FOOD ESTABLISHMENT that serves as a HIGHLY SUSCEPTIBLE POPULATION and reports a history of exposure as specified under Subparagraphs (A)(4) – (5), is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria as specified under ¶ 2-201.13(I).^P

Responsibility of the person in charge to exclude or restrict

(D) The PERSON IN CHARGE shall ensure that a FOOD EMPLOYEE who exhibits or reports a symptom, or who reports a diagnosed illness or a history of exposure as specified under Subparagraphs (A)(1) - (5) of this section is:

(1) EXCLUDED as specified under ¶¶ 2-201.12 (A) - (C), and Subparagraphs (D)(1), (E)(1), (F)(1), or (G)(1) and in compliance with the provisions specified under ¶¶ 2-201.13(A) - (G);^P or

(2) RESTRICTED as specified under Subparagraphs 2-201.12 (D)(2), (E)(2), (F)(2), (G)(2), or ¶¶ 2-201.12(H) or (I) and in compliance with the provisions specified under ¶¶ 2-201.13(D) - (I).^P

Responsibility of food employee and conditional employee to report

(E) A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report to the PERSON IN CHARGE the information as specified under ¶ (A) of this section.^{Pf}

Responsibility of food employees to comply

(F) A FOOD EMPLOYEE shall:

(1) Comply with an EXCLUSION as specified under ¶¶ 2-201.12(A) - (C) and Subparagraphs 2-201.12(D)(1), (E)(1), (F)(1), or (G)(1) and with the provisions specified under ¶¶ 2-201.13(A) - (G);^P or

(2) Comply with a RESTRICTION as specified under Subparagraphs 2-201.12(D)(2), (E)(2), (F)(2), (G)(2), or ¶¶ 2-201.12 (H) or (I) and comply with the provisions specified under ¶¶ 2-201.13(D) - (I).^P

conditions of exclusion and restriction

2-201.12 Exclusions and Restrictions.

The PERSON IN CHARGE shall EXCLUDE or RESTRICT a FOOD EMPLOYEE from a FOOD ESTABLISHMENT in accordance with the following:

Symptomatic with vomiting or diarrhea

(A) *Except when the symptom is from a noninfectious condition*, EXCLUDE a FOOD EMPLOYEE if the FOOD EMPLOYEE is:

(1) Symptomatic with vomiting or diarrhea;^P or

(2) Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, *Shigella* spp., or ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *E. COLI*.^P

Jaundiced or diagnosed with HEPATITIS A infection

(B) EXCLUDE a FOOD EMPLOYEE who is:

(1) Jaundiced and the onset of jaundice occurred within the last 7 calendar days, *unless the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER specifying that the jaundice is not caused by hepatitis A virus or other fecal-orally transmitted infection*;^P

(2) Diagnosed with an infection from hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within 7 calendar days of the onset of jaundice;^P or

(3) Diagnosed with an infection from hepatitis A virus without developing symptoms.^P

Diagnosed or reported previous infection due to S. TYPHI

(C) EXCLUDE a FOOD EMPLOYEE who is diagnosed with an infection from *Salmonella* Typhi, or reports a previous infection with *Salmonella* Typhi within the past 3 months as specified under Subparagraph 2-201.11(A)(3).^P

Diagnosed with an asymptomatic infection from NOROVIRUS

(D) If a FOOD EMPLOYEE is diagnosed with an infection from Norovirus and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;^P or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

Diagnosed with SHIGELLA SPP. Infection and asymptomatic

(E) If a FOOD EMPLOYEE is diagnosed with an infection from *Shigella* spp. and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;^P or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

Diagnosed with EHEC or STEC and asymptomatic

(F) If a FOOD EMPLOYEE is diagnosed with an infection from ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *E. COLI*, and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;^P or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

Symptomatic with SORE THROAT WITH FEVER

(G) If a FOOD EMPLOYEE is ill with symptoms of acute onset of sore throat with fever:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;^P or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.^P

Symptomatic with UNCOVERED INFECTED WOUND OR PUSTULAR BOIL

(H) If a FOOD EMPLOYEE is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under Subparagraph 2-201.11(A)(1)(e), RESTRICT the FOOD EMPLOYEE.^P

EXPOSED to foodborne pathogen and works in food establishment serving HSP

(I) If a FOOD EMPLOYEE is exposed to a foodborne pathogen as specified under Subparagraphs 2-201.11(A)(4) or (5), RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION.^P

Managing Exclusions and Restrictions

2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions.

The PERSON IN CHARGE shall adhere to the following conditions when removing, adjusting, or retaining the EXCLUSION or RESTRICTION of a FOOD EMPLOYEE:

(A) *Except when a FOOD EMPLOYEE is diagnosed with an infection from hepatitis A virus or Salmonella Typhi:*

Removing exclusion for food employee who was symptomatic and not diagnosed

(1) Reinstatement a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(1) if the FOOD EMPLOYEE:

(a) Is ASYMPTOMATIC for at least 24 hours;^P or

(b) Provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the symptom is from a noninfectious condition.^P

NOROVIRUS diagnosis

(2) If a FOOD EMPLOYEE was diagnosed with an infection from Norovirus and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met;^P or

retaining exclusion for food employee who was asymptomatic and is now asymptomatic and works in food establishment serving HSP

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met.^P

SHIGELLA SPP. diagnosis

(3) If a FOOD EMPLOYEE was diagnosed with an infection from *Shigella* spp. and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) of this section are met;^P or

retaining exclusion for food employee who was asymptomatic and is now asymptomatic

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) , or (E)(1) and (3)(a) of this section are met.^P

EHEC or STEC diagnosis

(4) If a FOOD EMPLOYEE was diagnosed with an infection from ENTEROHEMORRHAGIC or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) of this section are met;^P or

retaining exclusion for food employee who was symptomatic and is now asymptomatic and works in food establishment serving HSP

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY