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Document No. 4842

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44‑1‑140(2), 44‑1‑150, and 44‑1‑180

61‑25. Retail Food Establishments.

61‑37. Retail Food Establishment Inspection Fees.

**Synopsis:**

The intent of R.61-25, Retail Food Establishments, is to safeguard public health and provide consumers safe, unadulterated food and food products at the retail level. This regulation governs restaurants, grocery stores, school cafeterias, and other establishments where food is prepared and served to the public. R.61-25 was last amended in 2014.

The amendments herein will enable the Department of Health and Environmental Control (“Department” or “DHEC"), through regulation, to incorporate standards of the 2017 United States Food and Drug Administration (“FDA”) Food Code. The FDA Food Code is the national standard for state, local, and tribal food protection programs. The FDA Food Code offers practical, science‑based guidance that addresses the risk factors known to cause foodborne illness outbreaks in retail food establishment settings. The national Conference for Food Protection, comprised of food safety regulators, food scientists, industry representatives, and members of academia, amends the FDA Food Code every two (2) years and publishes it in full every four (4) years.

These amendments also include revisions to selected sections of R.61-25 to reflect the current business models of the food service industry based on comments and suggestions from the regulated community.

The amendments, furthermore, include combining R.61-25 with revised provisions of R.61-37, Retail Food Establishment Inspection Fees,which was last amended in 2002*.* Specifically, the Department revises fee schedules currently residing in R.61-37, places the fee schedules in R.61-25, and repeals R.61-37. This provides the retail food industry with one streamlined regulation, while allowing for necessary program support through an increase in inspection fees.

The amendments also include other changes as deemed necessary by the Department to improve the overall clarity, organization, and quality of the regulation. These changes include, but are not limited to, stylistic changes, updates to definitions and exemptions, corrections for clarity, readability, grammar, punctuation, references, and codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1‑23‑120(A), requires General Assembly review of these amendments and the repeal.

The Department had a Notice of Drafting published in the August 24, 2018, *South Carolina State Register*.

Changes made at the request of the House Regulations and Administrative Procedures Committee by letter dated April 9, 2019:

Removed proposed amendment to Section 2-402.11(A) that indicated beard restraints are required when a beard is not closely shaven.

Removed proposed amendment to Section 3-602.11 that indicated a label or placard is required to include a statement that no major allergens are present.

Section‑by‑Section Discussion of Final Regulation submitted by the Department of Health and Environmental Control on January 8, 2019, for legislative review:

**R.61‑25**

In Chapters 1 through 9 of the amendments to R.61‑25, capitalization, punctuation, spelling, and grammatical errors have been corrected. The superscripts for Priority (P) and Priority Foundation (Pf), as found in the FDA Food Code, have been added to all relevant citations. The word “Section” has been added to references in all citations where it was missing for clarity. To improve readability, all subsection titles have been bolded. For brevity and space, these modifications are not listed.

**In Contents**

Amended: All chapter titles were changed from all capitalization to capitalizing the first letter of each word for consistency.

Added: New section 4‑303 “Cleaning Agents and Sanitizers.”

Renamed Sections 9‑2 and 9‑11 of Chapter 9 to more accurately fit the content of these revised sections.

**In Chapter 1, Purpose and Definition, the following changes apply:**

Section 1‑2

Deleted: (19) “Conditional employee,” as the term is not used in the regulation; renumbered remaining items.

Amended: (35) to add “work” to the description of a person under a contractual agreement.

Amended: (54) “Hermetically sealed container” to add the word “commercial” to conform to the Food Code.

Added: (58) “Intact meat” from the 2017 FDA Food Code.

Amended: (73) “Nuisance” to clarify that premises is included but not limited to the structure.

Amended: (79)(b) “Personal care items” to remove unnecessary wording of “and other such items”.

Amended: (106) “Retail food establishment” by changing “any” to “an” to match the intent of exemptions in Chapter 8‑103.12(A) and by deleting “temporary food establishments” from the examples as they are not issued a retail food establishment permit.

Amended: (112) “Service animal” to clarify that the ADA service animal definition does not include “comfort animals” or any other type of support animal not recognized as a service animal under the ADA and its implementing regulations.

Amended: (117) to correct denotations of the E.coli strains listed.

Amended: (127)(b)(ii) Time/temperature control for safety food (TCS) Tables A and B to match the tables and wording in the 2017 FDA Food Code and include the term PA for product assessment.

Amended: (132)(a)(i) and (b)(i) to add “the violation of “ for clarity and that Priority and Priority Foundation violations are denoted in the body of the regulation with superscript of either “P” or “Pf.”

**In Chapter 2, Management and Personnel, the following changes apply:**

Section 2‑1

Added: 2‑102.11(C)(9) requiring knowledge of major allergens and renumbered remaining items.

Amended: 2‑102.12 to add “and Food Handler Certification” to title.

Amended: 2‑102.12(A) to add requirement for the certified food protection manager to be present at the facility frequently and to be responsible for ensuring employee health policies are implemented.

Added: 2‑102.12(B) requiring that at all times during food service operations a person in charge with a Food Handler Certification be on duty and renumbered remaining items.

Added: 2‑103.11(I) to supplement the duties of the person in charge from the 2017 FDA Food Code and renumbered remaining items.

Section 2‑2

Amended: 2‑201.11 Section title to add “Permit Holder.”

Amended: 2‑201.11(A) to remove “person in charge” and replace with “permit holder.” Added that the food employee is to report illness to the person in charge.

Amended: 2‑201.11(B)‑(E) by striking existing (B) through (D) and replacing them with new (B) through (E) to conform to the 2017 FDA Food Code. This section provides guidance to industry on identification and reporting of illnesses.

Amended: 2‑201.12 to add all of that section from the 2017 FDA Food Code not adopted from the 2013 FDA Food Code. This section provides clear guidance to industry on managing exclusion and restrictions of ill workers.

Added: 2‑201.13 to conform to the 2017 FDA Food Code. This section provides clear guidance to industry on how to manage reinstating excluded and restricted ill workers.

Section 2‑3

Amended: 2‑203.11(A) to delete duplicative “on their hands and arms”.

Section 2‑4

Added: 2‑401.13 Use of Bandages, Finger Cots, or Finger Stalls from the 2017 FDA Food Code.

Amended: 2‑403.11 to include 9‑3 “Outdoor Pet Dining.”

Section 2‑5

Amended: 2‑501.11 to require that vomiting and diarrheal event clean‑up procedures be in writing.

**In Chapter 3, Food, the following changes apply:**

Section 3‑2

Amended: 3‑201.11(E)(2) to delete written buyer specifications as the new definition of “intact beef” now addresses this need.

Amended: 3‑202.12 to correct the quoted CFR reference and delete “or Pesticide Residues” that is not part of the title of that section.

Section 3‑3

Amended: 3‑302.11(A) to correct reference from (c) to (d) and to add fruits and vegetables to the list of foods that must be separated from raw animal foods during storage, preparation, holding, and display.

Amended: 3-302.15 to correct the title of the quoted CFR reference.

Section 3‑4

Amended: 3‑304.11, 3‑304.15 and 3‑304.17 to add the word “Section” to references for clarity.

Amended: 3‑401.11(A)(1)(b) to add “intact” description to “meat.”

Amended: 3‑401.11(A)(2)‑(3) to change required cooking time as per 2017 FDA Food Code.

Amended: 3‑401.11(B)(1)‑(2) to update language and the oven cooking Tables 3.2 and 3.3 to comport with the 2017 FDA Food Code.

Amended: 3‑401.13 to change "fruits and vegetables” to the more inclusive “plant foods.”

Amended: 3‑404.11(A) to reflect the entire section, not just (B)‑(E).

Section 3‑5

Added: 3‑502.11(H) to clarify that a HACCP plan is not required for special processes that are for flavor enhancement only. A written statement must be provided indicating foods to be enhanced and food safety measures taken.

Amended: 3‑502.12(B) to correct reference of (B) to (C).

Amended: 3‑502.12(C) to add the requirement for a label indicating that fish must be kept frozen until time of use.

Amended: 3‑502.12(D)(1) and (E)(2) to correct reference of (B) to (C).

Section 3‑6

Added: 3‑602.11 (B)‑(D) These provisions specify labeling requirements from the 2017 FDA Food Code providing for allergen labeling on packaged “grab and go” foods where there is no interaction with a server. Labeling will not apply to takeout or delivered food. The requirement allows the consumer to be aware of allergens present.

**In Chapter 4, Equipment, Utensils, and Linens, the following changes apply:**

Section 4‑1

Amended: 4‑101.17 to correct internal references, allow single use of cedar cooking planks, and move the allowance of wicker baskets when suitably lined to (F).

Section 4‑2

Amended: 4‑204.16 to change “shall not” to “may not.”

Section 4‑3

Added: 4‑303.11 This is a new section on cleaning agents and sanitizers from the 2017 FDA Food Code. Clarifies that both must be present and available for use during operations.

Section 4‑4

Amended: 4‑402.11 to add “in place” to clarify the term “fixed”.

Amended: 4‑501.114(F) to correct reference from (C) to (A)‑(D).

Amended: 4‑502.12 to add the word “Section” to reference for clarity.

Amended: 4‑602.11(D)(2)(a) to add degrees to temperatures in chart.

Amended: 4‑602.11(D) to add new subsections (4) and (6) on cleaning schedules previously not included. Clarifies when certain equipment must be cleaned.

Amended: 4‑603.15(D) to add “in place” for clarity.

Amended: 4‑903.11(A) and (D) to provide new allowance for storage of packaged food on pallets less than 6” off floor from the 2017 FDA Food Code.

**In Chapter 5, Water, Plumbing, and Waste, the following changes apply:**

Section 5‑1

Amended: 5‑103.11(B) to remove the requirement for separate hot water systems for food preparation areas to allow for more flexibility in system design. Hot water systems should meet the local plumbing requirements and are evaluated operationally by the Department.

Section 5‑2

Amended: 5‑202.14 to clarify that an internal to the building water supply backflow preventer needs to be ASSE certified.

Amended: 5‑203.11 to clarify language that the number of handsinks required is related to the size and scope of the food service operation.

Section 5‑3

Amended: 5‑303.13 to correct the title to this subsection.

Section 5‑4

Amended: 5‑402.12 to add “areas” after food preparation in all references as needed for better clarity and readability.

Section 5‑5

Amended: 5‑501.111 to add “receptacles” to the requirement for clarity.

**In Chapter 6, Physical Facilities, the following changes apply:**

Section 6‑2

Amended: 6‑202.14 by adding “or for a public access restroom, an alcove opening as approved by local building codes” to allow for the industry standard of using alcove openings and to harmonize with building codes.

Amended: 6‑202.15(A)(3) by adding “tight‑fitting” to the requirement for outer doors to comport with the current FDA Food Code.

Amended: 6‑202.15(D) removed “temporary food establishment” as it was redundant to information in Section 9‑8 Temporary Food Service Establishments.

**In Chapter 7, Poisonous or Toxic Materials, the following changes apply:**

Section 7‑2

Amended: 7‑202.12(A)(2)‑(4) to add certification requirements for pesticide applicators from the 2017 FDA Food Code at the request of S.C. pesticide regulators.

Amended: 7‑204.12(A) to add clarification from the 2017 FDA Food Code regarding chemicals used in treatment, storage, and processing of fruits and vegetables.

Deleted: 7‑204.12(B) to remove provision on the use of ozone as an antimicrobial agent to match deletion in 2017 FDA Food Code.

**In Chapter 8, Compliance and Enforcement, the following changes apply:**

Section 8‑2

Amended: 8‑201.14, “contents of a HACCP plan” section, to include reorganizing existing language and adding clarified sections (A)‑(C), (E), and (F) from 2017 FDA Food Code regarding the plan to be submitted and what needs to be submitted as part of the flow diagram and supporting documents.

Amended: 8‑202.14(D)(4) added “each” before “critical control point” to provide clarity.

Section 8‑3

Amended: 8‑301.12(A)(19) to clarify introductory language and by adding (g) to allow the Department to make risk‑based decisions for permit exemptions for additional non‑time/temperature control for safety foods that use a low‑risk food process.

Added: 8‑301.12(A)(20) to extend permit exemption to include individuals preparing and selling additional non‑time temperature control for food safety foods (“cottage food” items such as jams/jellies/dried seasonings) from their homes and renumbered remaining items.

Amended: 8‑301.12(A)(21) to remove restriction on using a blender to make single‑serve smoothies with additional non‑time temperature control for food safety food ingredients in (b) and to add new (g)‑(h), exempting time‑controlled waffle/funnel cake/mini donut mix for hotel breakfast service and roadside sale.

Amended: 8‑301.12(A)(22) to delete “Vending machines” from (22) and moved them to new (23).

Added: 8‑301.12(A)(23) to separately address exempt vending machines (moved from (22).

Added: 8‑301.12(C) to clarify that operations that are exempt from permit requirements are subject to the Department’s authority to investigate complaints as necessary to protect the public from food safety related health risk.

Amended: 8‑302.13(D). As part of combining R.61‑37 into this regulation, the Department has added a new $100.00 fee for first‑time permit/preoperational inspections in addition to the annual inspection fee.

Amended: 8‑303.20(A)(1) through (A)(6) to reorganize and clarify how long the new owner has to make an application, pay fees, and achieve compliance at an inspection. This includes: deleting 8‑303.20(A)(1)(a) and (A)(1)(b); adding a new paragraph (A)(2) and renumbering the following paragraphs; amending 8‑303.20(A)(3)(b) to correct reference from 8‑302.12 to 8‑303.10; amending 8‑303.20(A)(3)(c) to clarify when the facility will be deemed to be operating without a permit; amending 8‑303.20(A)(4) to clarify that the Department will conduct an inspection to determine compliance after receiving a complete application; adding 8‑303.20(A)(5) and (6), which clarify the implications of failing to submit a complete and timely application, pay fees, or obtain compliance at the permit inspection, and when the facility will be deemed operating without a permit; and renumbering remaining items.

Added: 8‑304.11(A)(3). As part of combining R.61‑37 into this regulation, added the fee renewal requirement and scale and other material information currently contained in R.61‑37. The fee scale has been increased to provide for necessary support of the program.

Amended: 8‑304.11(A)(4) to remove requirement to maintain a copy of the regulation and instead require access to and knowledge of the regulation.

Added: 8‑304.11(A)(5) to require a facility to operate at least 15 consecutive days a year or one day a week for 15 weeks to retain its permit.

Added: 8‑304.11(B)(8) to require the permit holder to notify the Department when the billing or mailing address changes.

Added: 8‑304.11(B)(9) to require the permit holder to notify the Department of a change in the capacity of a shared use kitchen.

Amended: 8‑304.11(C) to delete the word “also” for grammatical correctness.

Amended: 8‑304.11(D) and (E) to update internal reference to “(B) and (C)” instead of “(A) and (B).”

Section 8‑4

Amended: 8‑402.20(C) to clarify that the Department may obtain a warrant if access is denied.

Amended: 8‑402.40 to clarify Department enforcement options when a facility denies the Department access to the retail food establishment.

Amended: 8‑403.10(E) to prohibit covering, obscuring, defacing, relocating, or removing the posted food grade.

Amended: 8‑405.11 (A)(3) and (C)(4) added “from the date of the inspection” to provide clarity of when follow up would occur.

Added: 8‑404.11(F) from 2017 FDA Food Code allowing a facility to continue to operate in emergency situations if it has a written emergency operating plan approved by the Department.

Amended: 8‑405.11(A)(1) and (A)(3) to clarify that the ten (10)‑day period is from the date of the inspection.

Amended: 8‑405.11(A)(2) to require all core violations, regardless of grade, to be corrected as soon as possible.

Section 8‑5

Amended: 8‑501.20 to remove references to conditional employees as they are not addressed in other parts of the regulation.

Section 8‑7

Deleted: 8‑701.11 “Implementation of Regulations,” as none of the additions will require delayed implementation, and all previously delayed items are now in regulatory effect.

Section 8‑9

Amended: 8‑904 to correct the title to read “Permit Suspension.”

Amended: 8‑904.10 to correct the title to read “Conditions Warranting Summary Suspension.”

Amended: 8‑904.30 to correct the title to read “Contents of the Summary Suspension Notice.”

Amended: 8‑904.50 to correct the title to read “Term of Summary Suspension, Reinstatement of Permit.”

Amended: 8‑904.110(A)(5) to clarify the Department’s authority to suspend a facility’s permit for failure to notify the Department of facility changes.

Amended: 8‑904.110(A)(7) to add “obscuring” to current wording.

Amended: 8‑904.110(A)(9) to clarify the Department’s authority to suspend a permit upon a facility’s failure to pay a civil penalty required by a Department order.

Amended: 8‑904.110(A)(10) by adding new language to reflect the requirement to operate for fifteen (15)consecutive days annually or at least one (1) day every week for at least fifteen (15) weeks and renumbered existing (10) to (11).

Added: 8‑904.110(B)(6) to authorize the Department to revoke a facility’s permit upon a failure to operate as a retail food establishment at least fifteen (15) consecutive days annually or at least one (1) day a week for fifteen (15) weeks.

Amended: 8‑904.120 to distinguish notice requirements of ordinary suspensions from those of summary suspensions.

Amended: 8‑913.10 to clarify the Department’s authority to impose civil penalties for violation of an order of the Department.

**Chapter 9, Standards for Additional Retail Food Establishment Operations, the following changes apply:**

Deleted: References to thermometer scales in requirements for thermometers in all sections.

Section 9‑1

Amended: (A)(1) Mobile food establishment definition to add that a mobile food unit can be a watercraft and is movable or portable.

Amended: (A)(2) commissary definition to provide that a retail food establishment that serves a highly susceptible population and is regulated by the Department as a health care facility may not be used as a commissary.

Amended: (B)(3) to remove the requirement for daily return to commissary and storage at commissary; added new requirements (a)‑(c) to allow for up to seventy‑two (72) hours of operation before servicing for fully self‑contained units and to allow Department approval of alternative storage locations for all types of units.

Amended: (F)(1)(b)(i) Service window size requirement so that windows can be configured as needed but no bigger than 576 inches square.

Amended: (H)(5) to align hot water requirement with 5‑103.11.

Added: (H)(6) to allow for units to hook up to a public water supply on a temporary basis at location provided that they can also hook up to approved wastewater disposal system. This provision supports the allowance for longer times between servicing at commissary.

Amended: (I)(3) to delete “only” and to add “or approved sewage disposal site.”

Amended: (K)(2) to clarify enclosure exemption is for units that serve only commercially, fully cooked, TCS foods that only require heating, not cooking.

Deleted: (K)(3) to remove exemption from CFPM requirements for mobile pushcarts. Mobile units will comply with Food Handler section of 2‑102.12 or be exempted under 2‑102.20 (B), depending on menu.

Deleted: (L)(8)(a) to delete requirement for drawings and renumbered remainder of section.

Amended: (L)(12) to delete the lettering size requirement, delete the requirement to print the commissary name and permit number, and require that signage must be conspicuous to the consumer as a replacement for these requirements.

Section 9‑2

Amended: Section title to read “Meat/Meat Product and Fish/Fish Product Sales” and made corresponding changes to all subsections. This allows for broader use of this section for roadside meat/fish sales and removes any requirement to inspect vehicles for any other type of food transport or storage unit not subject to Department regulatory authority. Clarified that this section applies to the transportation of meat and fish products from source to point of sale.

Amended: (C)(1) to clarify that ice must be obtained from approved sources.

Amended: (C)(7) to clarify language pertaining to temperature measuring during transport.

Amended: (D) to clarify the subsection title and requirements related to refrigeration.

Section 9‑3

Amended: (D)(3) and (D)(4) to change “exclusive” to “exclusively used” for clarity.

Amended: (D)(6) to add that the waste container needs to be in the outdoor pet dining area and used exclusively for storing pet waste.

Amended: (E)(1) to require that signs shall be posted at all dining entrances stating that the facility is pet friendly and has an outdoor pet friendly dining area.

Amended: (E)(6) to remove restriction allowing pets on chairs and to change the restriction to apply to food contact surfaces.

Section 9‑5

Amended: (A)(1) to add that a retail food establishment that serves a highly susceptible population and is regulated by the Department as a health care facility may not be used as a shared use operation.

Added: (B)(1) to move duties of the facilitator from (C)(1)(a) to the general section to clarify that it is applicable to the entire section.

Amended: (C) and (D) to combine sections (C) “Permits” and (D) “Compliance” into a single section titled “Compliance” to be consistent with other Chapter 9 sections.

Amended: (C)(1)(a) to remove language moved to (B)(1), to require the facilitator to provide the number of shared use operators the facility can accommodate and to require that the shared use operation will not exceed this number of operators without Department notification.

Section 9‑6

Amended: (E)(1) to add “pizza ovens designed for outdoor use” as accepted equipment for outdoor cooking.

Amended: (G)(2) to change “meet” to “have at” for readability and clarity.

Section 9‑7

Amended: The introduction to add that the standard is applicable to a smokehouse room.

Section 9‑8

Amended: (A) to add “movie or filming location” to the list of allowed events.

Added: (E)(7)‑(8) to require that food must be kept covered and that covers or lids may only be removed for stirring and similar actions.

Amended : (H)(3) changed “backsiphonage” to “backflow” to match term used in Chapter 5 for consistency.

Deleted: (J)(3) The reference to mechanical ventilation is not required as it was an unnecessary statement.

Amended: (K)(7) to correct error in section references in (K)(7) and renamed section 9‑11.

Section 9‑9

Added: (D)(13)‑(14) to require that food must be kept covered and that covers or lids may only be removed for stirring and similar actions.

Amended : (G)(3) changed “backsiphonage” to “backflow” to match term used in Chapter 5 for consistency.

Deleted: (I)(4) The reference to mechanical ventilation is not required as it was an unnecessary statement.

Section 9‑10

Amended : (G)(3) changed “backsiphonage” to “backflow” to match term used in Chapter 5 for consistency.

Deleted: (I)(4) The reference to mechanical ventilation is not required as it was an unnecessary statement. Renumbered remaining subparagraph.

Section 9‑11

Amended: Section title to read “Retail Food Establishment – South Carolina Farmers Markets, Seasonal Series and Remote Service” to allow this section to cover other types of events and activities not previously covered by the regulation. Made corresponding changes to introduction.

Added: (A)(3) to define “remote service operation.”

Amended: (B)(1) to add remote service sites.

Amended: (B)(3)‑(4) to expand the number of days a week allowed for these functions to two days a week to accommodate the schedules of the farmers’ markets and similar events.

Added: (D)(9)‑(10) to require food must be kept covered and that covers or lids may only be removed for stirring and similar actions.

Amended: (F)(1) to remove requirement for markets to provide a handsink and changed handsink requirements to match Chapter 9‑9 and 9‑10 facilities that operate for the same time period.

Added: (F)(1)(a)‑(b) as part of handsink clarification requirements.

Amended: (F)(2) to remove requirement for one hundred (100)‑degree Fahrenheit temperature water at handwashing facility and to require handwashing facility to be of adequate storage capacity to meet the demand of the food service operation.

Amended: (F)(3) to delete specific water storage requirements and replace them with requirement for soap and disposable towels.

Amended: (H) Title to include “and Refuse Removal” to accurately reflect the section.

Deleted: (I)(1) to remove the exemption from CFPM for seasonal series and community‑based farmers’ markets as the revised Food Handler requirements in the body of the regulation cover these operations.

Deleted: (I)(3) The reference to mechanical ventilation is not required as it was an unnecessary statement.

Amended: (J)(1) to add that remote service does not require pre‑approval authorization.

**R.61‑37**

R.61‑37 is repealed and stricken in its entirety, as its amended requirements are being incorporated into R.61‑25, Chapter 8.

**Instructions:**

Replace in entirety R.61-25, Retail Food Establishments, with this amendment.

Repeal in entirety R.61-37, Retail Food Establishment Inspection Fees, in the South Carolina Code of Regulations.

**Text:**

61‑25. Retail Food Establishments.

Statutory Authority: 1976 Code Sections 44‑1‑140(2), 44‑1‑150, and 44‑1‑180

**CONTENTS**

CHAPTER 1 Purpose and Definitions

CHAPTER 2 Management and Personnel

CHAPTER 3 Food

CHAPTER 4 Equipment, Utensils, and Linens

CHAPTER 5 Water, Plumbing, and Waste

CHAPTER 6 Physical Facilities

CHAPTER 7 Poisonous or Toxic Materials

CHAPTER 8 Compliance and Enforcement

CHAPTER 9 Standards for Additional Retail Food Establishment Operations

**Chapter 1 Purpose and Definitions**

**1‑1 Title, Intent, Scope**

1‑101 Title

1‑102 Intent

1‑103 Scope

**1‑2 Definitions**

1‑201 Applicability and Terms Defined

**Chapter 2 Management and Personnel**

**2‑1 Supervision**

2‑101 Responsibility

2‑102 Knowledge

2‑103 Duties

**2‑2 Employee Health**

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

**2‑3 Personal Cleanliness**

2‑301 Hands and Arms

2‑302 Fingernails

2‑303 Jewelry

2‑304 Outer Clothing

**2‑4 Hygienic Practices**

2‑401 Food Contamination Prevention

2‑402 Hair Restraints

2‑403 Animals

**2‑5 Responding to Contamination Events**

2‑501 Procedures for Responding

**Chapter 3 Food**

**3‑1 Characteristics**

3‑101 Condition

**3‑2 Sources, Specifications, and Original Containers and Records**

3‑201 Sources

3‑202 Specifications for Receiving

3‑203 Original Containers and Records

**3‑3 Protection from Contamination after Receiving**

3‑301 Preventing Contamination by Employees

3‑302 Preventing Food and Ingredient Contamination

3‑303 Preventing Contamination from Ice Used as a Coolant

3‑304 Preventing Contamination from Equipment, Utensils, and Linens

3‑305 Preventing Contamination from the Premises

3‑306 Preventing Contamination by Consumers

3‑307 Preventing Contamination from Other Sources

**3‑4 Destruction of Organisms of Public Health Concern**

3‑401 Cooking

3‑402 Freezing

3‑403 Reheating

3‑404 Other Methods

**3‑5 Limitation of Growth of Organisms of Public Health Concern**

3‑501 Temperature and Time Control

3‑502 Specialized Processing Methods

**3‑6 Food Identity, Presentation, and On‑premises Labeling**

3‑601 Accurate Representation

3‑602 Labeling

3‑603 Consumer Advisory

**3‑7 Contaminated Food**

3‑701 Disposition

**3‑8 Special Requirements for Highly Susceptible Populations**

3‑801 Additional Safeguards

**Chapter 4 Equipment, Utensils, and Linens**

**4‑1 Materials for Construction and Repair**

4‑101 Multiuse

4‑102 Single‑Service and Single‑Use

**4‑2 Design and Construction**

4‑201 Durability and Strength

4‑202 Cleanability

4‑203 Accuracy

4‑204 Functionality

4‑205 Acceptability

**4‑3 Numbers and Capacities**

4‑301 Equipment

4‑302 Utensils, Temperature Measuring Devices, and Testing Devices

4‑303 Cleaning Agents and Sanitizers

**4‑4 Location and Installation**

4‑401 Location

4‑402 Installation

**4‑5 Maintenance and Operation**

4‑501 Equipment

4‑502 Utensils and Temperature and Pressure Measuring Devices

**4‑6 Cleaning of Equipment and Utensils**

4‑601 Objective

4‑602 Frequency

4‑603 Methods

**4‑7 Sanitization of Equipment and Utensils**

4‑701 Objective

4‑702 Frequency

4‑703 Methods

**4‑8 Laundering**

4‑801 Objective

4‑802 Frequency

4‑803 Methods

**4‑9 Protection of Clean Items**

4‑901 Drying

4‑902 Lubricating and Reassembling

4‑903 Storing

4‑904 Preventing Contamination

**Chapter 5 Water, Plumbing, and Waste**

**5‑1 Water**

5‑101 Source

5‑102 Quality

5‑103 Quantity and Availability

5‑104 Distribution, Delivery, and Retention

**5‑2 Plumbing System**

5‑201 Materials

5‑202 Design, Construction, and Installation

5‑203 Numbers and Capacities

5‑204 Location and Placement

5‑205 Operation and Maintenance

**5‑3 Mobile Water Tank and Mobile Food Establishment Water Tank**

5‑301 Materials

5‑302 Design and Construction

5‑303 Numbers and Capacities

5‑304 Operations and Maintenance

**5‑4 Sewage, Other Liquid Waste, and Rainwater**

5‑401 Mobile Holding Tank

5‑402 Retention, Drainage, and Delivery

5‑403 Disposal Facility

**5‑5 Refuse, Recyclables, and Returnables**

5‑501 Facilities on the Premises

5‑502 Removal

5‑503 Facilities for Disposal and Recycling

**Chapter 6 Physical Facilities**

**6‑1 Materials for Construction and Repair**

6‑101 Indoor Areas

6‑102 Outdoor Areas

**6‑2 Design, Construction, and Installation**

6‑201 Cleanability

6‑202 Functionality

**6‑3 Numbers and Capacities**

6‑301 Handwashing Sinks

6‑302 Toilet and Urinals

6‑303 Lighting

6‑304 Ventilation

6‑305 Dressing Areas and Lockers

6‑306 Service Sinks

**6‑4 Location and Placement**

6‑401 Handwashing Sinks

6‑402 Toilet Rooms

6‑403 Employee Accommodations

6‑404 Distressed Merchandise

6‑405 Refuse, Recyclables, and Returnables

**6‑5 Maintenance and Operation**

6‑501 Premises, Structures, Attachments, and Fixtures – Methods

**Chapter 7 Poisonous or Toxic Materials**

**7‑1 Labeling and Identification**

7‑101 Original Containers

7‑102 Working Containers

**7‑2 Operational Supplies and Applications**

7‑201 Storage

7‑202 Presence and Use

7‑203 Container Prohibitions

7‑204 Chemicals

7‑205 Lubricants

7‑206 Pesticides

7‑207 Medicines

7‑208 First Aid Supplies

7‑209 Other Personal Care Items

**7‑3 Stock and Retail Sale**

7‑301 Storage and Display

**Chapter 8 Compliance and Enforcement**

**8‑1 Regulation Applicability**

8‑101 Use for Intended Purpose

8‑102 Additional Requirements

8‑103 Variances

**8‑2 Plan Submission and Approval**

8‑201 Operating Plans

8‑203 Construction Inspection and Approval

**8‑3 Permit to Operate**

8‑301 Requirement

8‑302 Application Procedure

8‑303 Issuance

8‑304 Conditions of Retention

**8‑4 Inspection and Correction of Violations**

8‑402 Access

8‑403 Report of Findings

8‑404 Imminent Health Hazard

8‑405 Correction of Violations

**8‑5 Prevention of Foodborne Disease Transmission by Employees**

8‑501 Investigation and Control

**8‑6 Constitutional Protection**

8‑602 Judicial Review

**8‑7 Authority**

8‑701 Legal Authority

**8‑9 Remedies**

**Administrative**

8‑903 Holding, Examination, and Destruction of Food

8‑904 Summary Permit Suspension

8‑905 Appeals

**Judicial**

8‑913 Civil Penalties

**Chapter 9 Standards for Additional Retail Food Establishment Operations**

9‑1 **Mobile Food**

9‑2 **Meat/Meat Product and Fish/Fish Product Sales**

9‑3 **Outdoor Pet Dining**

9‑4 **Wild Mushroom Foraging**

9‑5 **Shared Use Operations**

9‑6 **Immediate Outdoor Cooking**

9‑7 **Barbecue Pit and Pit‑Cooking Room Construction**

9‑8 **Temporary Food Service Establishments**

9‑9 **Community Festivals**

9‑10 **Special Promotions**

9‑11 **Retail Food Establishment – South Carolina Farmers Markets, Seasonal Series and Remote Service**

**Chapter 1 Purpose and Definitions**

**1‑1 TITLE, INTENT, SCOPE**

**1‑101 Title**

**1‑101.10 Regulation 61‑25.**

These provisions shall be known as Regulation 61‑25, hereinafter referred to as “this Regulation."

**1‑102 Intent**

**1‑102.10 Food Safety, Illness Prevention, and Honest Presentation.**

The purpose of this Regulation is to safeguard public health and provide to consumers food that is safe, unadulterated, and honestly presented.

**1‑103 Scope**

**1‑103.10 Statement.**

This Regulation establishes definitions; sets standards for management and personnel, food operations, equipment and facilities; and provides for retail food establishment permit issuance, inspection, employment restriction, permit suspension and revocation.

**1‑2 DEFINITIONS**

**1‑201 Applicability and Terms Defined.**

**1‑201.10 Statement of Application and Listing of Terms.**

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

(B) Terms Defined. As used in this Regulation, each of the terms listed in 1‑201.10(B) shall have the meanings stated below.

(1) **Accredited Program.**

(a) **"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.

(b) **"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.

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

(2) **Additives.**

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

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

(3) **“Adulterated”** means to make food unsafe for human consumption by any means, including, but not limited to, the addition of a foreign or inferior substance or food that has violated a critical limit.

(4) **“Approved”** means acceptable to the Department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

(5) **“Aw”** means a symbol for water activity, which measures the free moisture in a food. It is the quotient of water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

(6) “**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.

(7) **“Beverage”** means a liquid for drinking, including water.

(8) **“Boarding house”** means a private residence in which lodgers rent one or more rooms for extended periods of time, usually weeks, months or years. The common parts of the house are maintained, and some services, such as laundry and cleaning, may be supplied. They normally provide "bed and board" which will include some meals as well as accommodation.

(9) **"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.

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

(11) “**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.

(12) **“CFR”** means Code of Federal Regulations. Citations in this regulation 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.

(13) **CIP.**

(a) **"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.

(b) **"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.

(14) **“Commingle”** means:

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

(b) To combine shucked shellfish from containers with different container codes or different shucking dates.

(15) **Comminuted.**

(a) **“Comminuted”** means reduced in size by methods including chopping, flaking, grinding, or mincing.

(b) **“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 two (2) or more types of meat that have been reduced in size and combined.

(16) **“Commissary”** means a permitted retail food establishment that is authorized by the Department to provide a servicing area for mobile food unit or mobile food pushcarts for the purposes of storage of food, supplies, and single‑service articles. The commissary supports the following operations:

(a) Food preparation.

(b) Equipment and utensil washing.

(c) Disposal of sewage and solid waste.

(d) Obtainment of potable water.

(e) Provides a mobile food unit or mobile food pushcart servicing and storage area.

(17) **“Community‑based farmers market”** means a market sponsored by a community or governmental organization either having been certified by the SC Department of Agriculture as a SC Certified Farmer’s Market or a farmers market that meets the definition of the Farmers Market Coalition which states, “A farmers market operates multiple times per year and is organized for the purpose of facilitating personal connections that create mutual benefits for local farmers, shoppers, and communities and implements rule or guidelines of operation that ensure that the farmers market consists principally of farms selling directly to the public products that the farms have produced.”

(18) **"Community festivals"** means events sponsored by a community group, city/county/state organization, as a community celebration, that are generally theme related, and have multiple food vendors recruited to provide food to the public for a time period not to exceed three (3) consecutive days or no more than seventy‑two (72) continuous hours. Each community festival is unique and will not be held more frequently than annually, although a sponsoring organization or group might have multiple but differently themed community festivals in a year.

(19) “**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 retail food establishment or food processing plant, and does not offer the food for resale.

(20) **"Core violation”** See (132) “Violations.”

(21) **“Corrosion‑resistant materials”** 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.

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

(23) **“Critical control point”** means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

(24) **“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.

(25) **“Cut leafy greens”** means fresh leafy greens whose leaves have been further cut, shredded, sliced, chopped, or torn beyond any cut made to harvest intact leaves from a plant. The term “cut leafy greens” does not apply to leaves harvested intact from a plant. 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.

(26) **“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.

(27) **“Department”** means the South Carolina Department of Health and Environmental Control or agents thereof having responsibility for enforcing these regulations.

(28) **"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.

(29) **Drinking Water.**

(a) **"Drinking water"** means water that meets criteria as specified in 40 CFR 141, *National Primary Drinking Water Regulations* and R.61‑58, *State Primary Drinking Water Regulation*.

(b) **"Drinking water"** is traditionally known as "potable water."

(c) **"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.

(30) **"Dry storage area"** means a room or area designated for the storage of packaged or containerized bulk food that is not time/temperature control for safety food and dry goods such as single‑service items.

(31) **Easily cleanable.**

(a) **"Easily cleanable"** means a characteristic of a surface that:

(i) Allows effective removal of soil by normal cleaning methods;

(ii) Is dependent on the material, design, construction, and installation of the surface; and

(iii) Varies with the likelihood of the surface’s role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface’s approved placement, purpose, and use.

(b) **"Easily cleanable"** includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in (a) of this definition to different situations in which varying degrees of cleanability are required such as:

(i) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or

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

(32) **“Easily movable”** means:

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

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

(33) **Egg.**

(a) **“Egg”** means the shell egg of an avian species such as chicken, duck, goose, guinea, quail, ratites or turkey.

(b) **“Egg”** does not include:

(i) A balut;

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

(iii) An egg product.

(34) **Egg product**.

(a) **"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.

(b) **"Egg Product"** does not include food which contains eggs only in a relatively small proportion such as cake mixes.

(35) **“Employee”** means the permit holder, person in charge, food employee, person having supervisory or managerial duties, person on the payroll, family member, volunteer, person performing work under a contractual agreement, or any other person working in a retail food establishment.

(36) **“EPA”** means the U.S. Environmental Protection Agency.

(37) **Equipment.**

(a) **“Equipment”** means an article that is used in the operation of a retail food establishment such as a freezer, grinders, hood, ice makers, meat block, mixer, oven, reach‑in refrigerators, scale, sinks, slicer, stove, table temperature measuring device for ambient air, or warewashing machine.

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

(38) **“Exclude”** means to prevent a person from working as an employee in a retail food establishment or entering a retail food establishment as an employee.

(39) **“FDA”** means the U. S. Food and Drug Administration.

(40) **Fish.**

(a) **"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.

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

(41) **“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.

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

(43) “**Food‑contact surface**” means:

(a) A surface of equipment or a utensil with which food normally comes into contact; or

(b) A surface of equipment or a utensil from which food may drain, drip, or splash:

(i) Into a food, or

(ii) Onto a surface normally in contact with food.

(44) “**Food employee**” means an individual working with unpackaged food, food equipment or utensils, or food‑contact surfaces.

(45) **Food processing plant.**

(a) "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 retail food establishments.

(b) "Food processing plant" does not include a retail food establishment.

(46) **Game animal.**

(a) **“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.

(b) **“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.

(c) **“Game animal”** does not include ratites.

(47) **"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*.

(48) **“Grade A standards”** refers to milk that meets 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 or the requirements of the Department’s R.61‑34, *Raw Milk for Human Consumption*.

(49) **“Grade decal”** means an official decal issued by the Department that is posted by the Department in a retail food establishment, or on a mobile food unit or a mobile food pushcart that is representative of the most recent inspection.

(50) **“HACCP (Hazard Analysis and Critical Control Point) 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.

(51) **Handwashing sink**.

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

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

(52) **“Hazard”** means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

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

(54) **“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 food, is able to maintain the commercial sterility of its contents after processing.

(55) **“Highly susceptible population”** means persons who are more likely than other people in the general population to experience foodborne disease because they are:

(a) Immunocompromised; preschool age children or older adults; and

(b) Obtaining food at a facility that provides services such as: custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

(56) **"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 illness or injury based on:

(a) The number of potential illnesses or injuries, and

(b) The nature, severity, and duration of the anticipated illness or injury.

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

(58) **“Intact Meat”** means a cut of whole muscle(s) meat that has not undergone comminution, injection, mechanical tenderization, or reconstruction.

(59) **Juice**.

(a) **”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.

(b) **“Juice”** does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.

(60) **“Kitchenware”** means food preparation and storage utensils.

(61) **“Law”** means applicable local, state, and federal statutes, regulations, and ordinances.

(62) **“Linens”** means fabric items such as cloth hampers, cloth napkins, tablecloths, wiping cloths, and work garments including cloth gloves.

(63) **“Low‑risk food processes”** means food processes that have been determined and approved by the Department to be low risk. The Department will evaluate low‑risk food processes based on food items, food handling and preparation, and foodborne illness.

(64) **Major Food Allergen**.

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

(i) 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

(ii) A food ingredient that contains protein derived from a food, as specified in (a)(i) of this definition.

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

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

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

(65) **“Meat”** means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, goats, or other edible animals, except fish, poultry, and game animals as specified under 3‑201.17(A)(3) and (4).

(66) **Mechanically tenderized.**

(a) **"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.

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

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

(68) **“Mobile food establishment”** means a retail food establishment that consists of a commissary and mobile food units or mobile food pushcarts.

(69) **“Mobile food unit”** means fully enclosed mobile kitchens that prepare, cook, or serve time/temperature control for safety food as an extension of a commissary.

(70) **“Mobile food pushcart”** means limited food service units that operate as an extension of a commissary.

(71) **“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.

(72) **Non‑continuous cooking.**

(a) **“Non‑continuous cooking”** means the cooking of food in a retail food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service.

(b) **“Non‑continuous cooking”** does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

(73) **“Nuisance”** for the purpose of this Regulation is a public health nuisance and means whatever is dangerous to human life or detrimental to health, including but not limited to whatever structure or premises is not sufficiently ventilated, sewered, drained, cleaned, or lighted with respect to its intended occupancy.

(74) **Packaged.**

(a) **"Packaged"** means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a retail food establishment or a food processing plant.

(b) **"Packaged"** does not include wrapped or placed in a carry‑out container to protect the food during service or delivery to the consumer by a food employee upon consumer request.

(75) **“Permit”** means the document issued by the Department that authorizes a person or entity to operate a retail food establishment.

(76) **“Permit holder”** means the entity that:

(a) Is legally responsible for the operation of the retail food establishment such as the owner, the owner’s agent, or other person; and

(b) Possesses a valid permit to operate a retail food establishment.

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

(78) **“Person in charge”** means the individual present at a retail food establishment who is responsible for the operation at the time of inspection.

(79) **Personal care items.**

(a) **“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.

(b) **“Personal care items”** include items such as medicines, first aid supplies, cosmetics, and toiletries such as toothpaste and mouthwash.

(80) **“pH”** means the symbol for the negative logarithm of the hydrogen ion concentration, which it is a measure of the degree of the acidity or alkalinity of a solution. Values between zero (0) and seven (7.0) indicate acidity and values between seven (7.0) and fourteen (14.0) indicate alkalinity. The value for pure distilled water is seven (7.0), which is considered neutral.

(81) **"Physical facilities"** means the structure and interior surfaces of a retail food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

(82) **"Plumbing fixture"** means a receptacle or device that:

(a) Is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or

(b) Discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

(83) **"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.

(84) **“Poisonous or toxic materials”** means substances that are not intended for ingestion and are included in 4 categories:

(a) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(b) Pesticides, except sanitizers, which include substances such as insecticides and rodenticides;

(c) Substances necessary for the operation and maintenance of the retail food establishment such as nonfood grade lubricants and personal care items that may be deleterious to health; and

(d) Substances that are not necessary for the operation and maintenance of the retail food establishment and are on the premises for retail sale such as petroleum products and paints.

(85) **“Poultry”** means:

(a) 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

(b) 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.*

(86) **“Premises”** means:

(a) The physical facility, its contents, its land, and any adjacent or bordering contiguous land or property under the control of the permit holder; or

(b) The physical facility, its contents, and land or property not described in (a) of this definition if its facilities, contents, or land that are under the control of the permit holder and may impact the retail food establishment personnel, facilities, or operations, and the retail food establishment is only one component of a larger operation such as a healthcare facility, hotel, motel, school, recreational camp, or prison.

(87) **“Pre‑operational inspection”** means an inspection conducted by the Department to determine compliance with the regulation for the purpose of obtaining a permit.

(88) “**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.

(89) **Priority violation** See (132) “Violations.”

(90) **Priority foundation violation** See (132) “Violations.”

(91) **“Private residence”** means a domestic home or dwelling in which food is prepared or served for individual and family consumption. A private residence is exempt from compliance with this regulation.

(92) **“Process authority”** means a qualified person(s) approved by the Department who have expert knowledge and adequate facilities to assess and determine safe food handling and processing requirements, including but not limited to thermal processing requirements in hermetically sealed containers, reduced oxygen packaging, shelf stable non‑time/temperature control for safety foods, and cooking processes.

(93) **“Product assessment”** means a process by which a retail food establishment submits food to be tested at a lab approved by Department to determine if the food is time/temperature control for safety or non‑time/temperature control for safety. A product assessment shall test intrinsic and extrinsic factors necessary to determine if the food is capable of supporting the growth or toxic formation of pathogenic microorganisms.

(94) **“Public water system”** has the meaning stated in 40 CFR 141, *National Primary Drinking Water Regulations* and R.61‑58, *State Primary Drinking Water Regulation*.

(95) **“Ratite”** means a flightless bird such as an emu, ostrich, or rhea.

(96) **“Raw milk”** refers to milk that has not been pasteurized and that is approved for sale and human consumption in South Carolina under the Department’s R.61‑34, *Raw Milk for Human Consumption.*

(97) **Ready‑to‑Eat Food.**

(a) **“Ready‑to‑eat food”** means food that:

(i) Is in a form that is edible without additional preparation to achieve food safety, as specified under one of the following: 3‑401.11(A) or (B), 3‑401.12, or 3‑402.11, or as specified in 3‑401.11(C); or

(ii) Is a raw or partially cooked animal food and the consumer is advised as specified in 3‑401.11(D)(1) and (3); or

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

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

(b) **“Ready‑to‑eat food”** includes:

(i) Raw animal food that is cooked as specified under 3‑401.11 or 3­401.12, or frozen as specified under 3‑402.11;

(ii) Raw fruits and vegetables that are washed as specified under 3‑302.15;

(iii) Fruits and vegetables that are cooked for hot holding, as specified under 3‑401.13;

(iv) All time/temperature control for safety food that is cooked to the temperature and time required for the specific food under 3‑401 and cooled as specified under 3‑501.14;

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

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

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

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

(ix) Foods manufactured as specified in 21 CFR Part 113, *Thermally Processed Low‑Acid Foods Packaged in Hermetically Sealed Containers.*

(98) **Reduced Oxygen Packaging.**

(a) **“Reduced oxygen packaging”** means:

(i) 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 twenty-one (21) percent at sea level); and

(ii) A process as specified in (a)(i) of this definition that involves a food for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form.

(b) **“Reduced oxygen packaging”** includes:

(i) Vacuum packaging in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;

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

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

(iv) Cook chill packaging in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

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

(99) **"Refuse"** means solid waste not carried by water through the sewage system.

(100) **"Regulation"** refers to Regulation 61‑25.

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

(102) **“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.

(103) “**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.

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

(105) **"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.

(106) **“Retail food establishment”** means an operation that prepares, processes, packages, serves, or otherwise provides food for human consumption, either on or off the premises, regardless of whether there is a charge for the food. These establishments include, but are not limited to, restaurants, delicatessens, snack bars, catering operations, ice cream parlors, school cafeterias, independent living food service operations, licensed healthcare facilities, grocery stores, retail meat markets, fish/seafood markets, retail ice merchants, shared use operations, and mobile food establishments (to include the associated commissary and mobile units).

(107) **“Risk”** means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

(108) **"Safe material"** means:

(a) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food.

(b) An additive that is used as specified in 409 of the *Federal Food, Drug, and Cosmetic Act*; or

(c) Other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

(109) **“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 percent reduction, of representative disease microorganisms of public health importance.

(110) **“Sealed”** means free of cracks or other openings that allow the entry or passage of moisture.

(111) **“Seasonal series”** means a regularly occurring event sponsored by a community or governmental organization for promoting local business, culture, or other local specialties.

(112) **“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 as per the *Americans for Disabilities Act.* Service animal does not include emotional, comfort, or similar support animals not recognized under the Americans with Disabilities Act (ADA) regulations as service animals.

(113) **"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.

(114) **“Sewage”** means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

(115) **“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.

(116) **“Shellstock”** means raw in‑shell molluscan shellfish.

(117) **"Shiga toxin‑producing *Escherichia coli*"** (STEC) means any *E. coli* capable of producing Shiga toxins (also called verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild non‑bloody diarrhea, to hemorrhagic colitis (i.e., bloody diarrhea), to hemolytic uremic syndrome (HUS ‑ a type of kidney failure). Examples of serotypes of STEC include: *E.coli O157:H7*; *NM E.coli O26:H11*; *E.coli O145*:*NM*; *E.coli O103:H2* and *E. coli O111:NM*. STEC are sometimes referred to as VTEC (*verocytotoxigenic E.coli*) or as EHEC (*Enterohemorrhagic E. coli*). EHEC are a subset of STEC which can cause hemorrhagic colitis or HUS.

(118) “**Shucked shellfish**” means molluscan shellfish that have one of both shells removed.

(119) **“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.

(120) **Single‑use articles.**

(a) **“Single‑use articles”** means utensils and bulk food containers designed and constructed to be used once and discarded.

(b) **“Single‑use articles”** means food packaging and other 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 (ten) 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.

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

(122) **"Smooth"** means:

(a) A food‑contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of one hundred (100) grit number 3 (three) stainless steel;

(b) A non‑food‑contact surface of equipment having a surface equal to that of commercial grade hot‑rolled steel free of visible scale; and

(c) A floor, wall, or ceiling having an even or level surface with no roughness or projections that renders it difficult to clean.

(123) **“Standard Operating Procedures (SOPs)”** means established or prescribed methods to be followed for the performance of designated operations or in designated situations as determined by the Department.

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

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

(126) **“Temporary food establishment”** means an establishment that may be authorized by the Department to operate at a fixed location for a period of time not to exceed fourteen (14) consecutive days in connection with a fair, carnival, circus, trade show, golf, or other national sporting event and other transitory gatherings organized by the community.

(127) **Time/temperature control for safety food** (formerly “potentially hazardous food” (PHF))**.**

(a) **“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.

(b) “**Time/temperature control for safety food**” includes:

(i) An animal food that is raw or heat‑treated; a plant food that is heat‑treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes, or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic‑in‑oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

(ii) Except as specified in (c)(iv) of this definition, a food that because of the interaction of its Aw and pH values is designated as Product Assessment Required (PA) in Table (A) or (B) of this definition:

|  |  |  |  |
| --- | --- | --- | --- |
| **Table A. Interaction of pH and Aw for control of spores in food heat‑treated to destroy vegetative cells and subsequently packaged.** | | | |
| Aw values |  | | |
| pH: 4.6 or less | pH: Greater than 4.6 ‑ 5.6 | pH: Greater than 5.6 |
| Less than or equal to 0.92 | non‑TCS Food\* | non‑TCS Food | non‑TCS Food |
| Greater than 0.92 ‑ 0.95 | non‑TCS Food | non‑TCS Food | PA\*\* |
| Greater than 0.95 | non‑TCS Food | PA | PA |
| \* TCS Food means Time/Temperature Control For Safety Food  \*\* PA means Product Assessment required | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table B. Interaction of pH and Aw for control of vegetative cells and spores in food not heattreated or heat treated but not packaged.** | | | | |
| Aw values |  | | | |
| pH: Less than 4.2 | pH: 4.2 ‑ 4.6 | pH: Greater than 4.6 ‑ 5.0 | pH: Greater than 5.0 |
| Less than 0.88 | non‑TCS Food\* | non‑TCS Food | non‑TCS Food | non‑TCS |
| 0.88 ‑ 0.90 | non‑TCS | non‑TCS | non‑TCS Food | PA\*\* |
| Greater than 0.90 ‑ 0.92 | non‑TCS | non‑TCS | PA | PA |
| Greater than 0.92 | non‑TCS | PA | PA | PA |
| \* TCS Food means Time/Temperature Control For Safety Food  \*\* PA means Product Assessment required | | | | |

(c) **"Time/temperature control for safety food"** does not include:

(i) An air‑cooled hard‑boiled egg with shell intact, or an egg with shell that is not hard‑boiled but has been pasteurized to destroy all viable *Salmonellae*;

(ii) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non‑refrigerated storage and distribution;

(iii) A food that because of its pH or Aw value, or interaction of Aw and pH values, is designated as a non‑TCS food in Table A or B of this definition;

(iv) A food that is designated TCS\* and a product assessment (PA) required 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:

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

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

(cc) A combination of intrinsic and extrinsic factors; or

(v) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the (c)(i) through (c)(iv) 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.

(128) **“USDA”** means the U.S. Department of Agriculture.

(129) **“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.

(130) **“Variance”** means a written document issued by the Department that authorizes a modification or waiver of one or more requirements of this regulation if, in the opinion of the Department, a health hazard or nuisance will not result from the modification or waiver.

(131) **"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.

(132) **Violations.**

(a) **Priority violation.**

(i) **“Priority violation”** means the violation of a provision in this Regulation 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 violations are denoted in this regulation by the superscript “P”.

(ii) **“Priority violation”** includes violations with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing.

(b) **Priority Foundation violation.**

(i) **“Priority foundation violation”** means the violation of a provision in this Regulation whose application supports, facilitates or enables one or more priority violations. Priority foundation violations are denoted in this regulation by the superscript “Pf”.

(ii) **“Priority foundation violation”** includes a violation 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.

(c) **Core violation.**

(i) **“Core violation”** means the violation of a provision in this Regulation that is not designated as a priority item or a priority foundation violation.

(ii) **“Core violation”** includes a violation that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

(d) **“Consecutive violation”** means a priority or priority foundation or core violation that was recorded on routine or complaint inspection(s), and is recorded on consecutive routine or complaint inspection(s). Consecutive violations are the same violation citation and similar in nature.

(133) “**Warewashing**” means the cleaning and sanitizing of food‑contact surfaces of equipment and utensils.

(134) **“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**

**2‑1 SUPERVISION**

**2‑101 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 retail food establishment during all hours of operation. Pf

(B) In a retail 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 designate a single person in charge who is present on the premises during all hours of food preparation, production, and service, and who is responsible for each separately permitted retail food establishment on the premises. Pf

**2‑102 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 Department knowledge of foodborne disease prevention, application of the Hazard Analysis and Critical Control Point principles, and the requirements of this regulation. The person in charge shall demonstrate this knowledge by:

(A) Complying with this regulation by having no priority violations 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 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 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 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 retail 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 correct procedures for cleaning and sanitizing utensils and food‑contact surfaces of equipment; Pf

(11) 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 regulation, or an agreement between the Department and the retail food establishment. Pf

**2‑102.12 Certified Food Protection Manager and Food Handler Certification.**

(A) At least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

(B) At all times during operation, the person in charge shall be a certified food handler or a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

(C) This section does not apply to certain types of retail food establishments deemed by the Department to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and the extent of food preparation.

**2‑102.20 Food Protection Manager Certification.**

(A) 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).

(B) A retail food establishment that has an employee 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 2‑102.12.

**2‑103 Duties**

**2‑103.11 Person in Charge.**

The person in charge shall ensure that:

(A) Retail food establishment operations are not conducted in a private residence or in a room used as living or sleeping quarters; Pf

(B) Persons unnecessary to the retail food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except brief visits and tours may be authorized by the person in charge if steps are taken to ensure that food, clean equipment, utensils, 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 regulation; 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, unadulterated, by routinely monitoring the employees’ observations and periodically evaluating foods upon their receipt; Pf

(F) Employees are verifying that foods delivered to the retail food establishment during non‑operating hours are from approved sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented; Pf

(G) Employees are properly cooking time/temperature control for safety foods, 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; Pf

(H) Employees are using proper methods to rapidly cool time/temperature control for safety foods through daily oversight of the employees’ routine monitoring of food temperatures during cooling; Pf

(I) Employees are properly maintaining the temperatures of time/temperature control for safety foods during hot and cold holding through daily oversight of the employees’ routine monitoring of food temperatures; Pf

(J) Consumers who order raw or partially cooked ready‑to‑eat foods of animal origin are informed by a consumer advisory that the food is not cooked sufficiently to ensure its safety; Pf

(K) 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

(L) Consumers are notified that clean tableware is to be used when they return to self‑service areas such as salad bars and buffets; Pf

(M) 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

(N) Employees are properly trained in food safety as it relates to their assigned duties; Pf

(O) Food employees are informed of their responsibility to report to the person in charge information about their health and activities as they relate to diseases that are transmissible through food;Pf

(P) The retail food establishment has a written plan for the restriction, exclusion and re‑instatement of food employees when they are restricted or excluded for conditions as specified in 2‑201.12 Pf; and

(Q) Written procedures and plans, where specified by this regulation and as developed by the retail food establishment, are maintained and implemented as required. Pf

**2‑2 EMPLOYEE HEALTH**

**2‑201 Responsibilities of Permit Holder, Person in Charge, and Food Employees**

**2‑201.11 Responsibility and Reporting Symptoms and Diagnosis.**

(A) The permit holder shall require food 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 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:

(1) 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; P

(2) Has an illness diagnosed by a health practitioner due to:

(a) Norovirus, P

(b) Hepatitis A virus, P

(c) *Shigella* spp., P

(d) Shiga toxin‑producing *Escherichia coli*, P

(e) Typhoid fever (caused by *Salmonella* Typhi) P or

(f) *Salmonella* (nontyphoidal); P

(3) Had Typhoid fever diagnosed by a health practitioner within the past three (3) months without having received antibiotic therapy as determined by a health practitioner; P

(4) Has been exposed to or is the suspected source of a confirmed disease outbreak, because the food 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 forty‑eight (48) hours of the last exposure, P

(b) Shiga toxin‑producing *Escherichiacoli* or *Shigella* spp. within the past three (3) days of the last exposure, P

(c) Typhoid fever within the past fourteen (14) days of the last exposure, P or

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

(5) 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 having 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 having knowledge about, an individual diagnosed with an illness caused by:

(a) Norovirus within the past forty‑eight (48) hours of the last exposure, P

(b) Shiga toxin‑producing *Escherichia coli* or *Shigella* spp. within the past three (3) days of the last exposure, P

(c) Typhoid fever (caused by *Salmonella* Typhi) within the past fourteen (14) days of the last exposure, P or

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

(B) The person in charge shall notify the Department when a food employee is:

(1) Jaundiced, Pf or

(2) Diagnosed with an illness due to a pathogen as specified under (A)(2)(a) through (f) of this section. Pf

(C) 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 (A)(1) through (5) of this section, is:

(1) Excluded as specified under section 2‑201.12 (A) ‑(C), and (D)(1), (E)(1), (F)(1), (G) or (H)(1) and in compliance with the provisions specified under section 2‑201.13(A)through (H); P or

(2) Restricted as specified under 2‑201.12 (D)(2), (E)(2), (F)(2), (H)(2), or section 2‑201.12(I) or (J) and in compliance with the provisions specified under section 2‑201.13(D)through (J). P

(D)A food employee shall report to the person in charge the information as specified under (A) of this section. Pf

(E)A food employee shall:

(1) Comply with an exclusion as specified under section 2‑201.12(A) through(C) and 2‑201.12(D)(1), (E)(1), (F)(1), (G), or (H)(1) and with the provisions specified under section 2‑201.13(A)through (H); P or

(2) Comply with a restriction as specified under 2‑201.12(D)(2), (E)(2), (F)(2), (G), (H)(2), or section 2‑201.12 (H), (I), or (J) and comply with the provisions specified under section 2‑201.13(D) through (J). P

**2‑201.12 Exclusions and Restrictions.**

The person in charge shall exclude or restrict a food employee from a retail food establishment in accordance with the following:

(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., *Salmonella* (nontyphoidal), or Shiga toxin‑producing *E.coli*. P

(B) Exclude a food employee who is:

(1) Jaundiced and the onset of jaundice occurred within the last seven (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 fourteen (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

(C) Exclude a food employee who is diagnosed with Typhoid fever, or reports having had Typhoid fever within the past three (3) months as specified under 2‑201.11(A)(3). P

(D) If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:

(1) Exclude the food employee who works in a retail food establishment serving a highly susceptible population; Por

(2) Restrict the food employee who works in a retail food establishment not serving a highly susceptible population. P

(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 retail food establishment serving a highly susceptible population; P or

(2) Restrict the food employee who works in a retail food establishment not serving a highly susceptible population. P

(F) If a food employee is diagnosed with an infection from Shiga toxin‑producing *E. coli* and is asymptomatic:

(1) Exclude the food employee who works in a retail food establishment serving a highly susceptible population; Por

(2) Restrict the food employee who works in a retail food establishment not serving a highly susceptible population. P

(G) If a food employee is diagnosed with an infection from *Salmonella* (nontyphoidal) and is asymptomatic, restrict the food employee who works in a retail food establishment serving a highly susceptible population or in a retail food establishment not serving a highly susceptible population. P

(H) 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 retail food establishment serving a highly susceptible population; Por

(2) Restrict the food employee who works in a retail food establishment not serving a highly susceptible population. P

(I) 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 2‑201.11(A)(1)(e), restrict the food employee. P

(J) If a food employee is exposed to a foodborne pathogen as specified under 2‑201.11(A)(4)(a) through (d) or 2‑201.11(A)(5)(a) through (d), restrict the food employee who works in a retail food establishment serving a highly susceptible population. P

**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 Typhoid fever or an infection from hepatitis A virus:

(1) Reinstate a food employee who was excluded as specified under 2‑201.12(A)(1) if the food employee:

(a) Is asymptomatic for at least twenty‑four (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

(2) If a food employee was diagnosed with an infection from Norovirus and excluded as specified under 2‑201.12(A)(2):

(a) Restrict the food employee, who is asymptomatic for at least twenty‑four (24) hours and works in a retail food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified under (D)(1) or (2) of this section are met; P or

(b) Retain the exclusion for the food employee, who is asymptomatic for at least twenty‑four (24) hours and works in a retail food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified under (D)(1) or (2) of this section are met. P

(3) If a food employee was diagnosed with an infection from *Shigella* spp. and excluded as specified under 2‑201.12(A)(2):

(a) Restrict the food employee, who is asymptomatic for at least twenty‑four (24) hours and works in a retail food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified under (E)(1) or (2) of this section are met; P or

(b) Retain the exclusion for the food employee, who is asymptomatic for at least twenty‑four (24) hours and works in a retail food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified under (E)(1) or (2) or (E)(1) and (3)(a) of this section are met. P

(4) If a food employee was diagnosed with an infection from Shiga toxin‑producing *Escherichia coli* and excluded as specified under 2‑201.12(A)(2):

(a) Restrict the food employee, who is asymptomatic for at least twenty‑four (24) hours and works in a retail food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified under (F)(1) or (2) of this section are met; P or

(b) Retain the exclusion for the food employee, who is asymptomatic for at least twenty‑four (24) hours and works in a retail food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified under (F)(1) or (2) are met. P

(5) If a food employee was diagnosed with an infection from *Salmonella* (nontyphoidal) and excluded as specified under 2‑201.12(A)(2):

(a) Restrict the food employee, who is asymptomatic for at least thirty (30) days, until conditions for reinstatement as specified under (G)(1) or (2) of this section are met; P or

(b) Retain the exclusion for the food employee who is symptomatic, until conditions for reinstatement as specified under Paragraphs (G)(1) or (G)(2) of this section are met. P

(B) Reinstate a food employee who was excluded as specified under 2‑201.12(B) if the person in charge obtains approval from the Department and one of the following conditions is met;

(1) The food employee has been jaundiced for more than seven (7) calendar days; P

(2) The anicteric food employee has been symptomatic with symptoms other than jaundice for more than fourteen (14) calendar days; P or

(3) The food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Hepatitis A virus infection. P

(C) Reinstate a food employee who was excluded as specified under 2‑201.12(C) if the food employee provides to the person in charge written medical documentation from a health practitioner that states the food employee is free from Typhoid fever. P

(D) Reinstate a food employee who was excluded as specified under 2‑201.12(A)(2) or (D)(1) who was restricted under 2‑201.12(D)(2) if:

(1) The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Norovirus infection; P

(2) The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than forty‑eight (48) hours have passed since the food employee became asymptomatic; P or

(3) The food employee was excluded or restricted and did not develop symptoms and more than forty‑eight (48) hours have passed since the food employee was diagnosed. P

(E) Reinstate a food employee who was excluded as specified under 2‑201.12(A)(2) or (E)(1) or who was restricted under 2‑201.12(E)(2) if one of the following conditions is met:

(1) The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a *Shigella* spp. infection based on test results showing two (2) consecutive negative stool specimen cultures that are taken:

(a) Not earlier than forty‑eight (48) hours after discontinuance of antibiotics, P and

(b) At least twenty‑four (24) hours apart; P

(2) The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than seven (7) calendar days have passed since the food employee became asymptomatic; P or

(3) The food employee was excluded or restricted and did not develop symptoms and more than seven (7) calendar days have passed since the food employee was diagnosed. P

(F) Reinstate a food employee who was excluded or restricted as specified under 2‑201.12(A)(2) or (F)(1) or who was restricted under 2‑201.12(F)(2) if one of the following conditions is met:

(1) The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of an infection from Shiga toxin‑producing *Escherichia coli* based on test results that show two (2) consecutive negative stool specimen cultures that are taken:

(a) Not earlier than forty‑eight (48) hours after discontinuance of antibiotics; P and

(b) At least twenty‑four (24) hours apart; P

(2) The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than seven (7) calendar days have passed since the food employee became asymptomatic; P or

(3) The food employee was excluded or restricted and did not develop symptoms and more than seven (7) days have passed since the food employee was diagnosed. P

(G) Reinstate a food employee who was excluded as specified under 2‑201.12(A)(2) or who was restricted as specified under 2‑201.12(G) if one of the following conditions is met:

(1) The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a *Salmonella* (nontyphoidal) infection based on test results showing two (2) consecutive negative stool specimen cultures that are taken;

(a) Not earlier than forty‑eight (48) hours after discontinuance of antibiotics, P and

(b) At least twenty‑four (24) hours apart; P

(2) The food employee was restricted after symptoms of vomiting or diarrhea resolved and more than thirty (30) days have passed since the food employee became asymptomatic; P or

(3) The food employee was excluded or restricted and did not develop symptoms and more than thirty (30) days have passed since the food employee was diagnosed. P

(H) Reinstate a food employee who was excluded or restricted as specified under 2‑201.12(H)(1) or (2) if the food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee meets one of the following conditions:

(1) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than twenty‑four (24) hours; P

(2) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection; P or

(3) Is otherwise determined by a health practitioner to be free of a *Streptococcus pyogenes* infection. P

(I) Reinstate a food employee who was restricted as specified under 2‑201.12(I) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

(1) An impermeable cover such as a finger cot or stall and a single‑use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist; P

(2) An impermeable cover on the arm if the infected wound or pustular boil is on the arm; Por

(3) A dry, durable, tight‑fitting bandage if the infected wound or pustular boil is on another part of the body. P

(J) Reinstate a food employee who was restricted as specified under 2‑201.12(J) and was exposed to one of the following pathogens as specified under 2‑201.11(A)(4)(a) through (d) or 2‑201.11(A)(5)(a) through (d):

(1) Norovirus and one of the following conditions is met:

(a) More than forty‑eight (48) hours have passed since the last day the food employee was potentially exposed; P or

(b) More than forty‑eight (48) hours have passed since the food employee’s household contact became asymptomatic. P

(2) *Shigella* spp. or Shiga toxin‑producing *Escherichia coli* and one of the following conditions is met:

(a) More than three (3) calendar days have passed since the last day the food employee was potentially exposed; P or

(b) More than three (3) calendar days have passed since the food employee’s household contact became asymptomatic. P

(3) Typhoid fever (caused by *Salmonella* Typhi) and one of the following conditions is met:

(a) More than fourteen (14) calendar days have passed since the last day the food employee was potentially exposed; P or

(b) More than fourteen (14) calendar days have passed since the food employee’s household contact became asymptomatic. P

(4) Hepatitis A virus and one of the following conditions is met:

(a) The food employee is immune to Hepatitis A virus infection because of a prior illness from Hepatitis A; P

(b) The food employee is immune to Hepatitis A virus infection because of vaccination against Hepatitis A; P

(c) The food employee is immune to Hepatitis A virus infection because of IgG administration; P

(d) More than thirty (30) calendar days have passed since the last day the food employee was potentially exposed; P

(e) More than thirty (30) calendar days have passed since the food employee’s household contact became jaundiced; P or

(f) The food employee does not use an alternative procedure that allows bare hand contact with ready‑to‑eat food until at least thirty (30) days after the potential exposure as specified in (I)(4)(d) and (e) of this section, and the food employee receives additional training about:

(i) Hepatitis A symptoms and preventing the transmission of infection, P

(ii) Proper handwashing procedures, P and

(iii) Protecting ready‑to‑eat food from contamination introduced by bare hand contact. P

**2‑201.120 Departmental Action ‑ Disease Transmission Known or Suspected.**

(A) When the Department knows or has reasonable cause to suspect transmission of an enteric foodborne disease by a food employee of a facility, the Department may secure a medical history of the suspected food employee or make any other investigation necessary.

(B) The Department may require any or all of the following measures:

(1) The immediate exclusion of the food employee from employment in retail food establishments;

(2) The Department can declare an imminent health hazard requiring the immediate closure of the retail food establishment or any section thereof until no further danger of disease transmission exists;

(3) Restriction of the food employee’s services to some other activity in the retail food establishment where there would be no danger of transmitting disease;

(4) Medical and laboratory examination of the food employee;

(5) Laboratory examination of food samples and environmental swabs from the retail food establishment.

**2‑3 PERSONAL CLEANLINESS**

**2‑301 Hands and Arms**

**2‑301.11 Clean Condition.**

Food employees shall keep their hands and exposed portions of their arms clean. P

**2‑301.12 Cleaning Procedure**.

(A) Except as specified in (D) of this section, food employees shall clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands or arms, for at least twenty (20) seconds, using a cleaning compound in a handwashing sink that is equipped as specified under 5‑202.12 and 6‑301.P

(B) Food employees shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

(1) Rinse under clean, running warm water; P

(2) Apply an amount of cleaning compound recommended by the cleaning compound manufacturer; P

(3) Rub together vigorously for at least ten (10) to fifteen (15) seconds while:

(a) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure, P and

(b) Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger‑tips, and areas between the fingers; P

(4) Thoroughly rinse under clean, running warm water; P and

(5) Immediately follow the cleaning procedure with thorough drying using a method as specified under 6‑301.12.P

(C) To avoid recontaminating their hands or surrogate prosthetic devices, food employees may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a handwashing sink or the handle of a restroom door.

(D) If approved and capable of removing the types of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands or surrogate prosthetic devices.

**2‑301.14 When to Wash.**

Food employees shall clean their hands and exposed portions of their arms as specified under 2‑301.12 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single‑service and single‑use articlesP and:

(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms;P

(B) After using the toilet room; P

(C) After caring for or handling service animals, pets, or aquatic animals as specified in 2‑403.11(B);P

(D) Except as specified in 2‑401.11(B) after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; P

(E) After handling soiled equipment or utensils; P

(F) During food preparation as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; P

(G) When switching between working with raw food and working with ready‑to‑eat food; P

(H) Before donning gloves to initiate a task that involves working with food; P and

(I) After engaging in other activities that contaminate the hands. P

**2‑301.15 Where to Wash.**

Food employees shall clean their hands in a handwashing sink or approved automatic handwashing facility and may not clean their hands in a sink used for food preparation or warewashing or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste. Pf

**2‑301.16 Hand Antiseptics.**

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

(1) Comply with one of the following:

(a) Be an approved drug that is listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* as an approved drug based on safety and effectiveness; Pf or

(b) Have active antimicrobial ingredients that are listed in the FDA monograph for *OTC Health‑Care Antiseptic Drug Products* as an antiseptic handwash, Pf and

(2) Consist only of components which the intended use of each complies with one of the following:

(a) A threshold of regulation exemption under 21 CFR 170.39, *Threshold of Regulation for Substances Used in Food‑Contact Articles*; Pf or

(b) 21 CFR 178, *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers* as regulated for use as a food additive with conditions of safe use; Pf or

(c) A determination of generally recognized as safe (GRAS). Partial listings of substances with food uses that are GRAS may be found in 21 CFR 182, *Substances Generally Recognized as Safe*, 21 CFR 184, *Direct Food Substances Affirmed as Generally Recognized as Safe*, or 21 CFR 186, *Indirect Food Substances Affirmed as Generally Recognized as Safe for Use in Contact with Food*, and in FDA’s *Inventory of GRAS Notices;* Pf or

(d) A prior sanction listed under 21 CFR 181,*Prior Sanctioned Food Ingredients,* Pf or

(e) a *Food Contact Notification* that is effective, Pf and

(3) Be applied only to hands that are cleaned as specified under 2‑301.12. Pf

(B) If a hand antiseptic does not meet the criteria specified under (A)(2) of this section, use shall be:

(1) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; Pf or

(2) Limited to situations that involve no direct contact with food by the bare hands. Pf

(C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 MG/L chlorine. Pf

**2‑302 Fingernails**

**2‑302.11 Maintenance.**

(A) Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. Nail length shall not extend beyond the fingertips. Pf

(B) Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial fingernails when working with exposed food. Pf

**2‑303 Jewelry**

**2‑303.11 Prohibition.**

(A) Except for a plain ring such as a wedding band, while preparing food, food employees shall not wear jewelry, including medical information jewelry, on their arms or hands.

(B) If jewelry cannot be removed for medical or religious reasons, it must be covered with a clean intact single‑use glove when working with food.

**2‑304 Outer Clothing**

**2‑304.11 Clean Condition.**

Food employees shall wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single‑service and single‑use articles.

**2‑4 HYGIENIC PRACTICES**

**2‑401 Food Contamination Prevention**

**2‑401.11 Eating, Drinking, or Using Tobacco.**

(A) Except as specified in (B) of this section, an employee shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed food, clean equipment, utensils, linens, unwrapped single‑service and single‑use articles or other items needing protection cannot result.

(B) A food employee may drink from a closed beverage container if the container is handled to prevent contamination of:

(1) The food employee’s hands;

(2) The container; and

(3) Exposed food, clean equipment, utensils, and linens; and unwrapped single‑service and single‑use articles.

**2‑401.12 Discharges from the Eyes, Nose, and Mouth.**

Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth shall not work with exposed food, clean equipment, utensils, linens, or unwrapped single‑service or single‑use articles.

**2‑401.13 Use of Bandages, Finger Cots, or Finger Stalls.**

If used, an impermeable cover such as a bandage, finger cot, or finger stall located on the wrist, hand, or finger of a food employee working with exposed food shall be covered with a single‑use glove.

**2‑402 Hair Restraints**

**2‑402.11 Effectiveness.**

(A) Except as provided in (B) of this section, food employees shall wear hair restraints such as hats, hair covering and nets, beard restraints, and clothing that covers body hair that are designed and worn to effectively keep their hair from contacting exposed food, clean equipment, utensils, linens, and unwrapped single‑service or single‑use articles.

(B) This section does not apply to food employees such as counter staff who only serve beverages and wrapped or packaged food, hostesses, and wait staff, if they present a minimal risk of contaminating exposed food, clean equipment, utensils, linens and unwrapped single‑service or single‑use articles.

**2‑403 Animals**

**2‑403.11 Handling Prohibition.**

(A) Except as specified in (B) of this section, food employees may not care for or handle animals that may be present such as patrol dogs, service animals, or pets that are allowed as specified in 6‑501.115 (B)(2) through (5) or section 9‑3 “Outdoor Pet Dining”. Pf

(B) Food employees with service animals may handle or care for their service animals, and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacean in display tanks, if they wash their hands as specified in 2‑301.12 and 2‑301.14(C).

**2‑5 RESPONDING TO CONTAMINATION EVENTS**

**2‑501 Procedures for Responding**

**2‑501.11 Clean‑up of Vomiting and Diarrheal Events.**

A retail food establishment shall have written procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the retail food establishment. The procedures shall address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter. Pf

**Chapter 3 Food**

**3‑1 CHARACTERISTICS**

**3‑101 Condition**

**3‑101.11 Safe, Unadulterated, and Honestly Presented.**

Food shall be safe, unadulterated, and, as specified under 3‑601.12, honestly presented. P

**3‑2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS**

**3‑201 Sources**

**3‑201.11 Compliance with Food Law.**

(A) Food shall be obtained from sources that comply with law. P

(B) Food prepared in a private home shall not be used or offered for human consumption in a retail food establishment. P

(C) Packaged food shall be labeled as specified in law, including 21 CFR 101, *Food Labeling*, 9 CFR 317, *Labeling, Marking Devices, and Containers*, and 9 CFR 381 Subpart N, *Labeling and Containers*, and as specified under 3‑202.17 and 3‑202.18.Pf

(D) Fish, other than those specified in 3‑402.11(B), that are intended for consumption in raw or undercooked form and allowed as specified in 3‑401.11(D), may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified under 3‑402.11 or if they are frozen on the premises as specified under 3‑402.11 and records are retained as specified under 3‑402.12.

(E) Whole‑muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in 3‑401.11(C) shall be:

(1) Obtained from a food processing plant that, upon request by the purchaser, packages the steaks and labels them to indicate that the steaks meet the definition of whole‑muscle, intact beef, Pf or

(2) Deemed acceptable by the Department based on other evidence,Pf

(3) If individually cut in a retail food establishment:

(a) Cut from whole‑muscle intact beef that is labeled by a food processing plant as specified in (E)(1) of this section or identified as specified in (E)(2) of this section, P

(b) Prepared so they remain intact, Pf and

(c) If packaged for undercooking in a retail food establishment, labeled as specified in (E)(1) of this section or identified as specified in (E)(2) of this section. Pf

(F) Meat and poultry that is not a ready‑to‑eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

(G) Eggs that have not been specifically treated to destroy all viable *Salmonellae* shall be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

**3‑201.12 Food in a Hermetically Sealed Container.**

Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant. P

**3‑201.13 Fluid Milk, Dry Milk, and Milk Products.**

Fluid milk, dry milk, and milk products shall be obtained from sources that comply with Grade A standards as specified in law. P

**3‑201.14 Fish.**

(A) Fish that are received for sale or service shall be:

(1) Commercially and legally caught or harvested, P or

(2) Approved for sale or service. P

(B) Molluscan shellfish that are recreationally caught may not be received for sale or service. P

**3‑201.15 Molluscan Shellfish.**

(A) Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish*. P

(B) Molluscan shellfish received in interstate commerce shall be from sources that are listed in the *Interstate Certified Shellfish Shippers List*. P

**3‑201.16 Wild Mushrooms.**

(A) Except as specified in (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert as specified in *9‑4,Wild Mushroom Foraging*. P

(B) This section does not apply to:

(1) Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or

(2) Wild mushroom species, if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

**3‑201.17 Game Animals.**

(A) If game animals are received for sale or service they shall be:

(1) Commercially raised for food P and:

(a) Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, P or

(b) Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, P and

(c) Raised, slaughtered, and processed according to:

(i) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, P and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian’s designee; P

(2) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR 352, *Exotic Animals*; voluntary inspection or rabbits that are "inspected and certified" in accordance with 9 CFR 354, *Voluntary Inspection Of Rabbits And Edible Products Thereof*; P

(3) As allowed by law for wild game animals that are live‑caught:

(a) Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction, P and

(b) Slaughtered and processed according to:

(i) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, P and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian’s designee; P or

(4) As allowed by law, for field‑dressed wild game animals under a routine inspection program that ensures the animals:

(a) Receive a postmortem examination by an approved veterinarian or veterinarian’s designee, P or

(b) Are field‑dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program, P and

(c) Are processed according to laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program. P

(B) A game animal may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17, *Endangered and Threatened Wildlife and Plants*.

**3‑202 Specifications for Receiving**

**3‑202.11 Temperature.**

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

(B) If a temperature other than 41 degree F (5 degree C) for a time/temperature control for safety food is specified in law governing its distribution, such as laws governing milk and molluscan shellfish, the food may be received at the specified temperature.

(C) Raw eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 45 degrees F (7 degrees C) or less. P

(D) Time/temperature control for safety food that is cooked to a temperature and for a time specified under 3‑401.11 through 3‑401.13 and received hot shall be at a temperature of 135 degrees F (57 degrees C) or above. P

(E) A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen. Pf

(F) Upon receipt, time/temperature control for safety food shall be free of evidence of previous temperature abuse. Pf

**3‑202.12 Additives.**

Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170‑180 relating to *Food Additives, Generally Recognized as Safe* or prior sanctioned substances that exceed amounts specified in 21 CFR 181 through 186, substances that exceed amounts specified in 9 CFR Subpart C Section 424.21(b), *Food Ingredients and Sources of Radiation,* that exceed provisions specified in 40 CFR 180, *Tolerances for Pesticides Chemicals in Food, and Exceptions*. P

**3‑202.13 Eggs.**

Eggs shall be received clean and sound and shall not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in *United StatesStandards, Grades, and Weight Classes for Shell Eggs*, AMS 56.200 et seq., administered by the Agricultural Marketing Service of USDA.P

**3‑202.14 Egg and Milk Products, Pasteurized.**

(A) Egg products shall be obtained pasteurized. P

(B) Fluid and dry milk and milk products used and served shall, except as specified in (E) of this section:

(1) Be obtained pasteurized; P and

(2) Comply with Grade A standards as specified in law. P

(C) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135, *Frozen desserts*. P

(D) Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133, *Cheeses and Related Cheese Products,* for curing certain cheese varieties. P

(E) Packaged raw milk may be obtained for re‑sale provided it meets the requirements of R.61‑34, *Raw Milk for Human Consumption*.

**3‑202.15 Package Integrity.**

Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants. Pf

**3‑202.16 Ice.**

Ice for use as a food or cooling medium shall be made from drinking water. P

**3‑202.17 Shucked Shellfish, Packing and Identification.**

(A) Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the Pf:

(1) Name, address, and certification number of the shucker, packer, or repacker of the molluscan shellfish and

(2) The "sell by" or "best if used by" date for packages with a capacity of less than 1.89 L (one‑half gallon) or the date shucked for packages with a capacity of 1.89 L (one‑half gallon) or more. Pf

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

**3‑202.18 Shellstock Identification.**

(A) Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or dealer that depurates, ships, or reships the shellstock, as specified in the *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish*, and that list: Pf

(1) Except as specified under (C) of this section, on the harvester’s tag or label, the following information in the following order:

(a) The harvester’s identification number that is assigned by the shellfish control authority,Pf

(b) The date of harvesting, Pf

(c) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested, Pf

(d) The type and quantity of shellfish, Pf and

(e) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for ninety (90) days"; Pf and

(2) Except as specified in (D) of this section, on each dealer’s tag or label, the following information in the following order: Pf

(a) The dealer’s name, address, and the certification number assigned by the shellfish control authority, Pf

(b) The original shipper’s certification number including the abbreviation of the name of the state or country in which the shellfish are harvested, Pf

(c) The same information as specified for a harvester’s tag under (A)(1)(b) through (d) of this section, Pf and

(d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for ninety (90) days." Pf

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

(C) If a place is provided on the harvester’s tag or label for a dealer’s name, address, and certification number, the dealer’s information shall be listed first.

(D) If the harvester’s tag or label is designed to accommodate each dealer’s identification as specified under (A)(2)(a) and (b) of this section, individual dealer tags or labels need not be provided.

(E) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag.

**3‑202.19 Shellstock Condition.**

When received by a retail food establishment, shellstock shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells shall be discarded.

**3‑202.110 Juice Treated.**

Pre‑packaged juice shall:

(A) Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120, *Hazard Analysis and Critical Control (HACCP) Systems*; Pf and

(B) Be obtained pasteurized or otherwise treated to attain a 5‑log reduction of the most resistant microorganism of public health significance as specified in 21 CFR Part 120.24, *Process Controls.* P

**3‑203 Original Containers and Records**

**3‑203.11 Molluscan Shellfish, Original Container.**

(A) Except as specified in (B) through (D) of this section, molluscan shellfish may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(B) For display purposes, shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

(1) The source of the shellstock on display is identified as specified under 3‑202.18 and recorded as specified under 3‑203.12 and

(2) The shellstock are protected from contamination.

(C) Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer’s request if:

(1) The labeling information for the shellfish on display as specified under 3‑202.17 is retained and correlated to the date when or dates during which the shellfish are sold or served, and

(2) The shellfish are protected from contamination.

(D) Shucked shellfish may be removed from the container in which they were received and repacked in consumer self‑service containers where allowed by law if:

(1) The labeling information for the shellfish is on each consumer self‑service container as specified under 3‑202.17 and 3‑602.11;

(2) The labeling information as specified under 3‑202.17 is retained and correlated with the date when or dates during which the shellfish are sold or served;

(3) The labeling information and dates specified under (D)(2) of this section are maintained for ninety (90) days; and

(4) The shellfish are protected from contamination.

**3‑203.12 Shellstock, Maintaining Identification.**

(A) Except as specified under (C)(2) of this section, shellstock tags or labels shall remain attached to the container in which the shellstock are received until the container is empty. Pf

(B) The date when the last shellstock from the container is sold or served shall be recorded on the tag or label. Pf

(C) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for ninety (90) calendar days from the date that is recorded on the tag or label, as specified under (B) of this section, by: Pf

(1) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under (B) of this section; Pf and

(2) If shellstock are removed from its tagged or labeled container:

(a) Preserving source identification by using a record keeping system as specified under (C)(1) of this section, Pf and

(b) Ensuring that shellstock from one tagged or labeled container are not commingled with shellstock from another container with different certification numbers, different harvest dates, or different growing areas as identified on the tag or label before being ordered by the consumer. Pf

**3‑3 PROTECTION FROM CONTAMINATION AFTER RECEIVING**

**3‑301 Preventing Contamination by Employees**

**3‑301.11 Preventing Contamination from Hands.**

(A) Food employees shall wash their hands as specified under 2‑301.12.

(B) Except when washing fruits and vegetables as specified under 3‑302.15 or as specified in (D) of this section, food employees may not contact exposed, ready‑to‑eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single‑use gloves, or dispensing equipment. P

(C) Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready‑to‑eat form. Pf

(D) Paragraph (B) of this section does not apply to a food employee who contacts exposed, ready‑to‑eat food with bare hands at the time the ready‑to‑eat food is being added as an ingredient to a food that:

(1) Contains a raw animal food and is to be cooked in the retail food establishment to heat all parts of the food to the minimum temperatures specified in 3‑401.11(A) and (B) or 3‑401.12, or

(2) Does not contain a raw animal food but is to be cooked in the retail food establishment to heat all parts of the food to a temperature of at least 145 degree F (63 degree C).

**3‑301.12 Preventing Contamination When Tasting.**

A food employee may not use a utensil more than once to taste food that is to be sold or served.P

**3‑302 Preventing Food and Ingredient Contamination**

**3‑302.11 Packaged and Unpackaged Food ‑ Separation, Packaging, and Segregation.**

(A) Food shall be protected from cross contamination by:

(1) Except as specified in (1)(d) below, separating raw animal foods during storage, preparation, holding, and display from:

(a) Raw ready‑to‑eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready‑to‑eat food such as fruits and vegetables, P and

(b) Cooked ready‑to‑eat food; P and

(c) Fruits and vegetables before they are washed; P and

(d) Frozen, commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready‑to‑eat food.

(2) Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:

(a) Using separate equipment for each type, P or

(b) Arranging each type of food in equipment so that cross contamination of one type with another is prevented, P and

(c) Preparing each type of food at different times or in separate areas; P

(3) Cleaning equipment and utensils as specified under 4‑602.11(A) and sanitizing as specified under 4‑703.11;

(4) Except as specified under 3‑501.15(B)(2) and in (B) of this section, storing the food in packages, covered containers, or wrappings;

(5) Cleaning hermetically sealed containers of food of visible soil before opening;

(6) Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

(7) Storing damaged, spoiled, or recalled food being held in the retail food establishment as specified under 6‑404.11; and

(8) Separating fruits and vegetables before they are washed, as specified under 3‑302.15, from ready‑to‑eat food.

(B) Subparagraph (A)(4) of this section does not apply to:

(1) Whole, uncut, raw fruits and vegetables and nuts in the shell that require peeling or hulling before consumption;

(2) Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;

(3) Whole, uncut, processed meats such as country hams and smoked or cured sausages that are placed on clean, sanitized racks;

(4) Food being cooled as specified under 3‑501.15(B)(2); or

(5) Shellstock.

**3‑302.12 Food Storage Containers, Identified with Common Name of Food.**

Except for containers holding food that can be readily and unmistakably recognized, such as dry pasta, working containers holding food or food ingredients that are removed from their original packages for use in the retail food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar, shall be identified with the common name of the food.

**3‑302.13 Pasteurized Eggs, Substitute for Raw Eggs for Certain Recipes.**

Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg‑fortified beverages that are not: P

(A) Cooked as specified under 3‑401.11(A)(1) or (2); P or

(B) Included in 3‑401.11(D). P

**3‑302.14 Protection from Unapproved Additives.**

(A) Food shall be protected from contamination that may result from the addition of, as specified in 3‑202.12:

(1) Unsafe or unapproved food or color additives; P and

(2) Unsafe or unapproved levels of approved food and color additives. P

(B) A food employee may not:

(1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1,P or

(2) Except for grapes, serve or sell food specified under (B)(1) of this section that is treated with sulfiting agents before receipt by the retail food establishment. P

**3‑302.15 Washing Fruits and Vegetables.**

(A) Except as specified in (B) of this section and except for whole, raw fruits and vegetables that are intended for washing by the consumer before consumption, raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready‑to‑eat form.

(B) Fruits and vegetables may be washed by using chemicals as specified under 7‑204.12.

(C) Devices used for on‑site generation of chemicals meeting the requirements specified in 21 CFR 173.315, *Chemicals* *Used in the Washing or to Assist in the Peeling of Fruits and Vegetables*, for the washing of raw, whole fruits and vegetables shall be used in accordance with the manufacturer’s instructions. Pf

**3‑303 Preventing Contamination from Ice Used as a Coolant**

**3‑303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.**

After use as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice may not be used as food. P

**3‑303.12 Storage or Display of Food in Contact with Water or Ice.**

(A) Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

(B) Except as specified in (C) and (D) of this section, unpackaged food may not be stored in direct contact with undrained ice.

(C) Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.

(D) Raw poultry and raw fish that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.

**3‑304 Preventing Contamination from Equipment, Utensils, and Linens**

**3‑304.11 Food Contact with Equipment and Utensils.**

Food shall only contact surfaces of:

(A) Equipment and utensils that are cleaned as specified under Section 4‑6 of this regulation and sanitized as specified under Section 4‑7 of this regulation; P

(B) Single‑service and single‑use articles; P or

(C) Linens, such as cloth napkins, as specified in 3‑304.13 that are laundered as specified under Section 4‑8 of this regulation. P

**3‑304.12 In‑Use, Between‑Use Storage.**

During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

(A) Except as specified under (B) of this section, in the food with their handles above the top of the food and the container;

(B) In food that is not a time/temperature control for safety food with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;

(C) On a clean portion of the food preparation table or cooking equipment only if the in‑use utensil and the food‑contact surface of the food preparation table or cooking equipment are cleaned and sanitized at a frequency specified under 4‑602.11 and 4‑702.11;

(D) In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;

(E) In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not time/temperature control for safety food; or

(F) In a container of water if the water is maintained at a temperature of at least 135 degrees F (57 degrees C) and the container is cleaned at a frequency specified under 4‑602.11(D)(7).

**3‑304.13 Linens and Napkins, Use Limitation.**

Linens, such as cloth napkins, shall not be used in contact with food unless they are used to line a container for the service of foods and the linens and napkins are replaced each time the container is refilled for a new consumer.

**3‑304.14 Wiping Cloths, Use Limitation.**

(A) Cloths in‑use for wiping food spills from tableware and carry‑out containers that occur as food is being served shall be:

(1) Maintained dry; and

(2) Used for no other purpose.

(B) Cloths in‑use for wiping counters and other equipment surfaces shall be:

(1) Held between uses in a chemical sanitizer solution at a concentration specified under 4‑501.114, and

(2) Laundered daily as specified under 4‑802.11(D).

(C) Cloths in‑use for wiping surfaces in contact with raw animal foods shall be kept separate from cloths used for other purposes.

(D) Dry wiping cloths and the chemical sanitizing solutions specified in (B)(1) of this section in which wet wiping cloths are held between uses shall be free of food debris and visible soil.

(E) Containers of chemical sanitizing solutions specified in (B)(1) of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of food, equipment, utensils, linens, single‑service, or single‑use articles.

(F) Single‑use disposable sanitizer wipes shall be used in accordance with EPA‑approved manufacturer’s label use instructions.

**3‑304.15 Gloves, Use Limitation.**

(A) If used, single‑use gloves shall be used for only one task such as working with ready‑to‑eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation. P

(B) Except as specified in (C) of this section, slash‑resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under Section 3‑4 such as frozen food or a primal cut of meat.

(C) Slash‑resistant gloves may be used with ready‑to‑eat food that will not be subsequently cooked if the slash‑resistant gloves have a smooth, durable, and nonabsorbent outer surface; or if the slash‑resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a single‑use glove.

(D) Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required under Section 3‑4 such as frozen food or a primal cut of meat.

**3‑304.16 Using Clean Tableware for Second Portions and Refills.**

(A) Except for refilling a consumer’s drinking cup or container without contact between the pouring utensil and the lip‑contact area of the drinking cup or container, food employees may not use tableware, including single‑service articles, soiled by the consumer to provide second portions or refills.

(B) Except as specified in (C) of this section, self‑service consumers may not be allowed to use soiled tableware, including single‑service articles, to obtain additional food from the display and serving equipment.

(C) Drinking cups and containers may be reused by self‑service consumers if refilling is a contamination‑free process as specified under 4‑204.13(A), (B), and (D).

**3‑304.17 Refilling Returnables.**

(A) Except as specified in (B) through (E) of this section, empty containers returned to a retail food establishment for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.P

(B) A take‑home food container returned to a retail food establishment may be refilled at a retail food establishment with food if the food container is:

(1) Designed and constructed for reuse and in accordance with the requirements specified under Sections 4‑1 and 4‑2; P

(2) One that was initially provided by the retail food establishment to the consumer, either empty or filled with food by the retail food establishment, for the purpose of being returned for reuse;

(3) Returned to the retail food establishment by the consumer after use;

(4) Subject to the following steps before being refilled with food:

(a) Cleaned as specified under Section 4‑6 of this regulation;

(b) Sanitized as specified under Section 4‑7 of this regulation;

(c) Visually inspected by a food employee to verify that the container, as returned, meets the requirements specified under Sections 4‑1 and 4‑2.P

(C) A take‑home food container returned to a retail food establishment may be refilled at a retail food establishment with beverage if:

(1) The beverage is not a time/temperature control for safety food;

(2) The design of the container, the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the retail food establishment;

(3) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

(4) The consumer‑owned container returned to the retail food establishment for refilling is refilled for sale or service only to the same consumer; and

(5) The container is refilled by:

(a) An employee of the retail food establishment, or

(b) The owner of the container, if the beverage system includes a contamination‑free transfer process as specified under 4‑204.13(A), (B), and (D)that cannot be bypassed by the container owner.

(D) Consumer‑owned personal take‑out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination‑free process as specified under 4‑204.13(A), (B), and (D).

(E) Consumer‑owned containers that are not food‑specific may be filled at a water vending machine or system.

**3‑305 Preventing Contamination from the Premises**

**3‑305.11 Food Storage.**

(A) Except as specified in (B) and (C) of this section, food shall be protected from contamination by storing the food:

(1) In a clean, dry location;

(2) Where it is not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) Food in packages and working containers may be stored less than (6) inches (15 cm) above the floor on case lot handling equipment as specified under 4‑204.122.

(C) Pressurized beverage containers, cased food in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture.

**3‑305.12 Food Storage, Prohibited Areas.**

Food shall not be stored:

(A) In locker rooms;

(B) In toilet rooms;

(C) In dressing rooms;

(D) In garbage rooms;

(E) In mechanical rooms;

(F) Under drain or sewer lines that are not shielded to intercept potential drips;

(G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;

(H) Under open stairwells; or

(I) Under other sources of contamination.

**3‑305.14 Food Preparation.**

During preparation, unpackaged food shall be protected from environmental sources of contamination.

**3‑306 Preventing Contamination by Consumers**

**3‑306.11 Food Display.**

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards; display cases; or other effective means. P

**3‑306.12 Condiments, Protection.**

Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.

**3‑306.13 Consumer Self‑Service Operations.**

(A) Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish may not be offered for consumer self‑service. P This paragraph does not apply to:

(1) Consumer self‑service of ready‑to‑eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish;

(2) Ready‑to‑cook individual portions for immediate cooking and consumption on the premises such as consumer‑cooked meats or consumer‑selected ingredients for Mongolian barbecue; or

(3) Raw, frozen, shell‑on shrimp, or lobster.

(B) Consumer self‑service operations for ready‑to‑eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination. Pf

(C) Consumer self‑service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures. Pf

**3‑306.14 Returned Food and Re‑Service of Food.**

(A) Except as specified in (B) of this section, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption. P

(B) Except as specified under 3‑801.11(G), a container of food that is not a time/temperature control for safety food may be re‑served from one consumer to another if:

(1) The food is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow‑neck bottle containing catsup, steak sauce, or wine; or

(2) The food, such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition.

**3‑307 Preventing Contamination from Other Sources**

**3‑307.11 Miscellaneous Sources of Contamination.**

Food shall be protected from contamination that may result from a factor or source not specified under 3‑301 through 3‑306.

**3‑4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN**

**3‑401 Cooking**

**3‑401.11 Raw Animal Foods.**

(A) Except as specified under (B), (C), and (D) of this section, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:

(1) 145 degrees F (63 degrees C) or above for fifteen (15) seconds for: P

(a) Raw eggs that are broken and prepared in response to a consumer’s order and for immediate service, P and

(b) Except as specified under (A)(2) and (A)(3) and (B), and in (C) of this section, fish and intact meat including game animals commercially raised for food as specified under 3‑201.17(A)(1) and game animals under a voluntary inspection program as specified under 3‑201.17(A)(2);P

(2) 155 degrees F (68 degrees C) for seventeen (17) seconds or the temperature specified in the following chart that corresponds to the holding time for ratites, mechanically tenderized, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under 3‑201.17(A)(1), and game animals under a voluntary inspection program as specified under 3‑201.17(A)(2); and raw eggs that are not prepared as specified under (A)(1)(a) of this section, that corresponds to that temperature in Table 3.1: P

|  |  |
| --- | --- |
| **Table 3.1 Minimum** | |
| **Temperature**  **Degrees F (degrees C)** | **Time** |
| 145 (63) | 3 minutes |
| 150 (66) | 1 minute |
| 158 (70) | Less than 1 second (instantaneous) |

; or

(3) 165 degrees F (74 degrees C) or above for less than one (1) second(instantaneous) for poultry, baluts, wild game animals as specified under 3‑201.17(A)(3) and (4), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry, or ratites. P

(B) Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

(1) As specified in the following Table 3.2 to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature: P

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 3.2** | | | |
| **Temperature Degree**  **F (C)** | **Time1 in Minutes** | **Temperature Degree F (C)** | **Time1 in Seconds** |
| 130 (54.4) | 112 | 147 (63.9) | 134 |
| 131 (55.0) | 89 | 149 (65.0) | 85 |
| 133 (56.1) | 56 | 151 (66.1) | 54 |
| 135 (57.2) | 36 | 153 (67.2) | 34 |
| 136 (57.8) | 28 | 155 (68.3) | 22 |
| 138 (58.9) | 18 | 157 (69.4) | 14 |
| 140 (60.0) | 12 | 158 (70.0) | 0 |
| 142 (61.1) | 8 |  |  |
| 144 (62.2) | 5 |  |  |
| 145 (62.8) | 4 |  |  |
| 1Holding time may include post‑oven heat rise. | | | |

; and

(2) If cooked in an oven, use an oven that is preheated to the temperature specified for the roast’s weight in the following Table 3.3 and that is held at that temperature. Pf

|  |  |  |
| --- | --- | --- |
| **Table 3.3** | **Oven Temperature Based on Roast Weight** | |
| **Oven Type** |
| Less than 10 lbs (4.5 kg) | 10 lbs (4.5 kg) or more |
| **Still Dry** | 350 degrees F (177 degrees C) or more | 250 degrees F (121 degrees C) or more |
| **Convection** | 325 degrees F (163 degrees C) or more | 250 degrees F (121 degrees C) or more |
| **High Humidity1** | 250 degrees F (121 degrees C) or less | 250 degrees F (121 degrees C) or less |
| 1Relative humidity greater than 90 percent for at least 1 hour as measured in the cooking chamber, exit of the oven, or in a moisture‑impermeable bag that provides 100 percent humidity. | | |

(C) A raw or undercooked whole‑muscle, intact beef steak may be served or offered for sale in a ready‑to‑eat form if:

(1) The food establishment serves a population that is not a highly susceptible population,

(2) The steak is labeled to indicate that it meets the definition of "whole‑muscle, intact beef" as specified under 3‑201.11(E), and

(3) The steak is cooked on both the top and bottom to a surface temperature of 145 degrees F (63 degrees C) or above and a cooked color change is achieved on all external surfaces.

(D) A raw animal food, such as raw egg, raw fish, raw‑marinated fish, raw molluscan shellfish, or steak tartare, or a partially cooked food, such as lightly cooked fish, soft cooked eggs, or rare meat other than whole‑muscle, intact beef steaks, as specified in (C) of this section, may be served or offered for sale upon consumer request or selection in a ready‑to‑eat form if:

(1) As specified under 3‑801.11(C)(1) and (2), the retail food establishment serves a population that is not a highly susceptible population;

(2) The food, if served or offered for service by consumer selection from a children’s menu, does not contain comminuted meat; Pf and

(3) The consumer is informed as specified under 3‑603.11 that to ensure its safety, the food should be cooked as specified under (A) or (B) of this section; or

(4) The Department grants a variance from (A) or (B) of this section as specified in 8‑103.10 based on a HACCP plan that:

(a) Is submitted by the permit holder and approved as specified under 8‑103.11,

(b) Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food, and

(c) Verifies that equipment and procedures for food preparation and training of food employees at the retail food establishment meet the conditions of the variance.

**3‑401.12 Microwave Cooking.**

Raw animal foods cooked in a microwave oven shall be:

(A) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(B) Covered to retain surface moisture;

(C) Heated to a temperature of at least 165 degrees F (74 degrees C) in all parts of the food;P and

(D) Allowed to stand covered for two (2) minutes after cooking to obtain temperature equilibrium.

**3‑401.13 Plant Food for Cooking for Hot Holding.**

Plant foods that are cooked for hot holding shall be cooked to a temperature of 135 degrees F (57 degrees C).Pf

**3‑401.14 Non‑Continuous Cooking of Raw Animal Foods.**

Raw animal foods that are cooked using a non‑continuous cooking process shall be:

(A) Subject to an initial heating process that is no longer than sixty (60) minutes in duration; P

(B) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked time /temperature control for safety food under 3‑501.14(A); P

(C) After cooling, held frozen or cold, as specified for time/temperature control for safety food under 3‑501.16(A)(2);P

(D) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature and for a time as specified under section 3‑401.11 (A) through (C) of the regulation; P

(E) Cooled according to the time and temperature parameters specified for cooked time/temperature control for safety food under 3‑501.14(A) if not either hot held as specified under 3‑501.16(A), served immediately, or held using time as a public health control as specified under 3‑501.19 after complete cooking; P and

(F) Prepared and stored according to written procedures that:

(1) Have obtained prior approval from the Department; Pf

(2) Are maintained in the retail food establishment and are available to the Department upon request; Pf

(3) Describe how the requirements specified under (A) through (E) of this section are to be monitored and documented by the permit holder and the corrective actions to be taken if the requirements are not met; Pf

(4) Describe how the foods, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as foods that must be cooked as specified under (D) of this section prior to being offered for sale or service; Pf and

(5) Describe how the foods, after initial heating but prior to cooking as specified under (D) of this section, are to be separated from ready‑to‑eat foods as specified under 3‑302.11 (A). Pf

**3‑402 Freezing**

**3‑402.11 Parasite Destruction.**

(A) Except as specified in (B) of this section, before service or sale in ready‑to‑eat form, raw, raw‑marinated, partially cooked, or marinated‑partially cooked fish shall be:

(1) Frozen and stored at a temperature of ‑4 degrees F (‑20 degrees C) or below for a minimum of one hundred sixty‑eight (168) hours (seven (7) days) in a freezer; P

(2) Frozen at ‑31 degrees F (‑35 degrees C) or below until solid and stored at ‑31 degrees F (‑35 degrees C) or below for a minimum of fifteen (15) hours; P or

(3) Frozen ‑31 degrees F (‑35 degrees C) or below until solid and stored at ‑4 degrees F (‑20 degrees C) or below for a minimum of twenty‑four (24) hours. P

(B) Paragraph (A) of this section does not apply to:

(1) Molluscan shellfish;

(2) A scallop product consisting only of the shucked adductor muscle;

(3) Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern); or

(4) Aquacultured fish, such as salmon, that:

(a) If raised in open water, are raised in net‑pens, or

(b) Are raised in land‑based operations such as ponds or tanks, and

(c) Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish.

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

**3‑402.12 Records, Creation and Retention.**

(A) Except as specified in 3‑402.11(B) and (B) of this section, if raw, raw‑marinated, partially cooked, or marinated‑partially cooked fish are served or sold in ready‑to‑eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records of the food establishment for ninety (90) calendar days beyond the time of service or sale of the fish. Pf

(B) If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 3‑402.11 may substitute for the records specified under (A) of this section.

(C) If raw, raw‑marinated, partially cooked, or marinated‑partially cooked fish are served or sold in ready‑to‑eat form, and the fish are raised and fed as specified in 3‑402.11(B)(4), a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 3‑402.11(B)(4) shall be obtained by the person in charge and retained in the records of the food establishment for ninety (90) calendar days beyond the time of service or sale of the fish. Pf

**3‑403 Reheating**

**3‑403.10 Preparation for Immediate Service.**

Cooked and refrigerated food that is fully prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

**3‑403.11 Reheating for Hot Holding.**

(A) Except as specified under (B), (C) and (E) of this section, time/temperature control for safety food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165 degrees F (74 degrees C) for fifteen (15) seconds. P

(B) Except as specified under (C) of this section, time/temperature control for safety food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165 degrees F (74 degrees C) and the food is rotated or stirred, covered, and allowed to stand covered for two (2) minutes after reheating. P

(C) Ready‑to‑eat time/temperature control for safety food that has been commercially processed and packaged in a food processing plant that is inspected by the food regulatory authority that has jurisdiction over the plant shall be heated to a temperature of at least 135 degrees F (57 degrees C) for hot holding. P

(D) Reheating for hot holding as specified under (A) through (C) of this section shall be done rapidly and the time the food is between 41 degrees F (5 degrees C) and the temperatures specified under (A) through (C) of this section may not exceed two (2) hours. P

(E) Remaining unsliced portions of meat roasts that are cooked as specified under 3‑401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 3‑401.11(B).

**3‑404 Other Methods**

**3‑404.11 Treating Juice**.

Juice packaged in a retail food establishment shall be:

(A) Treated under a HACCP plan as specified in 8‑201.14 to attain a 5‑log reduction, which is equal to a 99.999 percent reduction, of the most resistant microorganism of public health significance; P or

(B) Labeled, if not treated to yield a 5‑log reduction of the most resistant microorganism of public health significance, as specified in 21 CFR 101.17(g), *Food Labeling, Warning, Notice, and Safe Handling Statements*, juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Pf

**3‑5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN**

**3‑501 Temperature and Time Control**

**3‑501.11 Frozen Food.**

Stored frozen foods shall be maintained frozen.

**3‑501.12 Time/Temperature Control for Safety, Slacking.**

Frozen time/temperature control for safety food that is slacked to moderate the temperature shall be held:

(A) Under refrigeration that maintains the food temperature at 41 degrees F (5 degrees C) or less; or

(B) At any temperature if the food remains frozen.

**3‑501.13 Thawing.**

Except as specified in (D) of this section, time/temperature control for safety food shall be thawed:

(A) Under refrigeration that maintains the food temperature at 41 degrees F (5 degrees C) or less; or

(B) Completely submerged under cold running water:

(1) At a water temperature of 70 degrees F (21 degrees C) or below,

(2) With sufficient water velocity to agitate and float off loose particles in an overflow, and

(3) For a period of time that does not allow thawed portions of ready‑to‑eat food to rise above 41 degrees F (5 degrees C), or

(4) For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under 3‑401.11(A) or (B) to be above 41 degrees F (5 degrees C) for more than four (4) hours including:

(a) The time the food is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the food temperature to 41 degrees F (5 degrees C);

(C) As part of a cooking process if the food that is frozen is:

(1) Cooked as specified under 3‑401.11(A) or (B) or 3‑401.12 or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking equipment with no interruption in the process; or

(D) Using any procedure if a portion of frozen ready‑to‑eat food is thawed and prepared for immediate service in response to an individual consumer’s order.

(E) Reduced oxygen packaged fish that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment:

(1) Prior to its thawing under refrigeration as specified in (A) of this section; or

(2) Prior to or immediately upon completion of its thawing using procedures specified in (B) of this section.

**3‑501.14 Cooling.**

(A) Cooked time/temperature control for safety food shall be cooled:

(1) Within two (2) hours from 135 degrees F (57 degrees C) to 70 degrees F (21 degrees C); P and

(2) Within a total of six (6) hours from 135 degrees F (57 degrees C) to 41 degrees F (5 degrees C) or less. P

(B) Time/temperature control for safety food shall be cooled within four (4) hours to 41 degrees F (5 degrees C) or less if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna. P

(C) Except as specified under (D) of this section, a time/temperature control for safety food received in compliance with laws allowing a temperature above 41 degrees F (5 degrees C) during shipment from the supplier as specified in 3‑202.11(B) shall be cooled within 4 hours to 41 degrees F (5 degrees C) or less; P

(D) Raw eggs shall be received as specified under 3‑202.11(C) and immediately placed in refrigerated equipment that maintains an ambient air temperature of 45 degrees F (7 degrees C) or less. P

**3‑501.15 Cooling Methods.**

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under 3‑501.14 by using one or more of the following methods based on the type of food being cooled:

(1) Placing the food in shallow pans; Pf

(2) Separating the food into smaller or thinner portions; Pf

(3) Using rapid cooling equipment; Pf

(4) Stirring the food in a container placed in an ice water bath; Pf

(5) Using containers that facilitate heat transfer; Pf

(6) Adding ice as an ingredient; or Pf

(7) Other effective methods. Pf

(B) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

(1) Arranged in the equipment to provide maximum heat transfer through the container walls; and

(2) Loosely covered or uncovered if protected from overhead contamination as specified in 3‑305.11(A)(2) during the cooling period to facilitate heat transfer from the surface of the food.

**3‑501.16 Time/Temperature Control for Safety Food, Hot and Cold Holding.**

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

(1) At 135 degrees F (57 degrees C) or above, except that roasts cooked to a temperature and for a time specified in 3‑401.11(B) or reheated as specified in 3‑403.11(E) may be held at a temperature of 130 degrees F (54 degrees C) or above; P or

(2) At 41 degrees F (5 degrees C) or less. P

(B) Eggs that have not been treated to destroy all viable *Salmonellae* shall be stored in refrigerated equipment that maintains an ambient air temperature of 45 degrees F (7 degrees C) or less. P

(C) Time/temperature control for safety food in a homogenous liquid form may be maintained outside of the temperature control requirements, as specified under (A) of this section, while contained within specially designed equipment that complies with the design and construction requirements as specified under 4‑204.13(E).

**3‑501.17 Ready to Eat, Time/Temperature Control for Safety Food, Date Marking.**

(A) Except when packaging food using a reduced oxygen packaging method as specified under 3‑502.12 and except as specified in (E) and (F) of this section, refrigerated, ready‑to‑eat, time/temperature control for safety food prepared and held in a retail food establishment for more than twenty‑four (24) hours shall be clearly marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded when held at a temperature of 41 degrees F (5 degrees C) or less for a maximum of seven (7) days. The day of preparation shall be counted as Day One (1).Pf

(B) Except as specified in (E) through (G) of this section, refrigerated, ready‑to‑eat, time/temperature control for safety food prepared and packaged by a food processing plant shall be clearly marked, at the time the original container is opened in a retail food establishment and if the food is held for more than twenty‑four (24) hours, to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in (A) of this section and: Pf

(1) The day the original container is opened in the retail food establishment shall be counted as Day One (1);Pf and

(2) The day or date marked by the retail food establishment may not exceed a manufacturer’s use‑by date if the manufacturer determined the use‑by date based on food safety. Pf

(C) A refrigerated, ready‑to‑eat, time/temperature control for safety food ingredient or a portion of a refrigerated, ready‑to‑eat, time/temperature control for safety food that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest‑prepared or first‑prepared ingredient. Pf

(D) A date marking system that meets the criteria stated in (A) and (B) of this section may include:

(1) Using a method approved by the Department for refrigerated, ready‑to‑eat time/temperature control for safety food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;

(2) Marking the date or day of preparation with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under (A) of this section;

(3) Marking the date or day the original container is opened in a retail food establishment with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under (B) of this section; or

(4) Using calendar dates, days of the week, color‑coded marks, or other effective marking methods, provided that the marking system is disclosed to the Department upon request.

(E) Paragraphs (A) and (B) of this section do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer’s request.

(F) Paragraphs (A) and (B) of this section do not apply to shellstock.

(G) Paragraph (B) of this section does not apply to the following foods prepared and packaged by a food processing plant inspected by the appropriate regulatory authority:

(1) Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR 110*, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food;*

(2) Hard cheeses containing not more than thirty‑ nine (39) percent moisture as defined in 21 CFR 133, *Cheeses and Related Cheese Products*, such as cheddar, gruyere, parmesan and reggiano, and romano;

(3) Semi‑soft cheeses containing more than thirty‑nine (39) percent moisture, but not more than fifty (50) percent moisture, as defined in 21 CFR 133, *Cheeses and Related Cheese Products*, such as blue, edam, gorgonzola, gouda, and monterey jack;

(4) Cultured dairy products as defined in 21 CFR 131, *Milk and Cream*, such as yogurt, sour cream, and buttermilk;

(5) Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products defined in 21 CFR 114, *Acidified Foods*;

(6) Shelf stable, dry fermented sausages, such as pepperoni and Genoa; and

(7) Shelf stable salt‑cured products such as prosciutto and Parma (ham).

**3‑501.18 Ready‑to‑Eat, Time/Temperature Control for Safety Food, Disposition.**

A food specified in 3‑501.17(A) or (B) shall be discarded if it:

(A) Exceeds the temperature and time combination specified in 3‑501.17(A), except time that the product is frozen; P

(B) Is in a container or package that does not bear a date or day; P or

(C) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in 3‑501.17(A).P

**3‑501.19 Time as a Public Health Control Measure.**

(A) Except as specified under (D) of this section, if time without temperature control is used as the public health control for a working supply of time/temperature control for safety food before cooking, or for ready‑to‑eat time/temperature control for safety food that is displayed or held for sale or service:

(1) Written procedures shall be prepared in advance, maintained in the retail food establishment and made available to the Department upon request that specify: Pf

(a) Methods of compliance with (B)(1) through (3) or (C)(1) through (5) of this section; Pf and

(b) Methods of compliance with 3‑501.14 for food that is prepared, cooked, and refrigerated before time is used as a public health control. Pf

(B) If time without temperature control is used as the public health control up to a maximum of four (4) hours:

(1) The food shall have an initial temperature of 41 degrees F (5 degrees C) or less when removed from cold holding temperature control, or 135 degrees F (57 degrees C) or greater when removed from hot holding temperature control; P

(2) The food shall be marked or otherwise identified to indicate the time that is four (4) hours past the point in time when the food is removed from temperature control; Pf

(3) The food shall be cooked and served, served at any temperature if ready‑to‑eat, or discarded, within four (4) hours from the point in time when the food is removed from temperature control; P and

(4) The food in unmarked containers or packages, or marked to exceed a four (4) hour limit shall be discarded. P

(C) If time without temperature control is used as the public health control up to a maximum of six (6) hours:

(1) The food shall have an initial temperature of 41 degrees F (5 degrees C) or less when removed from temperature control and the food temperature may not exceed 70 degrees F (21 degrees C) within a maximum time period of six (6) hours; P

(2) The food shall be monitored to ensure the warmest portion of the food does not exceed 70 degrees F (21 degrees C) during the six (6) hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 70 degrees F (21 degrees C) during the six (6) hour holding period;Pf

(3) The food shall be marked or otherwise identified to indicate: Pf

(a) The time when the food is removed from 41 degrees F (5 degrees C) or less cold holding temperature control, Pf and

(b) The time that is six (6) hours past the point in time when the food is removed from cold holding temperature control; Pf

(4) The food shall be:

(a) Discarded if the temperature of the food exceeds 70 degrees F (21 degrees C),P or

(b) Cooked and served, served at any temperature if ready‑to‑eat, or discarded within a maximum of six (6) hours from the point in time when the food is removed from 41 degrees F (5 degrees C) or less cold holding temperature control; P and

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

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

**3‑502 Specialized Processing Methods**

**3‑502.11 Special Processes Requiring a Variance.**

A retail food establishment shall obtain a variance from the Department as specified in 8‑103.10 and under 8‑103.11 before: Pf

(A) Smoking food as a method of food preservation rather than as a method of flavor enhancement;Pf

(B) Curing food; Pf

(C) Using food additives or adding components such as vinegar: Pf

(1) As a method of food preservation rather than as a method of flavor enhancement, Pf or

(2) To render a food so that it is not a time/temperature control of safety food; Pf

(D) Packaging time/temperature control for safety food using a reduced oxygen packaging method except where the growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled as specified under 3‑502.12; Pf

(E) Custom processing animals that are for personal use as food and not for sale or service in a food establishment; Pf

(F) Preparing food by another method that is determined by the Department to require a variance; Pf

(G) Sprouting seeds or beans; Pf or

(H) Using additives or acidification when the process is for flavor enhancement only. Retail food establishments using additives or acidification for flavor enhancement only shall provide a written statement, in lieu of a HACCP plan, which shall describe foods prepared and essential safety measures implemented.

**3‑502.12 Reduced Oxygen Packaging Without a Variance, Criteria.**

(A) Except for a retail food establishment that obtains a variance as specified under 3‑502.11, a retail food establishment that packages time/temperature control for safety food using a reduced oxygen packaging method shall control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*. P

(B) Except as specified under (F) of this section, a retail food establishment that packages time/temperature control for safety food using a reduced oxygen packaging method shall implement a HACCP plan that contains the information specified under 8‑201.14(C) and (D) and that: Pf

(1) Identifies the food to be packaged; Pf

(2) Except as specified under (C) through (E) of this section, requires that the packaged food shall be maintained at 41 degrees F (5 degrees C) or less and meet at least one of the following criteria: Pf

(a) Has an Aw of 0.91 or less, Pf

(b) Has a pH of 4.6 or less, Pf

(c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, *Use of Food Ingredients and Sources of Radiation*, and is received in an intact package, Pf or

(d) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables; Pf

(3) Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: Pf

(a) Maintain the food at 41 degrees F (5 degrees C) or below, Pf and

(b) Discard the food if within thirty (30) calendar days of its packaging it is not served for on‑premises consumption, or consumed if served or sold for off‑premises consumption; Pf

(4) Limits the refrigerated shelf life to no more than thirty (30) calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer’s "sell by" or "use by" date, whichever occurs first; P

(5) Includes operational procedures that:

(a) Prohibit contacting ready‑to‑eat food with bare hands as specified under 3‑301.11(B),Pf

(b) Identify a designated work area and the method by which: Pf

(i) Physical barriers or methods of separation of raw foods and ready‑to‑eat foods minimize cross contamination, Pf and

(ii) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, Pf and

(c) Delineate cleaning and sanitization procedures for food‑contact surfaces; Pf and

(6) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the: Pf

(a) Concepts required for a safe operation, Pf

(b) Equipment and facilities, Pf and

(c) Procedures specified under (B)(5) of this section and 8‑201.14 (C) and (D).Pf

(7) Is provided to the Department prior to implementation as specified under 8‑201.13 (B).

(C) Except for fish that is frozen before, during, and after packaging and bears a label indicating that it is to be kept frozen until time of use, a retail food establishment may not package fish using a reduced oxygen packaging method. P

(D) Except as specified under (C) and (F) of this section, a retail food establishment that packages time/temperature control for safety food using a cook‑chill or sous vide process shall:

(1) Provide to the Department prior to implementation a HACCP plan that contains the information as specified under 8‑201.14 (C) and (D); Pf

(2) Ensure the food is:

(a) Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer, Pf

(b) Cooked to heat all parts of the food to a temperature and for a time as specified under 3‑401.11 (A),(B), and (C),P

(c) Protected from contamination before and after cooking as specified under 3‑3 and 3‑4,P

(d) Placed in a package with an oxygen barrier and sealed before cooking or placed in a package and sealed immediately after cooking and before reaching a temperature below 135 degrees F (57 degrees C),P

(e) Cooled to 41 degrees F (5 degrees C) in the sealed package or bag as specified under 3‑501.14 and: P

(i) Cooled to 34 degrees F (1 degrees C) within forty‑eight (48) hours of reaching 41 degrees F (5 degrees C) and held at that temperature until consumed or discarded within thirty (30) days after the date of packaging; P

(ii) Held at 41 degrees F (5 degrees C) or less for no more than seven (7) days, at which time the food must be consumed or discarded; P or

(iii) Held frozen with no shelf life restriction while frozen until consumed or used. P

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily, Pf

(g) If transported off‑site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, Pf and

(h) Labeled with the product name and the date packaged; Pf and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan and:

(a) Make such records available to the Department upon requestPf and

(b) Hold such records for at least six (6) months; Pf and

(4) Implement written operational procedures as specified under (B)(5) of this section and a training program as specified under (B)(6) of this section. Pf

(E) Except as specified under (F) of this section, a retail food establishment that packages cheese using a reduced oxygen packaging method shall:

(1) Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the retail food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150, *Hard Cheeses*, 21 CFR 133.169, *Pasteurized Process Cheese* or 21 CFR 133.187, *Semisoft Cheeses*; P

(2) Have a HACCP plan that contains the information specified under 8‑201.14 (C) and (D) and as specified under (B)(1), (B)(3)(a), (B)(5), and (B)(6) of this section; Pf

(3) Labels the package on the principal display panel with a "use by" date that does not exceed thirty (30) days from its packaging or the original manufacturer’s "sell by" or "use by" date, whichever occurs first; Pf and

(4) Discards the reduced oxygen packaged cheese if it is not sold for off‑premises consumption or consumed within 30 calendar days of its packaging. Pf

(F) A HACCP plan is not required when a retail food establishment uses a reduced oxygen packaging method to package time/temperature control for safety food that is always:

(1) Labeled with the production time and date,

(2) Held at 41 degrees F (5 degrees C) or less during refrigerated storage, and

(3) Removed from its package in the retail food establishment within forty‑eight (48) hours after packaging.

**3‑6 FOOD IDENTITY, PRESENTATION, AND CONSUMER ADVISORY**

**3‑601 Accurate Representation**

**3‑601.11 Standards of Identity.**

Packaged food shall comply with standard of identity requirements in 21 CFR 131‑169 and 9 CFR 319, *Definitions and Standards of Identity or Composition*, and the general requirements in 21 CFR 130, *Food Standards: General* and 9 CFR 319 Subpart A, *General*.

**3‑601.12 Honestly Presented.**

(A) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

(B) Food or color additives, colored overwraps, or lights shall not be used to misrepresent the true appearance, color, or quality of a food.

**3‑602 Labeling**

**3‑602.11 Food Labels.**

(A) Food packaged in a retail food establishment shall be labeled as specified in law.

(B) Label information shall include:

(1) The common name of the food or, absent a common name, an adequately descriptive identity statement;

(2) The name and place of business of the manufacturer, packer, or distributor; and

(3) The name of the food source for each major food allergen contained in the food or a disclaimer that any major food allergen may be contained in the food.

(C) Bulk food that is available for consumer self‑dispensing shall be prominently labeled with the following information in plain view of the consumer:

(1) The manufacturer’s or processor’s label that was provided with the food or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1) - (3) of this section.

(D) Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:

(1) A health, nutrient content, or other claim is not made;

(2) There are no state or local laws requiring labeling; and

(3) The food is manufactured or prepared on the premises of the retail food establishment or at another retail food establishment or a food processing plant that is owned by the same person and is regulated by the food regulatory agency that has jurisdiction.

**3‑603 Consumer Advisory**

**3‑603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.**

(A) Except as specified in 3‑401.11(C), 3‑401.11(D)(4), and 3‑801.11(C), if an animal food, such as beef, eggs, fish, lamb, pork, poultry, or shellfish, is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready‑to‑eat form or as an ingredient in another ready‑to‑eat food, the permit holder shall inform consumers of the significantly increased risk of consuming such foods by way of a disclosure and reminder as specified in (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. Pf

(B) Disclosure shall include:

(1) A description of the animal‑derived foods, such as "oysters on the half shell (raw oysters)," "raw‑egg Caesar salad," and "hamburgers (can be cooked to order)";Pf or

(2) Identification of the animal‑derived foods by asterisking them to a footnote that states that the items are served raw, or undercooked, or contain (or may contain) raw or undercooked ingredients. Pf

(C) Reminder shall include asterisking the animal‑derived foods requiring disclosure to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request; Pf

(2) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness; Pf or

(3) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions. Pf

(D) Packaged raw milk may be sold in packaged form provided it is bottled pursuant to the requirements of R.61‑34, *Raw Milk for Human Consumption,* and provided a disclosure and reminder placard that is located at the point of sale. Pf

**3‑7 CONTAMINATED FOOD**

**3‑701 Disposition**

**3‑701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.**

(A) A food that is unsafe, adulterated, or not honestly presented as specified under 3‑101.11 shall be discarded or reconditioned according to an approved procedure. P

(B) Food that is not from an approved source as specified under 3‑201.11 through 3‑201.17 shall be discarded. P

(C) Ready‑to‑eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 2‑201.12 shall be discarded. P

(D) Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded. P

**3‑8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS**

**3‑801 Additional Safeguards**

**3‑801.11 Pasteurized Foods, Prohibited Re‑Service, and Prohibited Food.**

In a retail food establishment that serves a highly susceptible population:

(A) The following criteria shall apply to juice:

(1) For the purposes of this paragraph only, children who are age nine (9) or less and receive food in a school, day care setting, or similar facility that provides custodial care are included as highly susceptible populations;

(2) Prepackaged juice or a prepackaged beverage containing juice, that bears a warning label as specified in 21 CFR, 101.17(g) *Food Labeling, Warning, Notice, and Safe Handling Statements*, juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a packaged juice or beverage containing juice, that bears a warning label as specified under 3‑404.11(B) may not be served or offered for sale; P and

(3) Unpackaged juice that is prepared on the premises for service or sale in a ready‑to‑eat form shall be processed under a HACCP plan that contains the information specified under 8‑201.14(B) through (E) and as specified in 21 CFR Part 120, *Hazard Analysis and Critical Control Point (HACCP) Systems*, Subpart B, *Pathogen Reduction*, 120.24, *Process Controls*. P

(B) Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of: P

(1) Foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg‑fortified beveragesP and

(2) Except as specified in (F) of this section, recipes in which more than one egg is broken and the eggs are combined; P

(C) The following foods may not be served or offered for sale in a ready‑to‑eat form: P

(1) Raw animal foods such as raw fish, raw‑marinated fish, raw molluscan shellfish, and steak tartare, P

(2) A partially cooked animal food such as lightly cooked fish, rare meat, soft‑cooked eggs that are made from raw eggs, and meringue; P and

(3) Raw seed sprouts. P

(D) Food employees may not contact ready‑to‑eat food as specified under 3‑301.11(B). P

(E) Time only, as the public health control as specified under 3‑501.19(D), may not be used for raw eggs. P

(F) Subparagraph (B)(2) of this section does not apply if:

(1) The raw eggs are combined immediately before cooking for one consumer’s serving at a single meal, cooked as specified under 3‑401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled eggs;

(2) The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready‑to‑eat form, such as a cake, muffin, or bread; or

(3) The preparation of the food is conducted under a HACCP plan that:

(a) Identifies the food to be prepared,

(b) Prohibits contacting ready‑to‑eat food with bare hands,

(c) Includes specifications and practices that ensure:

(i) *Salmonella* Enteritidis growth is controlled before and after cooking, and

(ii) *Salmonella* Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in 3‑401.11(A)(2),

(d) Contains the information specified under 8‑201.14(D) including procedures that:

(i) Control cross contamination of ready‑to‑eat food with raw eggs and

(ii) Delineate cleaning and sanitization procedures for food‑contact surfaces, and

(e) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

(G) Except as specified in (H) of this section, food may be re‑served as specified under 3‑306.14(B)(1) and (2).

(H) Food may not be re‑served under the following conditions:

(1) Any food served to patients or clients who are under contact precautions in medical isolation or quarantine or protective environment isolation may not be re‑served to others outside.

(2) Packages of food from any patients, clients, or other consumers should not be re‑served to persons in protective environment isolation.

**Chapter 4 Equipment, Utensils, and Linens**

**4‑1 MATERIALS FOR CONSTRUCTION AND REPAIR**

**4‑101 Multiuse**

**4‑101.11 Characteristics.**

Materials that are used in the construction of utensils and food‑contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food and, under normal use conditions, utensils and food‑contact surfaces shall be: P

(A) Safe; P

(B) Durable, corrosion‑resistant, and nonabsorbent;

(C) Sufficient in weight and thickness to withstand repeated warewashing;

(D) Finished to have a smooth, easily cleanable surface; and

(E) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

**4‑101.12 Cast Iron, Use Limitation.**

(A) Except as specified in (B) and (C) of this section, cast iron may not be used for utensils or food‑contact surfaces of equipment.

(B) Cast iron may be used as a surface for cooking.

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

**4‑101.13 Lead, Use Limitation.**

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

|  |  |  |
| --- | --- | --- |
| **Utensil Category** | **Ceramic Article Description** | **Maximum Lead mg/L** |
| Beverage Mugs, Cups, Pitchers | Coffee Mugs | 0.5 |
| Large Hollowware (excluding pitchers) | Bowls greater than or equal to 1.1 Liter  (1.16 Quart) | 1.0 |
| Small Hollowware (excluding cups & mugs) | Bowls less than 1.1 Liter  (1.16 Quart) | 2.0 |
| Flat Tableware | Plates, Saucers | 3.0 |

(B) Pewter alloys containing lead in excess of 0.05 percent shall not be used as a food‑contact surface.P

(C) Solder and flux containing lead in excess of 0.2 percent shall not be used as a food‑contact surface.

**4‑101.14 Copper, Use Limitation.**

(A) Except as specified in (B) of this section, copper and copper alloys such as brass may not be used in contact with a food that has a pH below six (6.0) such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator. P

(B) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below six (6.0) in the pre‑fermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

**4‑101.15 Galvanized Metal, Use Limitation.**

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

**4‑101.16 Sponges, Use Limitation.**

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

**4‑101.17 Wood, Use Limitations.**

(A) Except as specified in (B), (C), (D), (E), and (F)of this section, wood and wood wicker may not be used as a food‑contact surface.

(B) Hard maple or an equivalently hard, close‑grained wood may be used for:

(1) Cutting boards; cutting blocks; bakers’ tables; and utensils such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and

(2) Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110 degrees C (230 degrees F) or above.

(3) Bagel boards including a laminated hardwood may be acceptable if the food‑contact surface is smooth and in good repair.

(C) Cedar planks intended for grilling fish, provided only for this purpose, and discarded after a single use.

(D) Whole, uncut, raw fruits and vegetables and nuts in the shell may be kept in the wood shipping containers in which they were received until the fruits, vegetables, or nuts are used.

(E) If the nature of the food requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw food may be kept in:

(1) Untreated wood containers; or

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

(F) Wicker may be used only when suitably lined.

**4‑101.18 Nonstick Coating, Use Limitation**

Multiuse kitchenware such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching utensils and cleaning aids.

**4‑101.19 Nonfood‑contact Surfaces.**

Nonfood‑contact surfaces of equipment that are exposed to splash, spillage, or other food soiling or that require frequent cleaning shall be constructed of a corrosion‑resistant, nonabsorbent, smooth material.

**4‑102 Single‑Service and Single‑Use**

**4‑102.11 Characteristics.**

Materials that are used to make single‑service and single‑use articles:

(A) Shall not:

(1) Allow the migration of deleterious substancesP or

(2) Impart colors, odors, or tastes to food; and

(B) Shall be:

(1) SafeP and

(2) Clean.

**4‑2 DESIGN AND CONSTRUCTION**

**4‑201 Durability and Strength**

**4.201.11 Equipment and Utensils.**

Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

**4‑201.12 Food Temperature Measuring Devices.**

Food temperature measuring devices may not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used. P

**4‑202 Cleanability**

**4‑202.11 Food‑Contact Surfaces.**

(A) Multiuse food‑contact surfaces shall be:

(1) Smooth; Pf

(2) Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections Pf

(3) Free of sharp internal angles, corners, and crevices; Pf

(4) Finished to have smooth welds and joints; Pf and

(5) Except as specified in (B) of this section, accessible for cleaning and inspection by one of the following methods:

(a) Without being disassembled, Pf or

(b) By disassembling without the use of tools, Pf or

(c) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open‑end wrenches, and Allen wrenches. Pf

(B) Subparagraph (A)(5) of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes*.*

**4‑202.12 CIP Equipment.**

(A) CIP equipment shall meet the characteristics specified under 4‑202.11 and shall be designed and constructed so that:

(1) Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food‑contact surfaces, Pf and

(2) The system is self‑draining or capable of being completely drained of cleaning and sanitizing solutions; and

(B) CIP equipment that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior food‑contact surfaces throughout the fixed system are being effectively cleaned.

**4‑202.13 "V" Threads, Use Limitation.**

Except for hot oil cooking or filtering equipment, "V" type threads may not be used on food‑contact surfaces.

**4‑202.14 Hot Oil Filtering Equipment.**

Hot oil filtering equipment shall meet the characteristics specified under 4‑202.11 or 4‑202.12 and shall be readily accessible for filter replacement and cleaning of the filter.

**4‑202.15 Can Openers.**

Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

**4‑202.16 Nonfood‑Contact Surfaces.**

Nonfood‑contact surfaces shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

**4‑202.17 Kick Plates, Removable.**

Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

(A) Removable by one of the methods specified under 4‑202.11(A)(5) or capable of being rotated open and

(B) Removable or capable of being rotated open without unlocking equipment doors.

**4‑202.18 Ventilation Hood Systems, Filters.**

Filters and other grease‑extracting equipment shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

**4‑203 Accuracy**

**4‑203.11 Temperature Measuring Devices, Food.**

(A) Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to plus or minus one (1) degrees C in the intended range of use. Pf

(B) Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to plus or minus two (2) degrees F in the intended range of use. Pf

**4‑203.12 Temperature Measuring Devices, Ambient Air and Water.**

(A) Ambient air and water temperature measuring devices that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to plus or minus one point five (1.5) degrees C in the intended range of use. Pf

(B) Ambient air and water temperature measuring devices that are scaled only in Fahrenheit shall be accurate to plus or minus three (3) degrees F in the intended range of use. Pf

**4‑203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.**

Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse shall have increments of one (1) pound per square inch (7 kilopascals) or smaller and shall be accurate to plus or minus two (2) pounds per square inch (plus or minus 14 kilopascals) in the range indicated on the manufacturer’s data plate.

**4‑204 Functionality**

**4‑204.11 Ventilation Hood Systems, Drip Prevention.**

Exhaust ventilation hood systems in food preparation and warewashing areas including components such as hoods, fans, filters, and ducting shall be of commercial type and designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single‑service and single‑use articles.

**4‑204.12 Equipment Openings, Closures, and Deflectors.**

(A) A cover or lid for equipment shall overlap the opening and be sloped to drain.

(B) An opening located within the top of a unit of equipment that is designed for use with a cover or lid shall be flanged upward at least five (5) millimeters (two‑tenths of an inch).

(C) Except as specified under (D) of this section, fixed piping, temperature measuring devices, rotary shafts, and other parts extending into equipment shall be provided with a watertight joint at the point where the item enters the equipment.

(D) If a watertight joint is not provided:

(1) The piping, temperature measuring devices, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the food; and

(2) The opening shall be flanged as specified under (B) of this section.

**4‑204.13 Dispensing Equipment, Protection of Equipment and Food.**

In equipment that dispenses or vends liquid food or ice in unpackaged form:

(A) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food;

(B) The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

(C) The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self‑service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self‑closing door if the equipment is:

(1) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment or

(2) Available for self‑service during hours when it is not under the full‑time supervision of a food employee; and

(D) The dispensing equipment actuating lever or mechanism and filling device of consumer self‑service beverage dispensing equipment shall be designed to prevent contact with the lip‑contact surface of glasses or cups that are refilled.

(E) Dispensing equipment in which time/temperature control for safety food in a homogenous liquid form is maintained outside of the temperature control requirements as specified under 3‑501.16(A) shall:

(1) Be specifically designed and equipped to maintain the commercial sterility of aseptically packaged food in a homogenous liquid form for a specified duration from the time of opening the packaging within the equipment; P and

(2) Conform to the requirements for this equipment as specified in NSF/ANSI 18‑2006, *Manual Food and Beverage Dispensing Equipment*. P

**4‑204.15 Bearings and Gear Boxes, Leakproof.**

Equipment containing bearing and gears that require lubricants shall be designed and constructed so that the lubricant cannot leak, drip, or be forced into food or onto food‑contact surfaces.

**4‑204.16 Beverage Tubing, Separation.**

Except for cold plates that are constructed integrally with an ice storage bin, beverage tubing and cold‑plate beverage cooling devices may not be installed in contact with stored ice.

**4‑204.17 Ice Units, Separation of Drains.**

Liquid waste drain lines shall not pass through an ice machine or ice storage bin.

**4‑204.18 Condenser Unit, Separation.**

If a condenser unit is an integral component of equipment, the condenser unit shall be separated from the food and food storage space by a dustproof barrier.

**4‑204.110 Molluscan Shellfish Tanks.**

Molluscan shellfish life support system display tanks may not be used to store or display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only. P

**4‑204.112 Temperature Measuring Devices.**

(A) In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.

(B) Except as specified in (C) of this section, cold or hot holding equipment used for time/temperature control safety food shall be designed to include and shall be equipped with at least one integral or permanently affixed temperature measuring device that is located to allow easy viewing of the device’s temperature display.

(C) Paragraph (B) of this section does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers, and salad bars.

(D) Temperature measuring devices shall be designed to be easily readable.

(E) Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale or digital readout in increments no greater than 2 degrees F (1 degree C) in the intended range of use. Pf

**4‑204.113 Warewashing Machine, Data Plate, Operating Specifications.**

A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine’s design and operation specifications including the:

(A) Temperature required for washing, rinsing, and sanitizing;

(B) Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and

(C) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

**4‑204.114 Warewashing Machines, Internal Curtains.**

Warewashing machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

**4‑204.115 Warewashing Machines, Temperature Measuring Devices.**

A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:

(A) In each wash and rinse tank; Pf and

(B) As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank. Pf

**4‑204.116 Manual Warewashing Equipment, Heaters and Baskets.**

If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be:

(A) Designed with an integral heating device, equipped with an integral thermometer, that is capable of maintaining water at a temperature not less than 171 degrees F (77 degrees C);Pf and

(B) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water. Pf

**4‑204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.**

A warewashing machine shall be equipped to:

(A) Automatically dispense detergents and sanitizers; Pf and

(B) Incorporate a visual means to verify that detergents and sanitizers are delivered or a visual or audible alarm to signal if the detergents and sanitizers are not delivered to the respective washing and sanitizing cycles. Pf

**4‑204.118 Warewashing Machines, Flow Pressure Device.**

(A) Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine and

(B) If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device shall be mounted in a 6.4 millimeter or one‑fourth inch Iron Pipe Size (IPS) valve.

(C) Paragraphs (A) and (B) of this section do not apply to a machine that uses only a pumped or recirculated sanitizing rinse.

**4‑204.119 Warewashing Sinks and Drainboards, Self‑Draining.**

Sinks and drainboards of warewashing sinks and machines shall be self‑draining.

**4‑204.120 Equipment Compartments, Drainage.**

Equipment compartments that are subject to accumulation of moisture due to conditions such as condensation, food or beverage drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

**4‑204.122 Case Lot Handling Apparatuses, Moveability.**

Apparatuses, such as dollies, pallets, racks, and skids used to store and transport large quantities of packaged foods received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available apparatuses such as hand trucks and forklifts.

**4‑205 Acceptability**

**4‑205.10 Food Equipment, Certification, and Classification.**

(A) Except as specified in (B) of this section, all equipment installed in a retail food establishment after the effective date of this regulation shall be certified or classified and listed to National Sanitation Foundation (NSF) / American National Standards Institute (ANSI) Commercial Food Equipment Standards, or Baking Industry Sanitation Standards Committee (BISSC), or other accredited ANSI food equipment sanitation certification recognized by the Department.

(B) Residential counter‑top appliances, such as, but not limited to, coffee makers, a crockpot, toaster, toaster oven, microwave oven; and shelving, residential chest and upright freezers are exempt, but shall meet the requirements of 4‑1 and 4‑2.

**4‑3 NUMBERS AND CAPACITIES**

**4‑301 Equipment**

**4‑301.11 Cooling, Heating, and Holding Capacities.**

Equipment for cooling and heating food and holding cold and hot foodshall be sufficient in number and capacity to maintain food temperatures as specified under Chapter 3.Pf

**4‑301.12 Manual Warewashing, Sink Compartment Requirements.**

(A) Except as specified in (C) of this section, a sink with at least three (3) compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils. Pf

(B) Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in (C) of this section shall be used. Pf

(C) Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include:

(1) High‑pressure detergent sprayers;

(2) Low‑ or line‑pressure spray detergent foamers;

(3) Other task‑specific cleaning equipment;

(4) Brushes or other implements;

(5) Two (2)‑compartment sinks as specified under (D) and (E) of this section; or

(6) Receptacles that substitute for the compartments of a multicompartment sink.

(D) Before a two (2) compartment sink is used:

(1) The permit holder shall have its use approved and

(2) The permit holder shall limit the number of kitchenware items cleaned and sanitized in the two (2) compartment sink, shall limit warewashing to batch operations for cleaning kitchenware such as between cutting one type of raw meat and another or cleanup at the end of a shift, and shall:

(a) Make up the cleaning and sanitizing solutions immediately before use and drain them immediately after use, and

(b) Use a detergent‑sanitizer to sanitize and apply the detergent‑sanitizer in accordance with the manufacturer’s label instructions and as specified under 4‑501.115, or

(c) Use a hot water sanitization immersion step as specified under 4‑603.16(C).

(E) A two (2) compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process.

**4‑301.13 Drainboards.**

Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary utensil holding before cleaning and after sanitizing.

**4‑301.14 Ventilation Hood Systems, Adequacy.**

Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

**4‑301.15 Clothes Washers and Dryers.**

(A) Except as specified in (B) of this section, if work clothes or linens are laundered on the premises, a mechanical clothes washer and dryer shall be provided and used.

(B) If on‑premises laundering is limited to wiping cloths intended to be used moist or wiping cloths are air‑dried as specified under 4‑901.12, a mechanical clothes washer and dryer need not be provided.

**4‑302 Utensils, Temperature Measuring Devices, and Testing Devices**

**4‑302.11 Utensils, Consumer Self‑Service.**

A food dispensing utensil shall be available for each container displayed at a consumer self‑service unit such as a buffet or salad bar. Pf

**4‑302.12 Food Temperature Measuring Devices.**

(A) Food temperature measuring devices required for the immersion into food shall be provided and used to ensure the attainment and maintenance of food temperatures as specified under Chapter 3.Pf

(B)A temperature measuring device with a suitable small diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin foods such as meat patties and fish filets. Pf

**4‑302.13 Temperature Measuring Devices, Manual and Mechanical Warewashing.**

(A) In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures. Pf

(B) In hot water mechanical warewashing operations, an irreversible registering temperature indicator shall be provided and readily accessible for measuring the utensil surface temperature. Pf

**4‑302.14 Sanitizing Solutions, Testing Devices.**

A test kit or other device that accurately measures the concentration in MG/L of sanitizing solutions shall be provided. Pf

**4‑303 Cleaning Agents and Sanitizers**

**4‑303.11 Cleaning Agents and Sanitizers, Availability.**

(A) Cleaning agents that are used to clean equipment and utensils as specified under section 4‑6 shall be provided and available for use during all hours of operation.

(B) Except for those that are generated on‑site at the time of use, chemical sanitizers that are used to sanitize equipment and utensils as specified under section 4‑7 shall be provided and available for use during all hours of operation.

**4‑4 LOCATION AND INSTALLATION**

**4‑401 Location**

**4‑401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.**

(A) Except as specified in (B) of this section, equipment, a cabinet used for the storage of food, or a cabinet that is used to store cleaned and sanitized equipment, utensils, laundered linens, and single‑service and single‑use articles may not be located:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) A storage cabinet used for linens or single‑service or single‑use articles may be stored in a locker room.

(C) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed food; clean equipment, utensils, and linens; and unwrapped single‑service and single‑use articles.

**4‑402 Installation**

**4‑402.11 Fixed Equipment, Spacing, or Sealing.**

(A) Equipment that is fixed in place because it is not easily movable shall be installed so that it is:

(1) Spaced to allow access for cleaning along the sides, behind, and above the equipment;

(2) Spaced from adjoining equipment, walls, and ceilings a distance of not more than one (1) millimeter or one thirty‑second inch; or

(3) Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.

(B) Counter‑mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being:

(1) Sealed; or

(2) Elevated on legs as specified under 4‑402.12(D).

**4‑402.12 Fixed Equipment, Elevation, or Sealing.**

(A) Except as specified in (B) and (C) of this section, floor‑mounted equipment that is not easily movable shall be sealed to the floor or elevated on legs that provide at least a six (6) inches (15 centimeters), of clearance between the floor and the equipment.

(B) If no part of the floor under the floor‑mounted equipment is more than six (6) inches (15 centimeters) from the point of cleaning access, the clearance space may be only four (4) inches (10 centimeters).

(C) This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the consumer shopping areas of a retail food store, if the floor under the units is maintained clean.

(D) Except as specified in (E) of this section, counter‑mounted equipment that is not easily movable shall be elevated on legs that provide at least a four (4) inch (10 centimeters) clearance between the table and the equipment.

(E) The clearance space between the table and counter‑mounted equipment may be:

(1) Three (3) inches (7.5 centimeters) if the horizontal distance of the table top under the equipment is no more than twenty (20) inches (50 centimeters) from the point of access for cleaning; or

(2) Two (2) inches (5 centimeters) if the horizontal distance of the table top under the equipment is no more than three (3) inches (7.5 centimeters) from the point of access for cleaning.

**4‑5 MAINTENANCE AND OPERATION**

**4‑501 Equipment**

**4‑501.11 Good Repair and Proper Adjustment.**

(A) Equipment shall be maintained in a state of repair and condition that meets the requirements specified under 4‑1 and 4‑2.

(B) Equipment components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer’s specifications.

(C) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

**4‑501.12 Cutting Surfaces.**

Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized or discarded if they are not capable of being resurfaced.

**4‑501.14 Warewashing Equipment, Cleaning Frequency.**

A warewashing machine; the compartment(s) of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, raw foods, or laundering wiping cloths; and drainboards or other equipment as specified in 4‑301.13 shall be cleaned:

(A) Before use;

(B) Throughout the day at a frequency necessary to prevent recontamination of equipment and utensils and to ensure that the equipment performs its intended function; and

(C) During use, at least once every twenty‑four (24) hours.

**4‑501.15 Warewashing Machines, Manufacturers**’ **Operating Instructions.**

(A) A warewashing machine and its auxiliary components shall be operated in accordance with the machine’s data plate and other manufacturer’s instructions.

(B) A warewashing machine’s conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer’s specifications.

**4‑501.16 Warewashing Sinks and Food Preparation Sinks, Use Limitation.**

(A) A warewashing sink may not be used for handwashing as specified under 2‑301.15.

(B) If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink shall be cleaned as specified under 4‑501.14 before and after each time it is used to wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified under 4‑7 before and after using the sink to wash produce or thaw food.

**4‑501.17 Warewashing Equipment, Cleaning Agents.**

When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 4‑301.12(C) shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer’s label instructions. Pf

**4‑501.18 Warewashing Equipment, Clean Solutions.**

The wash, rinse, and sanitize solutions shall be maintained clean.

**4‑501.19 Manual Warewashing Equipment, Wash Solution Temperature.**

The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 110 degrees F (43 degrees C) or the temperature as specified on the cleaning agent manufacturer’s label instructions. Pf

**4‑501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.**

(A) The temperature of the wash solution in spray type warewashers that use hot water to sanitize shall not be less than:

(1) For a stationary rack, single temperature machine, 165 degrees F (74 degrees C);Pf

(2) For a stationary rack, dual temperature machine, 150 degrees F (66 degrees C);Pf

(3) For a single tank, conveyor, dual temperature machine, 160 degrees F (71 degrees C);Pf or

(4) For a multitank, conveyor, multitemperature machine, 150 degrees F (66 degrees C).Pf

(B) The temperature of the wash solution in spray‑type warewashers that use chemicals to sanitize may not be less than 120 degrees F (49 degrees C). Pf

**4‑501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.**

If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 171 degrees F (77 degrees C) or above. P

**4‑501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.**

(A) Except as specified in (B) of this section, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than 194 degrees F (90 degrees C) or less than:Pf

(1) For a stationary rack, single temperature machine, 165 degrees F (74 degrees C); Pf or

(2) For all other machines, 180 degrees F (82 degrees C). Pf

(B) The maximum temperature specified under (A) of this section does not apply to the high pressure and temperature systems with wand‑type, hand‑held spraying devices used for in‑place cleaning and sanitizing of equipment such as meat saws.

**4‑501.113 Mechanical Warewashing Equipment, Sanitization Pressure.**

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

**4‑501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization Temperature, pH, Concentration, and Hardness.**

A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified in 4‑703.11(C) shall:

(A) Meet the criteria specified in 7‑204.11;

(B) Be used in accordance with the EPA registered label use instructions; P and

(C) Be used as follows:

(1) A chlorine solution shall have a: P

(a) Minimum temperature of 75 degrees F (24 degrees C).

(b) Concentration between fifty (50) ppm and two hundred (200) ppm.

(2) An iodine solution shall have a:

(a) Minimum temperature of 68 degrees F (20 degrees C). P

(b) Concentration between twelve‑point five (12.5) ppm and twenty‑five (25) ppm. P

(3) A quaternary ammonium compound solution shall:

(a) Have a minimum temperature of 75 degrees F (24 degrees C); P

(b) Have a concentration as specified in 7‑204.11 and as indicated by the manufacturer’s use directions included in the labeling; P and

(c) Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the EPA‑registered label use instructions. P

(D) If another solution of a chemical specified under (C) of this section is used, the permit holder shall demonstrate to the Department that the solution achieves sanitization and the use of the solution shall be approved; P

(E) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be approved by the EPA and applied in accordance with the EPA‑registered label use instructions; P

(F) If a chemical sanitizer is generated by a device located on‑site at the retail food establishment, it shall be used as specified in (A) through (D) of this section and shall be produced by a device that:

(1) Complies with regulations as specified in 2(q)(1) and 12 of the *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*; P

(2) Complies with 40 CFR 152.500, *Requirement for Devices* and 40 CFR 156.10, *Labeling Requirements*; P

(3) Displays the EPA device manufacturing facility registration number on the device, Pf and

(4) Is operated and maintained in accordance with manufacturer’s instructions. Pf

**4‑501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent‑Sanitizers.**

If a detergent‑sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step shall be the same detergent‑sanitizer that is used in the washing step.

**4‑501.116 Warewashing Equipment Determining Chemical Sanitizer Concentration.**

Concentration of the sanitizing solution shall be accurately determined by using a test or other device.Pf

**4‑502 Utensils and Temperature and Pressure Measuring Devices**

**4‑502.11 Good Repair and Calibration**.

(A) Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under 4‑1 and 4‑2 or shall be discarded.

(B) Food temperature measuring devices shall be calibrated in accordance with manufacturer’s specifications as necessary to ensure their accuracy. Pf

(C) Ambient air temperature, water pressure, and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use.

**4‑502.12 Single‑Service and Single‑Use Articles, Required Use.**

A retail food establishment without facilities specified under Section 4‑6 and Section 4‑7 for cleaning and sanitizing kitchenware and tableware shall provide only single‑use kitchenware, single‑service articles, and single‑use articles for use by food employees and single‑service articles for use by consumers. P

**4‑502.13 Single‑Service and Single‑Use Articles, Use Limitations.**

(A) Single‑service and single‑use articles may not be reused.

(B) A bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one (1) inch protruding from the chilled dispenser head.

**4‑502.14 Shells, Use Limitations.**

Mollusk and crustacean shells may not be used more than once as serving containers.

**4‑6 CLEANING OF EQUIPMENT AND UTENSILS**

**4‑601 Objective**

**4‑601.11 Equipment, Food Contact Surfaces, Nonfood Non‑food Contact Surfaces, and Utensils.**

(A) Equipment food contact surfaces and utensils shall be clean to sight and touch. Pf

(B) Food contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.

(C) Non‑food contact surfaces shall be cleaned and kept free of an accumulation of dust, dirt, food residue, and other debris.

**4‑602 Frequency**

**4‑602.11 Equipment Food Contact Surfaces, and Utensils.**

(A) Equipment food contact surfaces and utensils shall be cleaned:

(1) Except as specified in (B) of this section, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry; P

(2) Each time there is a change from working with raw foods to working with ready‑to‑eat foods;P

(3) Between uses with raw fruits and vegetables and with time/temperature control for safety food;P

(4) Before using or storing a food temperature measuring device; P and

(5) At any time during the operation when contamination may have occurred. P

(B) Subparagraph (A)(1) of this section does not apply if the food contact surface or utensil is in contact with a succession of different raw meats and poultry each requiring a higher cooking temperature as specified under 3‑401.11 than the previous type food.

(C) Except as specified in (D) of this section, if used with time/temperature control for safety food, equipment, food-contact surfaces, and utensils shall be cleaned throughout the day at least every four (4) hours.P

(D) Surfaces of utensils and equipment contacting time/temperature control for safety food may be cleaned less frequently than every four (4) hours if:

(1) In storage, containers of time/temperature control for safety food and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;

(2) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:

(a) The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature; and

|  |  |
| --- | --- |
| **Temperature** | **Cleaning Frequency** |
| 5.0C degrees (41F degrees) or less | 24 hours |
| Greater than 5.0C degrees‑ 7.2C degrees  (Greater than 41F degrees‑ 45F degrees) | 20 hours |
| Greater than 7.2C degrees‑ 10.0C degrees  (Greater than 45F degrees‑ 50F degrees) | 16 hours |
| Greater than 10.0C degrees ‑ 12.8C degrees  (Greater than 50F degrees– 55F degrees) | 10 hours |

(b) The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the retail food establishment.

(3) Containers in serving situations such as salad bars, delis, and cafeteria lines holding ready‑to‑eat time/temperature control for safety food that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every twenty‑four (24) hours;

(4) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under Chapter 3;

(5) Equipment is used for storage of packaged or unpackaged food, such as a reach‑in refrigerator, and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues;

(6) The cleaning schedule is based on consideration of:

(a) Characteristics of the equipment and its use,

(b) The type of food involved,

(c) The amount of food residue accumulation, and

(d) The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or

(7) In-use utensils are intermittently stored in a container of water in which the water is maintained at 135 degrees F (57 degrees C) or more, and the utensils and container are cleaned at least every twenty‑four (24) hours or at a frequency necessary to preclude accumulation of soil residues.

(E) Except when dry cleaning methods are used as specified under 4‑603.11, surfaces of utensils and equipment contacting food that is not time/temperature control for safety food shall be cleaned:

(1) At any time when contamination may have occurred;

(2) At least every twenty‑four (24) hours for iced tea dispensers and consumer self‑service utensils such as tongs, scoops, or ladles;

(3) Before restocking consumer self‑service equipment and utensils such as condiment dispensers and display containers; and

(4) In equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment:

(a) At a frequency specified by the manufacturer or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

**4‑602.12 Cooking and Baking Equipment.**

(A) The food-contact surfaces of cooking and baking equipment shall be cleaned at least every twenty‑four (24) hours. This section does not apply to hot oil cooking and filtering equipment if it is cleaned at a frequency specified by the manufacturer or at a frequency to preclude accumulation of soil or mold.

(B) The cavities and door seals of microwave ovens shall be cleaned at least every twenty‑four (24) hours by using the manufacturer’s recommended cleaning procedure.

**4‑602.13 Non‑food-Contact Surfaces.**

Non‑food-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

**4‑603 Methods**

**4‑603.11 Dry Cleaning.**

(A) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not a time/temperature control for safety food.

(B) Cleaning equipment used in dry cleaning food contact surfaces shall not be used for any other purpose.

**4‑603.12 Pre‑cleaning.**

(A) Food debris on equipment and utensils shall be scraped over a waste disposal unit or garbage receptacle or shall be removed in a warewashing machine with a prewash cycle.

(B) If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked, or scrubbed with abrasives.

**4‑603.13 Loading of Soiled Items, Warewashing Machines.**

Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

(A) Exposes all surfaces of the items to the unobstructed spray from all cycles and

(B) Allows the items to drain.

**4‑603.14 Wet Cleaning.**

(A) Equipment food contact surfaces and utensils shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high‑pressure sprays; or ultrasonic devices.

(B) The washing procedures selected shall be based on the type and purpose of the equipment or utensil and on the type of soil to be removed.

**4‑603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.**

If washing in sink compartments or a warewashing machine is impractical, such as when the equipment is fixed in place or the utensils are too large, washing shall be done by using alternative manual warewashing equipment as specified in 4‑301.12(C) and in accordance with the following procedures:

(A) Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts;

(B) Equipment components and utensils shall be scrapped or rough cleaned to remove food particle accumulation; and

(C) Equipment and utensils shall be washed as specified in 4‑603.14(A) to remove soils.

**4‑603.16 Rinsing Procedures.**

Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent‑sanitizer solution by using one of the following procedures:

(A) Use of a distinct, separate water rinse after washing and before sanitizing if using:

(1) A three (3) compartment sink;

(2) Alternative manual warewashing equipment equivalent to a three (3) compartment sink as specified in 4‑301.12(C);

(3) A three (3)‑step washing, rinsing, and sanitizing procedure in a warewashing system for CIP equipment;

(B) Use of a detergent‑sanitizer as specified under 4‑501.115 if using:

(1) Alternative warewashing equipment as specified in 4‑301.12(C) that is approved for use with a detergent‑sanitizer, or

(2) A warewashing system for CIP equipment;

(C) Use of a nondistinct water rinse that is integrated in the hot water sanitization immersion step of a two (2) compartment sink operation;

(D) If using a warewashing machine that does not recycle the sanitizing solution as specified under (E) of this section, or alternative manual warewashing equipment such as sprayers, use a nondistinct water rinse that is:

(1) Integrated in the application of the sanitizing solution and

(2) Wasted immediately after each application; or

(E) If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use a nondistinct water rinse that is integrated in the application of the sanitizing solution.

**4‑7 SANITIZATION OF EQUIPMENT AND UTENSILS**

**4‑701 Objective**

**4‑701.10 Food‑Contact Surfaces and Utensils.**

Equipment food‑contact surfaces and utensils shall be sanitized.

**4‑702 Frequency**

**4‑702.11 Before Use After Cleaning.**

Utensils and food contact surfaces of equipment shall be sanitized before use after cleaning. P

**4‑703 Methods**

**4‑703.11 Hot Water and Chemical.**

After being cleaned, equipment food contact surfaces and utensils shall be sanitized in:

(A) Hot water manual operations by immersion for at least thirty (30) seconds and as specified in 4‑501.111;P

(B) Hot water mechanical operations by being cycled through equipment that is set up as specified under 4‑501.15, 4‑501.112, and 4‑501.113 and achieving a utensil surface temperature of 160 degrees F (71 degrees C) as measured by an irreversible registering temperature indicator; P or

(C) Chemical, manual, or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 4‑501.114. Contact times shall be consistent with those on EPA‑registered label use instructions by providing:

(1) Except as specified under (C)(2) of this section, a contact time of at least ten (10) seconds for a chlorine solution specified under 4‑501.114(C), P

(2) A contact time of at least seven (7) seconds for a chlorine solution of 50 MG/L that has a pH of ten (10.0) or less and a temperature of at least 100 degrees F (38 degrees C) or a pH of eight (8.0) or less and a temperature of at least 75 degrees F (24 degrees C), P

(3) A contact time of at least thirty (30) seconds for other chemical sanitizing solutions, P or

(4) A contact time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in 1‑201.10(B).P

**4‑8 LAUNDERING**

**4‑801 Objective**

**4‑801.11 Linens.**

Clean linens shall be free from food residues and other soiling matter.

**4‑802 Frequency**

**4‑802.11 Specifications.**

(A) Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.

(B) Cloth gloves used as specified in 3‑304.15(D) shall be laundered before being used with a different type of raw animal food such as beef, fish, lamb, pork, or poultry.

(C) Linens that are used as specified in 3‑304.13 and cloth napkins shall be laundered between each use.

(D) Wet wiping cloths shall be laundered daily.

(E) Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

**4‑803 Methods**

**4‑803.11 Storage of Soiled Linens.**

Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single‑service and single‑use articles.

**4‑803.12 Mechanical Washing.**

(A) Except as specified in (B) of this section, linens that come in direct contact with food shall be mechanically laundered.

(B) In retail food establishments in which only wiping cloths are laundered as specified in 4‑301.15 (B), the wiping cloths may be laundered in a mechanical washer, a sink designated only for wiping cloths, or a warewashing or food preparation sink that is cleaned as specified in 4‑501.14.

**4‑803.13 Use of Laundry Facilities.**

(A) Except as specified in (B) of this section, laundry facilities located on the premises of a retail food establishment shall be used only for the washing and drying of items used in the operation of the establishment.

(B) Separate laundry facilities located on the premises for the purpose of general laundering such as institutions providing boarding and lodging may also be used for laundering retail food establishment linens.

**4‑9 PROTECTION OF CLEAN ITEMS**

**4‑901 Drying**

**4‑901.11 Equipment and Utensils, Air‑Drying Required.**

After cleaning and sanitizing, equipment and utensils:

(A) Shall be air‑dried or used after adequate draining as specified in the first paragraph of 40 CFR 180.940, *Tolerance Exemptions for Active and Inert Ingredients for use in Antimicrobial Formulations (Food‑Contact Surface Sanitizing Solutions)* before contact with food; and

(B) May not be cloth dried, except that utensils that have been air‑dried may be polished with cloths that are maintained clean and dry.

**4‑901.12 Wiping Cloths, Air‑Drying Locations.**

Wiping cloths laundered in a retail food establishment that does not have a mechanical clothes dryer as specified in 4‑301.15(B) shall be air‑dried in a location and in a manner that prevents contamination of food, equipment, utensils, linens and single‑service and single‑use articles and the wiping cloths. This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified under 4‑501.114.

**4‑902 Lubricating and Reassembling**

**4‑902.11 Food-Contact Surfaces.**

Lubricants as specified under 7‑205.11 shall be applied to food contact surfaces that require lubrication in a manner that does not contaminate food contact surfaces.

**4‑902.12 Equipment.**

Equipment shall be reassembled so that food contact surfaces are not contaminated.

**4‑903 Storing**

**4‑903.11 Equipment, Utensils, Linens, and Single‑Service and Single‑Use Articles.**

(A) Except as specified in (D) of this section, cleaned equipment and utensils, laundered linens and single‑service and single‑use articles shall be stored:

(1) In a clean, dry location; and

(2) Where they are not exposed to splash, dust, or other contamination; and

(3) At least six (6) inches (15 centimeters) above the floor.

(B) Clean equipment and utensils shall be stored as specified in (A) of this section and shall be stored:

(1) In a self‑draining position that allows for air drying; and

(2) Covered or inverted.

(C) Single‑service and single‑use articles shall be stored as specified under (A) of this section and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(D) Items that are kept in closed packages shall be stored less than six (6) inches (15 centimeters) above the floor on dollies, pallets, racks, and skids that are designed as specified under 4‑204.122.

**4‑903.12 Prohibitions.**

(A) Except as specified in (B) of this section, cleaned and sanitized equipment, utensils, laundered linens, and single‑service and single‑use articles shall not be stored:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) Laundered linens and single‑service and single‑use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

**4‑904 Preventing Contamination**

**4‑904.11 Kitchenware and Tableware.**

(A) Single‑service and single‑use articles and cleaned and sanitized utensils shall be handled, displayed, and dispensed so that contamination of food and lip‑contact surfaces is prevented.

(B) Knives, forks, and spoons that are not pre‑wrapped shall be presented so that only the handles are touched by employees and by consumers if consumer self‑service is provided.

(C) Except as specified in (B) of this section, single‑service articles that are intended for food or lip‑contact shall be furnished for consumer self‑service with the original individual wrapper intact or from an approved dispenser.

**4‑904.12 Soiled and Clean Tableware.**

Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated.

**4‑904.13 Preset Tableware.**

(A) Except as specified in (B) of this section, tableware that is preset shall be protected from contamination by being wrapped, covered, or inverted.

(B) Preset tableware may be exposed if:

(1) Unused settings are removed when a consumer is seated; or

(2) Settings not removed when a consumer is seated are cleaned and sanitized before further use.

**4‑904.14 Rinsing Equipment and Utensils after Cleaning and Sanitizing.**

After being cleaned and sanitized, equipment and utensils shall not be rinsed before air‑drying or use unless:

(A) The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified under 4‑204 and 4‑501 and

(B) The rinse is applied only after the equipment and utensils have been sanitized by the application of hot water or by the application of a chemical sanitizer solution whose EPA registered label use instructions call for rinsing off the sanitizer after it is applied in a commercial warewashing machine.

**Chapter 5 Water, Plumbing, and Waste**

**5‑1 WATER**

**5‑101 Source**

**5‑101.11 Approved System.**

Drinking water shall be obtained from an approved source that is:

(A) An existing public water system P (e.g., municipality);

(B) A new public water system (including a well) constructed for the purpose of serving the retail food establishment that is constructed, maintained, and operated according to R.61‑58, *State Primary Drinking Water Regulation*; P

(1) The owner shall provide the Department with a copy of the public water system *Operating Permit* or *Public Water Supply Construction Permit and Approval to Place into Operation* prior to the issuance of a permit to operate the retail food establishment;

(2) Upon the date of written notification from the Department to the owner/retail food establishment that the water supply to the retail food establishment does not meet acceptable standards for drinking water consumption, the retail food establishment shall immediately cease its food operation; P

(C) An approved water transport vehicle filled from a source that complies with (A) or (B) above;P

(D) An approved water container filled from a source that complies with (A) or (B) above; P or

(E) An on‑premises water storage tank filled from a source that complies with (A) or (B) above.P

**5‑101.12 System Flushing and Disinfection.**

A drinking water system shall be flushed and sampled for the presence of bacteria before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, or a water main break, that may introduce contaminants to the system. P

**5‑101.13 Bottled Drinking Water.**

Bottled drinking water used or sold in a retail food establishment shall be obtained from approved sources in accordance with 21 CFR 129, *Processing and Bottling of Bottled Drinking Water.* P

**5‑102 Quality**

**5‑102.11 Standards.**

Water from a public water system shall meet 40 CFR 141, *National Primary Drinking Water Regulations*, and R.61‑58, *State Primary Drinking Water Regulations*. P

**5‑102.12 Nondrinking Water.**

(A) A nondrinking water supply shall be used only if its use is approved. P

(B) Nondrinking water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, and fire protection. P

**5‑102.13 Sampling**.

Except when used as specified under 5‑102.12, water from a public water system shall be sampled and tested at least annually and as required by R.61‑58, *State Primary Drinking Water Regulations.* Pf

**5‑102.14 Sampling Report.**

The most recent sample report for the public water system shall be maintained as specified by R.61‑58, *State Primary Drinking Water Regulations*.

**5‑103 Quantity and Availability**

**5‑103.11 Capacity.**

(A) The water source and system shall be of sufficient capacity to meet the peak water demands of the retail food establishment. Pf

(B) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the retail food establishment. Pf

**5‑103.12 Pressure.**

Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under 5‑104.12(A) and (B) in response to a temporary interruption of a water supply need not be under pressure. Pf

**5‑104 Distribution, Delivery, and Retention**

**5‑104.11 System.**

Water shall be received from the source through the use of:

(A) An approved public water main; Pf or

(B) One or more of the following that shall be constructed, maintained, and operated according to law: Pf

(1) Water pumps, pipes, hoses, connections, and other appurtenances; Pf

(2) Water transport vehicles; Pf or

(3) Water containers. Pf

**5‑104.12 Alternative Water Supply.**

Water meeting the requirements specified under 5‑101, 5‑102, and 5‑103 shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a retail food establishment with a temporary interruption of its water supply through:

(A) A supply of containers of commercially bottled drinking water; Pf

(B) One or more closed portable water containers; Pf

(C) An enclosed vehicular water tank; Pf

(D) An on‑premises water storage tank; Pf or

(E) Piping, tubing, or hoses connected to an adjacent approved source. Pf

**5‑2 PLUMBING SYSTEM**

**5‑201 Materials**

**5‑201.11 Approved**

(A) A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to the law. P

(B) A water filter shall be made of safe materials. P

**5‑202 Design, Construction, and Installation**

**5‑202.11 Approved System and Cleanable Fixtures.**

(A) A plumbing system shall be designed, constructed, and installed according to law. P

(B) A plumbing fixture such as a handwashing sink, toilet, or urinal shall be easily cleanable.

**5‑202.12 Handwashing Sink, Installation.**

(A) A handwashing sink shall be equipped to provide water at a temperature of at least 100 degrees F (38 degrees C) through a mixing valve or combination faucet. Pf

(B) A steam mixing valve may not be used at a handwashing sink.

(C) A self‑closing, slow‑closing, or metering faucet shall provide a flow of water for at least fifteen (15) seconds without the need to reactivate the faucet.

(D) An automatic handwashing facility shall be installed in accordance with manufacturer’s instructions.

**5‑202.13 Backflow Prevention, Air Gap.**

An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than one (1) inch (25 mm).P

**5‑202.14 Backflow Prevention Device, Design Standard.**

A backflow prevention device installed on the internal water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device. P

**5‑202.15 Conditioning Device, Design.**

A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

**5‑203 Numbers and Capacities**

**5‑203.11 Handwashing Sinks.**

(A) Except as specified in (B) of this section, at least one (1) handwashing sink necessary for their convenient use by employees in areas specified under 5‑204.11 shall be provided. Additional handwashing sinks may be required based on the size and operational flow of the establishment. There shall not be fewer than the number of handwashing sinks required by law.

(B) If approved and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing sinks in a retail food establishment that has a least one (1) handwashing sink.

**5‑203.12 Toilets and Urinals.**

At least one (1) toilet, and not fewer than the toilets required by law, shall be provided. If authorized by law and urinals are substituted for toilets, the substitution shall be done as specified in law.

**5‑203.13 Service Sink.**

(A) At least one (1) service sink or one (1) curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

(B) Toilets and urinals may not be used as a service sink for the disposal of mop water and similar liquid waste.

**5‑203.14 Backflow Prevention Device, When Required.**

A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the retail food establishment, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law, by:

(A) Providing an air gap as specified under 5‑202.13; P or

(B) Installing an approved backflow prevention device as specified under 5‑202.14. P

**5‑203.15 Backflow Prevention Device, Carbonator.**

(A) If not provided with an approved air gap as specified under 5‑202.13, a dual check valve with an intermediate vent preceded by a screen of not less than one hundred (100) mesh to one (1) inch (100 mesh to 25.4 mm) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line. P

(B) A dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified in (A) of this section.

**5‑204 Location and Placement**

**5‑204.11 Handwashing Sinks.**

A handwashing sink shall be located:

(A) To allow convenient use by employees, in food preparation, food dispensing, and warewashing areas; Pf and

(B) In, or immediately adjacent to, toilet rooms. Pf

**5‑204.12 Backflow Prevention Device, Location.**

A backflow prevention device shall be located so that it may be serviced and maintained.

**5‑204.13 Conditioning Device, Location.**

A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

**5‑205 Operation and Maintenance**

**5‑205.11 Using a Handwashing Sink.**

(A) A handwashing sink shall be maintained so that it is accessible at all times for employee use. Pf

(B) A handwashing sink shall not be used for purposes other than handwashing. Pf

(C) An automatic handwashing facility shall be used in accordance with manufacturer’s instructions.Pf

**5‑205.12 Prohibiting a Cross Connection.**

(A) A person may not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality. P

(B) The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water. Pf

**5‑205.13 Scheduling Inspection and Service for a Water System Device.**

A device such as a water treatment device or backflow prevention device shall be scheduled for inspection and service in accordance with manufacturer’s instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge. Pf

**5‑205.14 Water Reservoir of Fogging Devices, Cleaning.**

(A) A reservoir that is used to supply water to a device such as a produce fogger shall be:

(1) Maintained in accordance with manufacturer’s specifications; P and

(2) Cleaned in accordance with manufacturer’s specifications or according to the procedures specified in (B) of this section, whichever is more stringent. P

(B) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

(1) Draining and complete disassembly of the water and aerosol contact parts; P

(2) Brush‑cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution; P

(3) Flushing the complete system with water to remove the detergent solution and particulate accumulation; P and

(4) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/l hypochlorite solution. P

**5.205.15 System Maintained in Good Repair.**

A plumbing system shall be:

(A) Repaired according to lawP and

(B) Maintained in good repair.

**5‑3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT WATER TANK**

**5‑301 Materials**

**5‑301.11 Approved.**

Materials that are used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances shall comply with NSF 372 and shall have a weighted average lead content of 0.25 percent or less and meet either ANSI/NSF Standard 59 or 61.P

**5‑302 Design and Construction**

**5‑302.11 Enclosed System, Sloped to Drain.**

A mobile water tank shall be:

(A) Enclosed from the filling inlet to the discharge outlet and

(B) Sloped to an outlet that allows complete drainage of the tank.

**5‑302.12 Inspection and Cleaning Port, Protected and Secured.**

If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

(A) Flanged upward at least one‑half inch (13 mm) and

(B) Equipped with a port cover assembly that is:

(1) Provided with a gasket and a device for securing the cover in place and

(2) Flanged to overlap the opening and sloped to drain.

**5‑302.13 “V” Type Threads, Use Limitation.**

A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

**5‑302.14 Tank Vent, Protected.**

If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

(A) Sixteen (16) mesh to one (1) inch (25.4 mm) screen or equivalent when the vent is in a protected area or

(B) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

**5‑302.15 Inlet and Outlet, Sloped to Drain.**

(A) A water tank and its inlet and outlet shall be sloped to drain.

(B) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

**5‑302.16 Hose, Construction, and Identification.**

A hose used for conveying drinking water from a water tank shall be:

(A) Safe; P

(B) Durable, corrosion resistant, and nonabsorbent;

(C) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, or decomposition;

(D) Finished with a smooth interior surface; and

(E) Clearly and durably identified as to its use if not permanently attached.

**5‑303 Numbers and Capacities**

**5‑303.11 Filter, Compressed Air.**

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is used to pressurize the water tank system. P

**5‑303.12 Protective Cover or Device.**

A cap and keeper chain, closed cabinet, closed storage tube, or other approved protective cover or device shall be provided for a water inlet, outlet, and hose.

**5‑303.13 Mobile Food Establishment Tank Inlets.**

A mobile food establishment water tank inlet shall be:

(A) Nineteen‑point one (19.1) mm (three‑fourths inch) in inner diameter or less and

(B) Provided with a hose connection of a size or type that will prevent its use for any other service.

**5‑304 Operation and Maintenance**

**5‑304.11 System Flushing and Sanitization.**

A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of non‑use. P

**5‑304.12 Using a Pump and Hoses, Backflow Prevention.**

A person shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

**5‑304.13 Protecting Inlet, Outlet, and Hose Fitting.**

If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified in 5‑303.12.

**5‑304.14 Tank, Pump, and Hoses Dedication.**

(A) Except as specified in (B) of this section, a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose. P

(B) Water tanks, pumps, and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

**5‑4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER**

**5‑401 Mobile Holding Tank**

**5‑401.11 Capacity and Drainage.**

A sewage holding tank in a mobile food establishment shall be:

(A) Sized fifteen (15) percent larger in capacity than the water supply tank; and

(B) Sloped to a drain that is one (1) inch (25 mm) in inner diameter or greater and equipped with a shut‑off valve.

**5‑402 Retention, Drainage, and Delivery**

**5‑402.10 Establishment Drainage System.**

Retail food establishment drainage systems, including grease traps that convey sewage, shall be designed and installed as specified under 5‑202.11(A).

**5‑402.11 Backflow Prevention.**

(A) Except as specified in (B), (C), and (D) of this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed. P

(B) Paragraph (A) of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.

(C) If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within five (5) feet (1.5 m) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

(D) If allowed by law, a warewashing or culinary sink may have a direct connection.

**5‑402.12 Grease Traps and Grease Interceptors.**

If used, a grease trap or grease interceptor shall be located to be easily accessible for cleaning.

(A) Grease Traps.

(1) When required by the sewer purveyor, grease traps shall be located outside to be easily accessible for cleaning and servicing, except when the building is the property line; a grease trap may be installed inside a retail food establishment, provided the grease trap complies as specified in (2), (3), and (4) of this section.

(2) Grease traps shall not be installed in food preparation areas, food storage areas, equipment and utensil washing areas, food dispensing areas, or in areas where food equipment and single‑service articles are stored.

(3) Grease trap servicing hoses and pumps shall not run through food preparation areas, food storage areas, equipment and utensil washing areas, food dispensing areas, or in areas where food equipment and single‑service articles are stored.

(4) Facilities with existing grease traps that are located in food preparation areas, food storage areas, equipment and utensil washing areas, or food dispensing areas, prior to the effective date of this regulation, which require inspection, servicing, or maintenance shall:

(a) Temporarily close for business and shall cease all food preparation and utensils washing activities during inspection, servicing, or maintenance of the grease trap; and

(b) Immediately after inspection, servicing, or maintenance, clean and sanitize the grease trap area and adjacent surfaces before re‑opening for business and resuming food service activities.

(B) Grease Interceptors.

(1) When required by the sewer purveyor, grease interceptors may be installed in food preparation, food storage, equipment, and utensil washing areas.

(2) Grease interceptors on the floor shall have a minimum unobstructed clearance of twenty‑four (24) inches above the interceptors to allow access for servicing and maintenance and shall have a minimum of six (6) inch spacing to walls or adjacent surfaces to allow access for cleaning around the grease interceptor.

(3) Grease interceptors fully recessed or recessed with an extension to floor level shall not have equipment placed on top of the unit and shall have a minimum unobstructed clearance of twenty‑four (24) inches above the grease interceptor, except for floor–mounted equipment that is mobile or portable.

(4) Grease interceptors shall be manually serviced. Grease servicing hoses and pumps are prohibited in food preparation areas, food storage areas, equipment and utensil washing areas, food dispensing areas, or in areas where food equipment and single‑service articles are stored.

(5) Immediately following an inspection, servicing, or maintenance of a grease interceptor located inside a retail food establishment, the grease interceptor and the surrounding area shall be cleaned and sanitized.

**5‑402.13 Conveying Sewage.**

Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law. P

**5‑402.14 Removing Mobile Food Establishment Wastes.**

Sewage and other liquid wastes shall be removed from a mobile food establishment at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created or that sewage is not discharged to the environment. Pf

**5‑402.15 Flushing a Waste Retention Tank.**

A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

**5‑403 Disposal Facility**

**5‑403.11 Approved Sewage Disposal System.**

Sewage shall be disposed through an approved facility that is:

(A) A public sewage treatment plantP or

(B) An individual sewage disposal system that is sized, constructed, maintained, and operated according to law.P

**5‑403.12 Other Liquid Wastes and Rainwater.**

Condensate drainage and other nonsewage liquids and rainwater shall be drained from the point of discharge to disposal according to law.

**5‑5 REFUSE, RECYCLABLES, AND RETURNABLES**

**5‑501 Facilities on the Premises**

**5‑501.10 Indoor Storage Area.**

If located within the retail food establishment, a storage area for refuse, recyclables, and returnables shall meet the requirements specified under 6‑101.11, 6‑201.11 through 6‑201.18, 6‑202.15, and 6‑202.16.

**5‑501.11 Outdoor Storage Surface.**

An outdoor storage surface for refuse, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be smooth, durable, and sloped to drain.

**5‑501.12 Outdoor Enclosure.**

If used, an outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials.

**5‑501.13 Receptacles.**

(A) Except as specified in (B) of this section, receptacles and waste handling units for refuse, recyclables, and returnables, and for use with materials containing food residue shall be durable, cleanable, insect and rodent‑resistant, leakproof, and nonabsorbent.

(B) Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the retail food establishment, or within closed outside receptacles.

**5‑501.15 Outside Receptacles.**

(A) Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the retail food establishment shall be designed and constructed to have tight‑fitting lids, doors, or covers.

(B) Receptacles and waste handling units for refuse and recyclables, such as an on‑site compactor, shall be installed so that accumulation of debris, insect and rodent attraction, and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

**5‑501.16 Storage Areas, Rooms, and Receptacles, Capacity and Availability.**

(A) An inside storage room and area, outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate.

(B) A receptacle shall be provided in each area of the retail food establishment or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.

(C) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

**5‑501.17 Toilet Room Receptacle, Covered.**

A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

**5‑501.18 Cleaning Implements and Supplies.**

(A) Except as specified in (B) of this section, suitable cleaning implements and supplies, such as high pressure pumps, hot water, steam, and detergent, shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.

(B) If approved, off‑premises‑based cleaning services may be used if on‑premises cleaning implements and supplies are not provided.

**5‑501.19 Storage Areas, Redeeming Machines, Receptacles, and Waste Handling Units, Location.**

(A) An area designated for refuse, recyclables, returnables, and, except as specified in (B) of this section, a redeeming machine for recyclables or returnables shall be located so that it is separate from food, equipment, utensils, linens, and single‑service and single‑use articles and a public health hazard or nuisance is not created.

(B) A redeeming machine may be located in the packaged food storage area or consumer area of a retail food establishment if food, equipment, utensils, linens, and single‑service and single‑use articles are not subject to contamination from the machines and a public health hazard or nuisance is not created.

(C) The location of receptacles and waste handling units for refuse, recyclables, and returnables may not create a public health hazard or nuisance or interfere with the cleaning of adjacent space.

**5‑501.110 Storing Refuse, Recyclables, and Returnables.**

Refuse, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

**5‑501.111 Areas, Enclosures, and Receptacles, Good Repair.**

Storage areas, receptacles, and enclosures for refuse, recyclables, or returnables shall be maintained in good repair.

**5‑501.112 Outside Storage Prohibitions.**

(A) Except as specified in (B) of this section, refuse receptacles not meeting the requirements specified under 5‑501.13(A) such as receptacles that are not rodent‑resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue may not be stored outside.

(B) Cardboard or other packaging material that does not contain food residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.

**5‑501.113 Covering Receptacles.**

Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept covered:

(A) Inside the retail food establishment if the receptacles and units:

(1) Contain food residue and are not in continuous use or

(2) After they are filled and

(B) With tight‑fitting lids or doors if kept outside the retail food establishment.

**5‑501.114 Using Drain Plugs.**

Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place.

**5‑501.115 Maintaining Refuse Areas and Enclosures.**

A storage area and enclosure for refuse, recyclables, or returnables shall be maintained free of unnecessary items, as specified under 6‑501.114, and clean.

**5‑501.116 Cleaning Receptacles.**

(A) Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single‑service and single‑use articles, and waste water shall be disposed of as specified under 5‑402.13.

(B) Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

**5‑502 Removal**

**5‑502.11 Frequency.**

Refuse, recyclables, and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

**5‑502.12 Receptacles or Vehicles.**

Refuse, recyclables, and returnables shall be removed from the premises by way of:

(A) Portable receptacles that are constructed and maintained according to law or

(B) A transport vehicle that is constructed, maintained, and operated according to law.

**5‑503 Facilities for Disposal and Recycling**

**5‑503.11 Community or Individual Facility.**

Solid waste not disposed of through the sewage system such as through grinders and pulpers shall be recycled or disposed of in an approved public or private community recycling or refuse facility; or solid waste shall be disposed of in an individual refuse facility, such as a landfill or incinerator, which is sized, constructed, maintained, and operated according to law.

**Chapter 6 Physical Facilities**

**6‑1 MATERIALS FOR CONSTRUCTION AND REPAIR**

**6‑101 Indoor Areas**

**6‑101.11 Surface Characteristics.**

Materials for indoor floor, wall, and ceilings surfaces under conditions of normal use shall be:

(A) Smooth, durable, and easily cleanable for areas where retail food establishment operations are conducted;

(B) Closely woven and easily cleanable carpet for carpeted areas; and

(C) Nonabsorbent for areas subject to moisture such as food preparation areas, walk‑in refrigerators, warewashing areas, toilet rooms, mobile food establishment servicing areas, and areas subject to flushing or spray cleaning methods.

**6‑102 OUTDOOR AREAS**

**6‑102.11 Surface Characteristics.**

(A) The outdoor walking and driving areas shall be surfaced with concrete, asphalt, gravel, or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(B) Exterior surfaces of buildings and mobile food establishments shall be of weather‑resistant materials and shall comply with law.

(C) Outdoor storage areas for refuse, recyclables, or returnables shall be of materials specified under 5‑501.11 and 5‑501.12.

**6‑2 DESIGN, CONSTRUCTION, AND INSTALLATION**

**6‑201 Cleanability**

**6‑201.11 Floors, Walls, and Ceilings.**

Except as specified under 6‑201.14 and except for antislip floor coverings or applications that may be used for safety reasons, floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are smooth and easily cleanable.

**6‑201.12 Floors, Walls, and Ceilings, Utility Lines.**

(A) Utility service lines and pipes may not be unnecessarily exposed.

(B) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

(C) Exposed horizontal utility service lines and pipes may not be installed on the floor.

**6‑201.13 Floor and Wall Junctures, Coved and Enclosed or Sealed.**

(A) In retail food establishments in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than one (1) thirty‑second inch (1 mm).

(B) The floors in retail food establishments in which water flush cleaning methods are used shall be provided with drains and be graded to drain. The floor and wall junctures shall be coved and sealed.

**6‑201.14 Floor Carpeting, Restrictions and Installation.**

(A) A floor covering such as carpeting or similar material may not be installed as a floor covering in food preparation areas, walk‑in refrigerators, warewashing areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(B) If carpeting is installed as a floor covering in areas other than those specified under (A) of this section, it shall be:

(1) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(2) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

**6‑201.15 Floor Covering, Mats and Duckboards.**

Mats and duckboards shall be designed to be removable and easily cleanable.

**6‑201.16 Wall and Ceiling Coverings and Coatings.**

(A) Wall and ceiling covering materials shall be attached so that they are easily cleanable.

(B) Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and sealed to provide a smooth, nonabsorbent, easily cleanable surface.

**6‑201.17 Wall and Ceiling, Attachments.**

(A) Except as specified in (B) of this section, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be easily cleanable.

(B) In a consumer area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.

**6‑201.18 Walls and Ceiling, Studs, Joists, and Rafters.**

Except for temporary food establishments, studs, joists, and rafters may not be exposed in areas subject to moisture.

**6‑202 Functionality**

**6‑202.11 Light Bulbs, Protective Shielding.**

(A) Except as specified in (B) of this section, light bulbs shall be shielded, coated, or otherwise shatter‑resistant in areas where there is exposed food, clean equipment, utensils and linens, or unwrapped single‑service and single‑use articles.

(B) Shielded, coated, or otherwise shatter‑resistant bulbs need not be used in areas used only for storing food in unopened packages, if:

(1) The integrity of the packages cannot be affected by broken glass falling onto them and

(2) The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

(C) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

**6‑202.12 Heating, Ventilating, Air‑conditioning System Vents.**

Heating, ventilating, and air conditioning systems shall be designed and installed so that make‑up air intake and exhaust vents do not cause contamination of food, food‑contact surfaces, equipment, or utensils.

**6‑202.13 Insect Control Devices, Design, and Installation.**

(A) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

(B) Insect control devices shall be installed so that:

(1) The devices are not located over a food preparation area and

(2) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed food, clean equipment, utensils, linens, and unwrapped single‑service and single‑use articles.

**6‑202.14 Toilet Rooms, Enclosed.**

Except where a toilet room is located outside a retail food establishment and does not open directly into the retail food establishment such as a toilet room that is provided by the management of a shopping mall, a toilet room located on the premises shall be completely enclosed and provided with a tight‑fitting and self‑closing door or, for a public access restroom, an alcove opening as approved by local building codes.

**6‑202.15 Outer Openings Protected.**

(A) Except as specified in (B), (C), (E), and under (D) of this section, outer openings of a retail food establishment shall be protected against the entry of insects and rodents by:

(1) Filling or closing the holes and other gaps along floors, walls, and ceiling;

(2) Closed tight‑fitting windows; and

(3) Solid, self‑closing, tight‑fitting doors.

(B) Paragraph (A) of this section does not apply if a retail food establishment opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.

(C) Exterior doors used as exits need not be self‑closing if they are:

(1) Solid and tight‑fitting;

(2) Designated for use, only when an emergency exists, by the fire protection authority that has jurisdiction over the retail food establishment; and

(3) Limited‑use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.

(D) Except as specified in (B) and (E) of this section, if the windows or doors of a retail food establishment or of a larger structure within which a retail food establishment is located, are kept open for ventilation or other purposes the openings shall be protected against the entry of insects and rodents by:

(1) Sixteen (16) mesh to one (1) inch (16 mesh to 25.4 mm) screens;

(2) Properly designed and installed air curtains to control flying insects; or

(3) Other effective means.

(E) Paragraph (D) of this section does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting conditions.

**6‑202.16 Exterior Walls and Roofs, Protective Barrier.**

Perimeter walls and roofs shall effectively protect the retail food establishment from the weather and the entry of insects, rodents, and other animals.

**6‑202.18 Outdoor Servicing Areas, Overhead Protection.**

Except for areas used only for the loading of water or the discharge of sewage and other liquid waste through the use of a closed system of hoses, servicing areas shall be provided with overhead protection.

**6‑202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.**

Exterior walking and driving surfaces shall be graded to drain.

**6‑202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.**

Outdoor refuse areas shall be constructed in accordance with law and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the refuse and from cleaning the area and waste receptacles.

**6‑202.111 Private Residence and Living or Sleeping Quarters, Use Prohibition.**

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting retail food establishment operations. P

**6‑202.112 Living or Sleeping Quarters, Separation.**

Living or sleeping quarters located in the premises of a retail food establishment, such as those provided for lodging registration clerks or resident managers, shall be separated from rooms and areas used for retail food establishment operations by complete partitioning and solid self‑closing doors.

**6‑3 NUMBERS AND CAPACITIES**

**6‑301 Handwashing Sinks**

**6‑301.10 Minimum Number.**

Handwashing sinks shall be provided as specified under 5‑203.11.

**6‑301.11 Handwashing Cleanser, Availability.**

Each handwashing sink or group of two (2) adjacent handwashing sinks shall be provided with a supply of hand cleaning liquid, powder, or bar soap. Pf

**6‑301.12 Hand Drying Provision.**

Each handwashing sink or group of adjacent handwashing sinks shall be provided with:

(A) Individual disposable towels; Pf or

(B) A continuous towel system that supplies the user with a clean towel; Pf or

(C) A heated‑air hand drying device; Pf or

(D) A hand-drying device that employs an air‑knife system that delivers high velocity, pressurized air at ambient temperatures. Pf

**6‑301.13 Handwashing Aids and Devices, Use Restrictions.**

A sink used for food preparation or utensil washing, a service sink, or curbed cleaning facility used for the disposal of mop water or similar wastes may not be provided with the handwashing aids and devices required for a handwashing sink as specified under 5‑501.16(C), 6‑301.11 and 6‑301.12.

**6‑301.14 Handwashing Signage.**

A sign or poster that notifies food employees to wash their hands shall be provided at all handwashing sinks used by food employees and shall be clearly visible to food employees.

**6‑301.20 Disposable Towels, Waste Receptacle.**

A handwashing sink or group of adjacent handwashing sinks that is provided with disposable towels shall be provided with a waste receptacle as specified under 5‑501.16(C).

**6‑302 Toilets and Urinals**

**6‑302.10 Minimum Number.**

Toilets and urinals shall be provided as specified under 5‑203.12.

**6‑302.11 Toilet Tissue, Availability**.

A supply of toilet tissue shall be available at each toilet. Pf

**6‑303 Lighting**

**6‑303.11 Intensity.**

The light intensity shall be:

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

(B) At least twenty (20) foot‑candles (215 lux):

(1) At a surface where food is provided for customer self‑service such as buffets and salad bars or where fresh produce or packaged foods are sold or offered for consumption;

(2) Inside equipment such as reach‑in and under‑counter refrigerators; and

(3) At a distance of thirty (30) inches (75 cm) above the floor in areas used for handwashing, warewashing, and equipment and utensil storage, and in toilet rooms; and

(C) At least fifty (50) foot‑candles (540 lux) at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders, and saws where employee safety is a factor.

**6‑304 Ventilation**

**6‑304.11 Mechanical.**

If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.

**6‑305 Dressings Areas and Lockers**

**6‑305.11 Designation.**

(A) Dressing rooms or dressing areas shall be designated if employees routinely change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be provided for the orderly storage of employees’ clothing and other possessions.

**6‑306 Service Sinks**

**6‑306.10 Availability.**

A service sink or curbed cleaning facility shall be provided as specified in 5‑203.13(A).

**6‑4 LOCATION AND PLACEMENT**

**6‑401 Handwashing Sinks**

**6‑401.10 Conveniently Located.**

Handwashing sinks shall be conveniently located as specified in 5‑204.11.

**6‑402 Toilet Rooms**

**6‑402.11 Convenience and Accessibility.**

Toilet rooms shall be conveniently located and shall be accessible to employees during all hours of operation.

**6‑403 Employee Accommodations**

**6‑403.11 Designated Areas.**

(A) Areas designated for employees to eat, drink, and use tobacco shall be located so that food, equipment, linens, and single‑service and single‑use articles are protected from contamination.

(B) Lockers or other suitable facilities shall be located in a designated room or area where contamination of food, equipment, utensils, linens, and single‑service or single‑use articles can not occur.

**6‑404 Distressed Merchandise**

**6‑404.11 Segregation and Location.**

Products that are held by the permit holder for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from food, equipment, utensils, linens, and single‑service and single‑use articles. Pf

**6‑405 Refuse, Recyclables, and Returnables**

**6‑405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.**

Units, receptacles, and areas designated for storage of refuse and recyclable and returnable containers shall be located as specified under 5‑501.19.

**6‑5 MAINTENANCE AND OPERATION**

**6‑501 Premises, Structures, Attachments, and Fixtures ‑ Methods**

**6‑501.11 Repairing.**

Physical facilities shall be maintained in good repair.

**6‑501.12 Cleaning, Frequency and Restrictions.**

(A) Physical facilities shall be cleaned as often as necessary to keep them clean.

(B) Except for cleaning that is necessary due to a spill or other accident, cleaning shall be done during periods when the least amount of food is exposed, such as after closing.

**6‑501.13 Cleaning Floors, Dustless Methods.**

(A) Except as specified in (B) of this section, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust‑arresting compounds.

(B) Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:

(1) Without the use of dust‑arresting compounds and

(2) In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.

**6‑501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.**

(A) Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

(B) If vented to the outside, ventilation systems may not create a public health hazard, nuisance or unlawful discharge.

**6‑501.15 Cleaning Maintenance Tools, Preventing Contamination.**

Food preparation sinks, handwashing sinks, and warewashing equipment may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes. Pf

**6‑501.16 Drying Mops.**

After use, mops shall be placed in a position that allows them to air‑dry without soiling walls, equipment, or supplies.

**6‑501.17 Absorbent Material on Floors, Use Limitation.**

Except as specified in 6‑501.13(B), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

**6‑501.18 Cleaning of Plumbing Fixtures.**

Plumbing fixtures such as handwashing sinks, toilets, and urinals shall be cleaned as often as necessary to keep them clean.

**6‑501.19 Closing Toilet Room Doors.**

Except during cleaning and maintenance operations, toilet room doors as specified under 6‑202.14 shall be kept closed.

**6‑501.110 Using Dressing Rooms and Lockers.**

(A) Dressing rooms shall be used by employees if the employees regularly change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.

**6‑501.111 Controlling Pests.**

The premises shall be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests shall be controlled to eliminate their presence on the premises by:

(A) Routinely inspecting incoming shipments of food and supplies;

(B) Routinely inspecting the premises for evidence of pests;

(C) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under 7‑202.12, 7‑206.12, and 7‑206.13; Pf and

(D) Eliminating harborage conditions.

**6‑501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.**

Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

**6‑501.113 Storing Maintenance Tools.**

Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

(A) Stored so they do not contaminate food, equipment, utensils, linens, and single‑service and single‑use articles; and

(B) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

**6‑501.114 Maintaining Premises, Unnecessary Items, and Litter.**

The premises shall be free of:

(A) Items that are unnecessary to the operation or maintenance of the establishment such as equipment that is nonfunctional or no longer used; and

(B) Litter.

**6‑501.115 Prohibiting Animals.**

(A) Except as specified in (B) and (C) of this section, live animals may not be allowed on the premises of a retail food establishment. Pf

(B) Live animals may be allowed in the following situations if the contamination of food, clean equipment, utensils, linens, and unwrapped single‑service and single‑use articles can not result:

(1) Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

(2) Patrol dogs accompanying police or security officers in offices, dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

(3) In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals as defined by the *Americans with Disabilities Act* that are controlled by the disabled employee or person, if a health or safety hazard will not result from the presence or activities of the service animal;

(4) Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:

(a) Effective partitioning and self‑closing doors separate the common dining areas from food storage or food preparation areas,

(b) Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present, and

(c) Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and

(5) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals.

(C) Live or dead fish bait may be stored if contamination of food, clean equipment, utensils, linens, and unwrapped single‑service and single‑use articles cannot result.

**Chapter 7 Poisonous or Toxic Materials**

**7‑1 LABELING AND IDENTIFICATION**

**7‑101 Original Containers**

**7‑101.11 Identifying Information, Prominence.**

Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer’s label.Pf

**7‑102 Working Containers**

**7‑102.11 Common Name.**

Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies shall be clearly and individually identified with the common name of the material. Pf

**7‑2 OPERATIONAL SUPPLIES AND APPLICATION**

**7‑201 Storage**

**7‑201.11 Separation.**

Poisonous or toxic materials shall be stored so that they cannot contaminate food, equipment, utensils, linens, and single‑service and single‑use articles by:

(A) Separating the poisonous or toxic materials by spacing or partitioning; P and

(B) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single‑service and single‑use articles. This paragraph does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single‑service and single‑use articles P

**7‑202 Presence and Use**

**7‑202.11 Restriction.**

(A) Only those poisonous or toxic materials that are required for operation and maintenance of the retail food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a retail food establishment. Pf

(B) This requirement does not apply to packaged poisonous or toxic materials and medicines that are offered for retail sale.

**7‑202.12 Conditions of Use.**

Poisonous or toxic materials shall be:

(A) Used according to:

(1) Law and this regulation, and

(2) Manufacturer’s use directions included in labeling, and, for a pesticide, manufacturer’s label instructions that state that use is allowed in a retail food establishment, and P

(3) The conditions of certification, if certification is required, for use of the pest control materials, P and

(4) Additional conditions that may be established by the Department; and

(B) Applied so that:

(1) A hazard to employees or other persons is not constituted, P and

(2) Contamination including toxic residues due to drip, drain, fog, splash, or spray on food, equipment, utensils, linens, and single‑service and single‑use articles is prevented by and for a restricted use pesticide; this is achieved by: P

(a) Removing the items, P

(b) Covering the items with impermeable covers, P or

(c) Taking other appropriate preventive actions, P and

(d) Cleaning and sanitizing equipment and utensils after the application. P

(C) A restricted use pesticide shall be applied only by an applicator certified as defined in 7 USC 136, *Definitions*, *(e)Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act*, or a person under the direct supervision of a certified applicator. Pf

**7‑203 Container Prohibitions**

**7‑203.11 Chemical, Poisonous, or Toxic Material Containers.**

A container previously used to store chemicals, including poisonous or toxic materials, may not be used to store, transport, or dispense food. P

**7‑204 Chemicals**

**7‑204.11 Sanitizers, Criteria.**

Chemical sanitizers, including chemical sanitizing solutions generated on‑site, and other chemical antimicrobials applied to food‑contact surfaces shall:

(A) Meet the requirements specified in 40 CFR 180.940, *Tolerance Exemptions for Active and Inert Ingredients for use in Antimicrobial Formulations (Food‑Contact Surface Sanitizing Solutions*), P or

(B) Meet the requirements as specified in 40 CFR 180.2020, *Pesticide Chemicals Not Requiring a Tolerance or Exemption from Tolerance‑Non‑Food Determinations.* P

**7‑204.12 Chemicals for Washing, Treatment, Storage, and Processing Fruits and Vegetables.**

Chemicals, including those generated on‑site, used to wash or peel raw, whole fruits and vegetables or used in the treatment, storage, and processing of fruits and vegetables shall:

(A) Be an approved food additive listed for this intended use in 21 CFR 173, Por

(B) Be generally recognized as safe (GRAS) for this intended use, P or

(C) Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification), P and

(D) Meet the requirements in 40 CFR 156 *Labeling Requirements for Pesticide and Devices*. P

**7‑204.13 Boiler Water Additives, Criteria.**

Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310, *Boiler Water Additives*. P

**7‑204.14 Drying Agents Criteria.**

Drying agents used in conjunction with sanitization shall:

(A) Contain only components that are listed as one of the following:

(1) Generally recognized as safe for use in food as specified in 21 CFR 182, *Substances Generally Recognized as Safe,* or 21 CFR 184, *Direct Food Substances Affirmed as Generally Recognized as Safe*; P

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186, *Indirect Food Substances Affirmed as Generally Recognized as Safe*; P

(3) Generally recognized as safe for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to food as described in 21 CFR 170.30, *Eligibility for Classification as Generally Recognized as Safe (GRAS*);P

(4) Subject of an effective *Food Contact Notification* as described in the *Federal Food Drug and Cosmetic Act (FFDCA)* Section 409(h),P

(5) Approved for use as a drying agent under a prior sanction as described in the *Federal Food Drug and Cosmetic Act (FFDCA)* 201(s)(4)), P

(6) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 174 through 178,P or

(7) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39, *Threshold of regulation for substances used in food‑contact articles*; P and

(B) When sanitization is with chemicals, the approval required under (A)(5) or (A)(7) of this section or the regulation as an indirect food additive required under (A)(6) of this section shall be specifically for use with chemical sanitizing solutions. P

**7‑205 Lubricants**

**7‑205.11 Incidental Food Contact, Criteria.**

Lubricants shall meet the requirements specified in 21 CFR 178.3570, *Lubricants with Incidental Food Contact*, if they are used on food contact surfaces, on bearings and gears located on or within food contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food contact surfaces. P

**7‑206 Pesticides**

**7‑206.11 Restricted Use Pesticides, Criteria.**

Restricted use pesticides specified in 7‑202.12(C) shall meet the requirements specified in 40 CFR 152, Subpart I, *Classification of Pesticides*. P

**7‑206.12 Rodent Bait Stations.**

Rodent bait shall be contained in a covered, tamper‑resistant bait station. P

**7‑206.13 Tracking Powders, Pest Control, and Monitoring.**

(A) Except as specified in (B) of this section, a tracking powder may not be used in retail food establishments. P

(B) If used, a nontoxic tracking powder, such as talcum or flour, may not contaminate food, equipment, utensils, linens, and single‑service and single‑use articles.

**7‑207 Medicines**

**7‑207.11 Restriction and Storage.**

(A) Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a retail food establishment. Pf

(B) Medicines that are in a retail food establishment for the employees’ use shall be labeled as specified under 7‑101.11 and located to prevent the contamination of food, equipment, utensils, linens, and single‑service and single‑use articles.P

**7‑207.12 Refrigerated Medicines, Storage.**

Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

(A) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; P and

(B) Located so they are inaccessible to children. P

**7‑208 First Aid Supplies**

**7‑208.11 Storage.**

First aid supplies that are in a retail food establishment for the employees’ use shall be:

(A) Labeled as specified under 7‑101.11 Pf and

(B) Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, linens, and single‑service and single‑use articles. P

**7‑209 Other Personal Care Items**

**7‑209.11 Storage.**

Except as specified under 7‑207.12 and 7‑208.11, employees shall store their personal care items in facilities as specified under 6‑305.11(B).

**7‑3 STOCK AND RETAIL SALE**

**7‑301 Storage and Display**

**7‑301.11 Separation.**

Poisonous or toxic materials shall be stored and displayed for retail sale so they cannot contaminate food, equipment, utensils, linens, and single‑service and single‑use articles by:

(A) Separating the poisonous or toxic materials by spacing or partitioning P and

(B) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single‑service or single‑use articles. P

**Chapter 8 Compliance and Enforcement**

**8‑1 REGULATION APPLICABILITY**

**8‑101 Use for Intended Purpose**

**8‑101.10 Public Health Protection.**

Retail food establishments in operation prior to the effective date of this regulation and in compliance with the previous regulation, but which do not fully comply with all the construction, equipment, and physical requirements of this regulation, shall be deemed acceptable provided the facilities and equipment:

(A) Are capable of being maintained in a sanitary condition;

(B) Are not a public health hazard or nuisance; and

(C) Are replaced in the normal course of operation with equipment and facilities that meet the requirements of this regulation.

(D) This section shall not apply to equipment installed or construction begun after the effective date of this regulation.

**8‑102 Additional Requirements**

**8‑102.10 Preventing Health Hazards, Provision for Conditions Not Addressed.**

(A) If necessary to protect against public health hazards or nuisances, the Department may impose specific requirements that are authorized by law in addition to the requirements contained in this regulation.

(B) The Department shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the permit applicant or permit holder and a copy shall be maintained in the Department file for the retail food establishment.

**8‑103 Variances**

**8‑103.10 Modifications and Waivers.**

(A) The Department may grant a variance by modifying or waiving the requirements of this regulation if, in the opinion of the Department, a health hazard or nuisance will not result from the variance. If a variance is granted, the Department shall retain the information specified under 8‑103.11 in its records for the retail food establishment.

(B) When a retail food establishment desires to use a construction procedure inconsistent with the regulation or use materials and/or equipment other than specified in this regulation, a variance may be requested from the Department. Such a request must:

(1) Be submitted in writing,

(2) Include a description of the material(s), equipment, and/or construction procedure(s) proposed, and

(3) Identify the material, equipment and/or procedure required by the regulation, and include proof of equivalency.

(C) The Department shall only consider a complete request for approval of a variance. The Department’s decision on such a variance will be final.

**8‑103.11 Documentation of Proposed Variance and Justification.**

Before a variance from a requirement of this regulation is approved, the information provided by the retail food establishment requesting the variance and retained in the Department’s file shall include:

(A) A statement of the proposed variance of this regulation requirement citing relevant regulation section(s);P

(B) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant regulation sections will be alternatively addressed by the proposal; P and

(C) A HACCP plan if required as specified under 8‑201.13(A) that includes the information specified under 8‑201.14 as it is relevant to the variance requested. Pf

**8‑103.12 Conformance with Approved Procedures.**

If the Department grants a variance as specified in 8‑103.10 or a HACCP plan is otherwise required as specified under 8‑201.13, the permit holder shall:

(A) Comply with the HACCP plans and procedures that are submitted as specified under 8‑201.14 and approved as a basis for the modification or waiver; P and

(B) Maintain and provide to the Department, upon request, records specified under 8‑201.14(D) and (E) that demonstrate that the following are routinely employed:

(1) Procedures for monitoring the critical control points, Pf

(2) Monitoring of the critical control points, Pf

(3) Verification of the effectiveness of the operation or process, Pf and

(4) Necessary corrective actions if there is failure at a critical control point. Pf

**8‑2 PLAN SUBMISSION AND APPROVAL**

**8‑201 Operating Plans**

**8‑201.13 When a HACCP Plan is Required.**

(A) Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the Department for approval a properly prepared HACCP plan as specified under 8‑201.14 and the relevant provisions of this regulation if:

(1) Submission of a HACCP plan is required by a section of this regulation;

(2) A variance is required as specified under 3‑401.11(D)(4) and 3‑502.11;

(3) The Department determines that a food preparation or processing method requires a variance based on a plan submittal, an inspectional finding, or a variance request.

(B) Before engaging in reduced oxygen packaging without a variance as specified under 3‑502.12, a permit applicant or permit holder shall submit a properly prepared HACCP plan to the Department.

**8‑201.14 Contents of a HACCP Plan.**

For a retail food establishment that is required under 8‑201.13 to have a HACCP plan, the permit applicant or permit holder shall submit to the Department a properly prepared HACCP plan that includes:

(A) The name of the permit applicant or permit holder, the retail food establishment address, and contact information;

(B) A categorization of the types of time/temperature control for safety foods that are to be controlled under the HACCP plan; Pf

(C) A flow diagram or chart for each specific food or category type that identifies:

(1) Each step in the process; Pf

(2) The hazards and controls for each step in the flow diagram or chart; Pf

(3) The steps that are critical control points; Pf

(4) Ingredients, materials, and equipment used in the preparation of that food;Pf and

(5) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved. Pf

(D) A critical control points summary for each specific food or category type that clearly identifies:

(1) Each critical control point, Pf

(2) The critical limits for each critical control point, Pf

(3) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge, Pf

(4) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring each critical control point, Pf

(5) Action to be taken by the designated food employee or person in charge if the critical limits for each critical control point are not met, Pf and

(6) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed; Pf and

(E) Supporting documents including:

(1) Food employee and supervisory training plan that addresses the food safety issues of concern;Pf

(2) Copies of blank record forms that are necessary to implement the HACCP plan; Pf and

(3) Additional scientific data or other information, as required by the Department, supporting the determination that food safety is not compromised by the proposal; Pf and

(F) Any other information required by the Department.

**8‑203 Construction Inspection and Approval**

**8‑203.10 Preoperational Inspections.**

The Department shall conduct preoperational inspection(s) to verify that the retail food establishment is constructed and equipped in accordance with this regulation. The permit holder or representative of the permit holder must request the preoperational inspection fourteen (14) days prior to an inspection to issue a permit.

**8‑3 PERMIT TO OPERATE**

**8‑301 Requirement**

**8‑301.11 Prerequisite for Operation.**

(A) No person shall operate a retail food establishment without a valid permit to operate issued by the Department. Pf

(B) Only a person who complies with the requirements of this regulation shall be entitled to receive and retain such a permit.

(C) The permit shall be kept in the retail food establishment and shall be accessible at all times.

**8‑301.12 Retail Food Establishment Permits Not Required.**

(A) The following establishments shall not be required to have a permit from the Department:

(1) Churches or charitable organizations where the food service is limited to members and their invited guests.

(2) Churches or charitable organizations who prepare and serve food to the public on their own premises at one function a month or not more than twelve functions a year.

(3) Food service such as soup kitchens and food banks operated by organizations that are providing food at no cost and not for profit or gain to the public who are in need of food assistance.

(4) A bed and breakfast with 10 or fewer rental rooms and a residential kitchen that provides food service.

(5) Retail food establishments or facilities located on United States Government property and regulated by federal authorities.

(6) Retail food establishments or facilities operated by the United States Government.

(7) Retail food establishments or facilities serving solely as commissaries for interstate carriers.

(8) Retail food establishments or facilities on vehicles or common carriers for hire such as airplanes, trains (including maintenance crew cook cars), ships, and other similar conveyances.

(9) Retail food establishments or facilities governed by other regulations when such regulations are determined by the Department to be satisfactory.

(10) Food from retail food establishments outside the jurisdiction of the Department or the State of South Carolina which is sold within the State of South Carolina if such retail food establishments conform to the provisions of this regulation or to substantially equivalent provisions. To determine the extent of compliance with such provisions, the Department may accept reports from responsible authorities in other jurisdictions where such retail food establishments are located.

(11) Bake sales operated by churches or charitable organizations where homemade cakes, breads, and cookies may be offered for sale only if they are not time/temperature control for safety foods.

(12) Home Based Food Production Operations, which prepare non‑time/temperature control for safety foods, such as homemade cakes, breads, cookies, and candy, in a private residence kitchen for sale directly to the end consumer.

(13) Boarding houses which provide room and board, which restrict food service to residents only, and do not provide food service to the non‑renting public.

(14) Hunt lodges and outdoor‑adventure tours that provide room and board as part of a package, and food service is restricted to participants only.

(15) Motels and hotels that prepare non‑time/temperature control for safety food breakfast foods or serve pre‑packaged food.

(16) Taverns that are primarily engaged in the sale of alcoholic beverages and do not engage in the preparation of food.

(17) Cooking schools or classes where registered students are active participants in preparing the food and are the exclusive consumers of the foods prepared.

(18) Personal chefs that are employed to cook for the owner and occupants of a private residence and their guests. A personal chef may purchase the food and shall prepare, cook and serve the food at the private residence only.

(19) Businesses that serve the following non‑time/temperature control for safety foods that use a low risk food process:

(a) Popcorn, cotton candy, candy apples;

(b) Snocones or shaved ice;

(c) Soft drinks or beverages;

(d) Nachos served with heated cheese product;

(e) Commercially dehydrated pre‑packaged pork skins;

(f) Pre‑formed or prepared pretzels that require baking or warming only; or

(g) Other Department‑approved non‑time/temperature control for safety foods that use a low risk food process.

(20) An individual, operating out of the individual’s dwelling, who prepares and sells the following non‑time/temperature control for safety foods that use a low risk food process:

(a) Jams, jellies, preserves, and dried fruits

(b) Dry herbs, seasonings, and mixtures

(c) Vinegar and flavored vinegars

(d) Other Department‑approved non‑time/temperature control for safety foods that use a low risk food process.

The preparation and sale of food items which present a food safety risk such as acidified foods, low acid canned foods, garlic in oil, and fresh fruit or vegetable juices are not exempt from permitting under this provision.

(21) Businesses that serve the following low risk food processes of time/temperature control for safety foods:

(a) Coffee or coffee based beverages served with pasteurized milk or cream prepared and served either heated or cold.

(b) Beverages individually prepared upon consumer’s request from a commercially pre‑packaged powdered mix with no additional ingredients that are time/temperature control for safety foods, and served in a single service cup;

(c) Commercially pre‑packaged, pre‑cut frozen french fries;

(d) Salt boiled peanuts;

(e) Boiled or grilled corn;

(f) Snow cones or shaved ice served with pasteurized cold milk or cream from a non‑reusable container;

(g) Waffle or pancake mix that is commercially pre‑packaged and dispensed from self‑serve units for service not to exceed four (4) hours in duration. Leftover portions of these products shall be discarded at the end of service; and

(h) Funnel cakes, minidonuts, or similar type products prepared from a single unit having no more than three fryers. Mixed batters shall not be held out of temperature more than four (4) hours. Leftover portions of these products shall be discarded at the end of service.

For the purpose of 8‑301.12(A)(21), the low risk food processes of time/temperature control for safety foods shall not include meat, poultry, fish, or game animals.

(22) Convenience stores or other businesses that offer for sale only pre‑packaged food from a food processing plant.

(23) Vending machines that provide only pre‑packaged food from a food processing plant.

(B) The Department may require a facility to submit information sufficient to determine if the facility is exempt from the permit requirement or must apply for and obtain a retail food establishment permit. This information may include, but is not limited to, designation of charitable status, leases or proof of ownership, equipment specifications, menus, ingredient lists, food packaging, and food preparation methods.

(C) Although the establishments listed in 8‑301.12(A) do not require a permit, the Department retains the authority to conduct an investigation in response to a complaint. The Department may require corrective action and issue orders as deemed necessary in response to food safety or health risks identified during the investigation.

**8‑302 Application Procedure**

**8‑302.11 Submission Thirty (30) Calendar Days Before Proposed Opening.**

An applicant shall submit a complete application for a permit at least thirty (30) calendar days before the date planned for opening a retail food establishment except as specified in 8‑303.20 (A)(1).

**8‑302.12 Form of Submission.**

A person desiring to operate a retail food establishment shall submit to the Department a written application for a permit on a form provided by the Department.

**8‑302.13 Qualifications and Responsibilities of Applicants.**

To qualify for a permit, an applicant shall:

(A) Be an owner of the proposed retail food establishment or an officer of the legal entity owning the proposed retail food establishment;

(B) Comply with the requirements of this regulation;

(C) As specified under 8‑402.11, agree to allow access to the retail food establishment and to provide required information; and

(D) Pay the applicable Initial Permit/First Year Operational fee of one hundred dollars ($100.00) plus the applicable annual inspection fee for the anticipated gross sales of food and food products as identified in the table in section 8‑304.11(A)(3) at the time the application is submitted. The fee shall be paid prior to the issuance of the permit.

**8‑302.14 Contents of the Application.**

(A) The following application documentation shall be submitted as part of the application process:

(1) A complete retail food establishment application and any applicable supplement form(s);

(2) Menu or list of foods to be served;

(3) Anticipated volume of food to be stored, prepared, and sold or served;

(4) Approval of variances;

(5) Verification of approved drinking water supply;

(6) Verification of approved method of sewage disposal;

(7) Documentation that the construction of this facility meets the standards set forth in this regulation and all other applicable regulations and codes;

(8) For new facilities, based on facility type, proposed layout, mechanical schematics, construction materials, and finish schedules to comply with the applicable sections of the regulation;

(9) For new facilities, based on facility type, proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications to comply with the applicable sections of the regulation;

(10) Documentation of completed training if required.

(B) Only when an application has been submitted, is considered complete, and the applicable inspection fee has been paid, may the applicant request a preoperational inspection for the proposed retail food establishment.

(C) If at any time during the preoperational inspection the information provided during the application process changes or is altered, the Department may require a new application to be submitted.

(D) The Department shall not issue a permit until the facility is in full compliance with the requirements of this regulation.

(E) The Department may deny a new permit based on past compliance or enforcement history.

**8‑303 Issuance**

**8‑303.10 New, Converted, or Remodeled Establishments.**

The Department shall issue a permit to the applicant only after the following are submitted or completed:

(A) A properly completed application;

(B) Documentation that the construction of this facility meets the standards set forth in this regulation and all other applicable regulations and codes; and

(C) A preoperational inspection as specified in 8‑203.10 shows that the establishment is built or remodeled in accordance with this regulation.

**8‑303.20 Existing Establishments and Change of Ownership.**

(A) Routine Change of Ownership.

(1) When a retail food establishment is in the process of changing ownership, the Department shall be notified immediately.

(2) Within fifteen (15) calendar days from the date of the change of ownership, the new owner shall submit a complete application for a new permit as required in 8‑302.12 and pay applicable Department fees as provided in 8‑302.13(D).

(3) The Department shall review the application for a change of ownership, and

(a) If the Department determines, pursuant to 8‑304.11, the new owner is making changes to the existing permit operations, the change of ownership protocol shall not apply; and

(b) The retail food establishment shall then be subject to all requirements of 8‑303.10; and

(c) The facility may be required to close while changes to the facility are evaluated for compliance with the requirements of the regulation. Failure to cease operations and close the facility as required by the Department during evaluation of changes to existing permit operations will constitute operation of a retail food establishment without a permit in violation of this regulation. The facility must remain closed unless and until a new permit is issued to the facility.

(4) Upon receipt of a complete application, the Department will conduct an inspection to determine compliance with Regulation 61‑25. A permit shall not be issued to a retail food establishment for a change of ownership if:

(a) The retail food establishment has conditions that constitute an imminent health hazard;

(b) Has any priority or priority foundation violations; or

(c) Has a score of 87 or below.

(5) If the new owner fails to submit a complete and timely application, fails to pay applicable fees under (A)(2) of this section, or fails to obtain compliance at the permit inspection under (A)(4)(a) of this section, the retail food establishment shall cease and close all food operations immediately. Any continued operation of the facility will constitute operation of a retail food establishment without a permit in violation of this regulation. The facility must remain closed until a new permit is issued to the facility.

(6) If the new owner fails to obtain compliance at the permit inspection under (A)(4)(b) or (A)(4)(c), the retail food establishment may continue food operations for a time period not to exceed fifteen (15) calendar days. The retail food establishment must obtain compliance at a follow‑up permit inspection during the fifteen (15) day period. If the new owner fails to obtain compliance within the fifteen (15) day period, the retail food establishment shall cease and close all food operations immediately. Any continued operation of the facility will constitute operation of a retail food establishment without a permit in violation of this regulation. The facility must remain closed until a new permit is issued to the facility.

(7) Within ninety (90) calendar days of the permitted change of ownership, the retail food establishment shall be in full compliance with 5‑103.11, 5‑203.11, 5‑203.13, and 5‑204.12 of this regulation.

(a) Failure to comply with this requirement will result in permit suspension and

(b) The permit will then remain suspended until the retail food establishment obtains full compliance with all parts of this regulation.

(B) Change of Ownership in Facilities under Enforcement Action.

(1) Retail food establishments under enforcement action are not eligible for a change of ownership protocol as stated in section (A) above.

(2) A person who wants to take ownership of a retail food establishment under enforcement action shall apply for a new permit and shall provide documentation that demonstrates a bona fide change of ownership. This documentation includes, but is not limited to, a bill of sale for the business, a new lease or bill of sale for the building, a new business or liquor license, or applications for these licenses in the new owner’s name, and documentation of management and staffing changes the new owner proposes.

(3) If the Department determines that the change of ownership is bona fide, the Department shall notify the new owner in writing that the retail food establishment is subject to a pending enforcement action and that any and all actions necessary to satisfy the enforcement action must be completed before the Department will issue a permit to the new applicant.

(4) If the Department determines that the change of ownership is not bona fide, the Department shall return the permit application and the inspection fee to the applicant and shall notify the applicant in writing that the retail food establishment is subject to a pending enforcement action and that any and all actions necessary to satisfy the enforcement action must be completed before the Department will process an application for a new permit.

**8‑303.30 Denial of Application for Permit, Notice.**

If an application for a permit to operate is denied, the Department shall provide the applicant with a notice that includes:

(A) The specific reasons and regulation citations for the permit denial;

(B) The actions, if any, that the applicant must take to qualify for a permit.

**8‑304 Conditions of Retention**

**8‑304.10 Responsibilities of the Department.**

(A) At the time a permit is first issued, the permit holder shall demonstrate access to a copy of this regulation and that the permit holder is knowledgeable of the compliance requirements and the conditions of retention, as specified under 8‑304.11, that are applicable to the permit.

(B) Failure to provide the information specified in (A) of this section does not prevent the Department from taking authorized action or seeking remedies if the permit holder fails to comply with this regulation or an order, warning, or directive of the Department.

**8‑304.11 Requirement to Comply with Regulation and Conditions of Permit.**

(A) Once a permit has been issued by the Department, the permit holder, in order to retain the permit, shall:

(1) Comply with the provisions of this regulation and all terms and conditions stated on the permit document;

(2) As specified under 8‑402.11, agree to allow the Department access to the retail food establishment and to provide required information; and

(3) Pay to the Department annual inspection fees as follows:

(a) Annually, each retail food establishment shall determine and pay to the Department the applicable inspection fee, based on the gross sales of food and food products for the facility’s previous business year, using the table below. As provided in 8‑302.13(D), a person or facility applying for an Initial/First Year Operational Permit or change of ownership for a retail food establishment shall determine and pay to the Department the applicable inspection fee using the table below, based on anticipated gross sales of food and food products during the facility’s first year of operations. Payment shall be due thirty (30) days from the Department billing date. A penalty charge of fifty dollars ($50.00) shall be assessed for fees that are thirty (30) days past due. A second penalty charge of fifty dollars ($50.00) shall be assessed for fees that are sixty (60) days past due. Permit holders of retail food establishments shall furnish previous business year sales information upon request of the Department. This information shall be exempt from disclosure pursuant to the South Carolina Freedom of Information Act, S.C. Code Section 30‑4‑40(a)(2).

|  |  |
| --- | --- |
| Sales | Fee |
| $0‑$250,000 | $100.00 |
| $250,000 ‑ $500,000 | $150.00 |
| $500,000‑ $750,000 | $200.00 |
| $750,000‑ $1,000,000 | $250.00 |
| $1,000,000 ‑ $1,250,000 | $300.00 |
| $1,250,000 ‑ $1,500,000 | $350.00 |
| $1,500,000 ‑ $1,750,000 | $400.00 |
| $1,750,000 and above | $450.00 |

(b) Failure to meet the requirements of 8‑304.11(A)(3)(a) will result in initial permits not being issued or existing permits being suspended. Retail food establishments that have not paid their inspection fee and late payment penalties after ninety (90) days from the original billing date shall have their permit suspended following service of notice of suspension. The Department may reinstate a permit suspended for failure to pay renewal fees upon payment of the fees, penalties, and a $25.00 reinstatement fee.

(c) The following retail food establishments shall be exempt from fees:

(i) Retail food establishments that are operated by a public or private school (kindergarten through grade twelve) or that are operated by a child care facility that is licensed and inspected by the Department of Social Services.

(ii) Retail food establishments operated by health care facilities that are regulated and inspected by the Department.

(iii) Retail food establishments operated by other state agencies or local governments that provide food for patients, clients, or inmates.

(iv) Retail food establishments operated by non‑profit organizations for the purpose of providing meals or food to needy persons at little or no cost, or for the purpose of raising money for a charitable cause. Non‑profit organizations claiming exemption from fee charges shall certify annually to the Department that the organization meets these criteria and, upon request, provide documentation supporting any such certification.

(4) Have access to and knowledge of this regulation. Copies may be viewed on the Department website.

(5) Operate as a retail food establishment (serve or sell food) for no less than fifteen (15) consecutive days annually, or be in operation for at least one (1) day a week for no less than fifteen (15) weeks annually.

(B) The Department shall be notified prior to any retail food establishment changes including, but not limited to, the following items:

(1) Location;

(2) Service or seating capacity;

(3) Drinking water or sewage disposal provider;

(4) Change of hot water generation and distribution system(s);

(5) Change of ownership;

(6) Permanent closure;

(7) Installation of equipment and/or structural modifications;

(8) A corrected billing or mailing address within ten (10) calendar days of any change of address;

(9) Shared use operations capacity.

(C) The Department shall be notified prior to adding a food item to the menu that:

(1) Involves a food preparation process which may consist of cooking, cooling, or reheating food which was not performed in the retail food establishment or

(2) Poses a health risk to consumers because it is a raw animal food served raw or undercooked.

(D) Once the Department is notified or becomes aware of changes under (B)or (C) of this section, the Department may amend the permit and may require additional changes as required by this regulation.

(E) Any change under (B) or (C) of this section, not previously approved or authorized by the Department, may subject the retail food establishment to enforcement action, including, but not limited to, civil penalties, permit suspension, permit revocation, or a combination of these.

**8‑304.20 Permits Not Transferable.**

A permit may not be transferred:

(A) From one person or legal entity to another person or legal entity,

(B) From one retail food establishment to another, or

(C) From one type of operation to another if the food operation changes from the type of operation specified in the application and the change in operation is not approved or authorized.

**8‑4 INSPECTION AND CORRECTION OF VIOLATIONS**

**8‑402 Access**

**8‑402.11 Access.**

(A) The Department staff, after proper identification, shall be allowed to enter any retail food establishment at any time the establishment is occupied for the purpose of making an announced, unannounced, or complaint inspection(s) to determine compliance with this regulation.

(B) The Department staff shall be allowed to examine all areas of the facility and all records of the retail food establishment to obtain information pertaining to equipment, food, or supplies purchased, received, or used.

**8‑402.20 Refusal, Notification of Right to Access, and Final Request for Access.**

If a person denies access to the Department, the Department shall inform the person that:

(A) The permit holder is required to allow access by Department as specified under 8‑402.11 of this regulation,

(B) Access is a condition of the acceptance and retention of a retail food establishment permit to operate as specified under 8‑304.11, and

(C) If access is denied, the Department may issue an order for access pursuant to 8‑402.11, obtain a warrant, or pursue access as allowed by other applicable laws.

**8‑402.30 Refusal, Reporting.**

If after the Department presents credentials as specified under 8‑402.11, explains the authority upon which access is required, and the person in charge continues to refuse access, the Department shall provide details of the denial of access on an inspection report form.

**8‑402.40 Order to Gain Access.**

If, after an order has been issued by the Department pursuant to 8‑402.20(C), the Department is denied access to a retail food establishment for an authorized purpose, the Department may initiate enforcement action including assessment of civil penalties, permit suspension, and/or permit revocation as provided in 8‑904.110 and 8‑913.10.

**8‑403 Report of Findings**

**8‑403.10 Documenting Information and Observations.**

(A) The findings shall be recorded on the inspection report, and upon completion of the inspection, the weighted sum of the items in violation shall be totaled and subtracted from one hundred (100) to determine the numerical score.

(B) The Department may use whatever means necessary to record violations, including, but not limited to, electronic inspection programs, manual inspection forms, photographs, video, and printed materials.

(C) Grades of permitted retail food establishments shall be as follows:

(1) Grade A ‑ A permitted retail food establishment having a rating score of eighty‑eight to one hundred (88‑100) points.

(2) Grade B ‑ A permitted retail food establishment having a rating score of seventy eight to eighty seven (78‑87) points.

(3) Grade C ‑ A permitted retail food establishment having a rating score of seventy‑seven (77) or less points.

(D) Immediately following each inspection, the Department shall post the appropriate grade decal in the retail food establishment, and shall furnish a copy of the completed inspection report to the permit holder, person in charge, or an employee of the retail food establishment.

(E) A grade decal shall be posted by the Department in a location that is conspicuous to consumers. The retail food establishment shall not obscure, cover, deface, relocate, or remove the posted grade decal.

(F) Notwithstanding the grade criteria established in (C) of this section, when a consecutive violation is discovered, the Department may:

(1) Schedule appropriate follow‑up inspections as specified in 8‑405.11; or

(2) Downgrade the retail food establishment to the next lower grade; or

(3) Suspend the permit.

(G) Notwithstanding the grade criteria established in (C) of this section, there are circumstances and conditions under which the grade decal posted may differ from the numerical score of the inspection report:

(1) When the retail food establishment is under enforcement action; or

(2) When the retail food establishment has a consecutive violation(s).

(3) When, in accordance with S.C. Code Ann. Section 1‑23‑370, the retail food establishment is under the following pending enforcement actions,

(a) Imminent health hazard,

(b) Permit suspension, or

(c) Permit revocation.

(H) The permit holder or operator of any retail food establishment in which the grade has been lowered may request an inspection for the purpose of re‑grading the retail food establishment. The request shall include a signed statement by the permit holder, person in charge, or employee that all violations have been corrected. The Department shall respond to the request within ten (10) calendar days.

**8‑403.20 Specifying Time Frame for Corrections.**

The Department shall specify on the inspection report form the time frame for correction of the violations as specified under 8‑404.11 and 8‑405.11.

**8‑403.30 Issuing Report and Obtaining Acknowledgment of Receipt.**

A copy of the completed inspection report form shall be furnished to the permit holder, person in charge, or an employee at the conclusion of the inspection. The report may be furnished in either electronic or printed form.

**8‑403.40 Refusal to Sign Acknowledgement.**

The Department shall inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in 8‑403.30 that:

(A) An acknowledgment of receipt is not an agreement with findings;

(B) Refusal to sign an acknowledgment of receipt will not affect the permit holder’s obligation to correct the violations noted in the inspection report within the time frames specified; and

(C) Refusal to sign an acknowledgment of receipt is noted in the inspection report and maintained in the Department’s record for the retail food establishment.

**8‑403.50 Public Information.**

The Department shall treat inspection reports as public documents and shall make them available for disclosure to persons upon request as provided in law.

**8‑404 Imminent Health Hazard**

**8‑404.11 Imminent Health Hazard.**

(A) The Department, without prior notice or hearing, may suspend the permit to operate a retail food establishment when it is determined that the operation of the retail food establishment constitutes an imminent health hazard to public health except as specified under (E) of this section. P

(B) Following permit suspension due to an imminent health hazard, all food service operations shall immediately cease.

(C) The Department shall promptly notify, in writing, the permit holder, person in charge, or an employee of the specific reasons for which the permit was suspended.

(D) A retail food establishment may voluntarily close prior to the Department declaring an imminent health hazard but shall remain closed until authorized by the Department to resume operations.

(E) A permit holder may continue operations in areas of the establishment that are unaffected by the imminent health hazard.

(F) Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the Department may, but is not required to, agree to continuing operations in the event of an extended interruption of electrical or water service if:

(1) A written emergency operating plan has been approved by the Department;

(2) Immediate corrective action is taken to eliminate, prevent, or control any food safety risk and imminent health hazard associated with the electrical or water service interruption; and

(3) The Department is informed upon implementation of the written emergency operating plan.

**8‑404.12 Resumption of Operations.**

(A) If operations are discontinued as specified under 8‑404.11 or otherwise according to law, the permit holder shall obtain approval from the Department before resuming operation.

(B) Notwithstanding 8‑904.20, a permit suspended for an imminent health hazard shall remain suspended until the imminent health hazard has been corrected.

**8‑405 Correction of Violations**

**8‑405.11 Correction of Violations.**

(A) The completed inspection report form shall specify a period of time for the correction of the violations found. Implementation of corrective action of all violations shall be within the following specified time periods:

(1) All priority and priority foundation violations shall be corrected immediately. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the Department may schedule a follow‑up inspection not to exceed ten (10) calendar days from the date of the inspection. Pf

(2) All core violations that are operational shall be corrected as soon as possible. Verification of correction will be made at the time of the next routine inspection or earlier if deemed necessary by the Department.

(3) Except as specified in (4) of this section, all consecutive core violations shall be corrected as soon as possible. A follow‑up inspection shall be conducted to confirm correction within ten (10) calendar days from the date of the inspection.

(4) All core violations that are structural shall be corrected by the next routine inspection; however, additional time, not to exceed twelve (12) months, may be granted when such allowances present no public health hazard and the permit holder provides a written schedule for compliance.

(B) When a retail food establishment’s routine inspection score is in the Grade C range or lower (less than 78 points), a subsequent routine inspection must be performed within sixty (60) calendar days of that C grade or lower inspection.

(C) Other than occurrences where a third consecutive inspection is rated below seventy (70) as described in 8‑904.110 (C), when the rating score of the retail food establishment is less than seventy (70):

(1) The retail food establishment shall be downgraded to a grade C.

(2) Immediate corrective action on all identified priority, priority foundation, and core violations shall be initiated. Pf

(a) If priority and priority foundation violations cannot be corrected immediately the retail food establishment will be given the opportunity to cease all operations and close the facility voluntarily.

(b) If the retail food establishment refuses to cease operations voluntarily, the Department shall declare an imminent health hazard under 8‑404.10.P

(3) Once a retail food establishment is closed, the retail food establishment will be allowed to reopen when all priority and priority foundation violations are corrected, as determined by the Department.

(4) A follow‑up inspection shall be conducted within seventy‑two (72) hours from the date of the inspection and as often as necessary to assure correction. If the retail food establishment fails to score seventy (70) or above on the follow‑up inspection, action to suspend the permit shall be initiated.

**8‑5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES**

**8‑501 Investigation and Control**

**8‑501.10 Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis.**

The Department shall act when it has reasonable cause to believe that a food employee or conditional employee has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through food; may be a carrier of infectious agents that cause a disease that is transmissible through food; or is affected with a boil, an infected wound, or acute respiratory infection, by:

(A) Securing a confidential medical history of the food employee or conditional employee suspected of transmitting disease or making other investigations as deemed appropriate; and/or

(B) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected food employee or conditional employee.

**8‑501.20 Restriction or Exclusion of Food Employee or Summary Suspension of Permit.**

Based on the findings of an investigation related to a food employee who is suspected of being infected or diseased, the Department may issue an order to the suspected food employee or permit holder instituting one or more of the following control measures:

(A) Restricting the food employee;

(B) Excluding the food employee; or

(C) Closing the retail food establishment by summarily suspending a permit to operate in accordance with law.

**8‑501.30 Restriction or Exclusion Order: Prior Warning or Hearing Not Required, Information Required in Order.**

Based on the findings of the investigation as specified in 8‑501.10 and to control disease transmission, the Department may issue an order of restriction or exclusion to a suspected food employee or the permit holder without prior warning, notice of a hearing, or a hearing if the order:

(A) States the reasons for the restriction or exclusion that is ordered;

(B) States the evidence that the food employee or permit holder shall provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated; and

(C) States that the suspected food employee or the permit holder may request a hearing as provided in law.

**8‑501.40 Removal of Exclusions and Restrictions.**

A food employee, or conditional employee shall be released from restriction or exclusion when the employee or conditional employee no longer poses a threat to the public health.

**8‑6 CONSTITUTIONAL PROTECTION**

**8‑602 Judicial Review**

**8‑602.10 Rights of Recipients of Orders or Decisions.**

A recipient of a Department decision or order may appeal the decision or order in accordance with applicable law.

**8‑7 AUTHORITY**

**8‑701 Legal Authority**

**8‑701.10 Adoption of Regulations and Enforcement.**

(A) This regulation is issued under the authority of S.C. Code of Laws, Section 44‑1‑140, and shall be enforced by the Department.

(B) Should any chapter, paragraph, sentence, clause, or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

**8‑701.20 Enforcement.**

Any facility found to be in violation of this regulation, in non‑compliance with the requirements of this regulation, or in violation of an order issued by the Department shall be subject to civil penalties, permit suspension, and/or revocation pursuant to S.C. Code Ann. Section 44‑1‑150 and this regulation.

**8‑9 REMEDIES**

**8‑903 Holding, Examination, and Destruction of Food**

**8‑903.10 Hold Orders, Justifying Conditions, and Removal of Food.**

(A) The Department may place a hold order on a food which is believed to be in violation of this regulation that:

(1) Originated from an unapproved source;

(2) May be unsafe, adulterated, or not honestly presented;

(3) Is not labeled according to law, or, if raw molluscan shellfish, is not tagged or labeled according to law; or

(4) Is otherwise not in compliance with this regulation.

(B) Should the hold order be violated, action may be initiated to suspend the permit.

(C) The Department may condemn, forbid the sale of, or cause to be removed or destroyed, any food, which is determined to be in violation of this regulation, unwholesome, contaminated, adulterated, or from an unapproved source.

**8‑903.20 Hold Order, Prior Warning, or Hearing Not Required.**

The Department may issue a hold order to a permit holder or to a person who owns or controls the food, as specified in 8‑903.10, without prior warning, notice of a hearing, or a hearing on the hold order.

**8‑903.30 Hold Order, Contents.**

The hold order shall:

(A) State that food subject to the order may not be used, sold, moved from the retail food establishment, or destroyed without a written release from the Department;

(B) State the specific reasons for placing the food under the hold order with reference to the applicable provisions of this regulation and the hazard or adverse effect created by the observed condition;

(C) Completely identify the food subject to the hold order by the common name, the label information, a container description, the quantity, tag or identification information, and location;

(D) State that the permit holder has the right to a hearing and may request a hearing in accordance with applicable law; and

(E) State that the Department may order the destruction of the food if a timely request for a hearing is not received.

**8‑903.40 Hold Order, Official Tagging of Food.**

(A) The Department shall securely place an official tag or label on the food or containers or otherwise conspicuously identify food subject to the hold order.

(B) The tag or other method used to identify a food that is the subject of a hold order shall be signed and dated by the Department.

**8‑903.51 Hold Order, Food May Not Be Used or Moved.**

(A) Except as specified in (B) of this section, a food placed under a hold order may not be used, sold, served, or moved from the establishment by any person.

(B) The Department may allow the permit holder the opportunity to store the food in an area of the retail food establishment if the food is protected from subsequent deterioration and the storage does not restrict operations of the establishment.

**8‑903.70 Hold Order, Removing the Official Tag.**

Only the Department may remove hold order tags, labels, or other identification from food subject to a hold order.

**8‑903.80 Destroying or Denaturing Food.**

If a hold order is sustained upon appeal or if a timely request for a hearing is not filed, the Department may order the permit holder or other person who owns or has custody of the food to bring the food into compliance with this regulation or to destroy or denature the food under the Department’s supervision.

**8‑903.90 Releasing Food from Hold Order.**

The Department shall issue a notice of release from a hold order and shall remove hold tags, labels, or other identification from the food if the hold order is vacated.

**8‑904 Permit Suspension**

**8‑904.10 Conditions Warranting Summary Suspension.**

The Department may summarily suspend a permit to operate a retail food establishment if it determines through inspection, or examination of employees, food, records, or other means as specified in this regulation, that an imminent health hazard exists.

**8‑904.20 Summary Suspension, Warning, or Hearing Not Required.**

The Department may summarily suspend a retail food establishment’s permit by providing written notice of the summary suspension to the permit holder or person in charge, without prior warning, notice of a hearing, or a hearing.

**8‑904.30 Contents of the Summary Suspension Notice.**

A summary suspension notice shall state:

(A) That the retail food establishment permit is immediately suspended and that all food operations shall immediately cease;

(B) The reasons for summary suspension with reference to the provisions of this regulation that are in violation;

(C) The name and address of the Department representative to whom a written request for re‑inspection may be made and who may certify that reasons for the suspension are eliminated; and

(D) That the permit holder may request a hearing in accordance with applicable law.

**8‑904.40 Time Frame for Re‑inspection.**

After receiving a written request from the permit holder stating that the conditions cited in the summary suspension order no longer exist, the Department shall conduct a re‑inspection of the retail food establishment for which the permit was summarily suspended within five (5) business days, which means five (5) days during which the Department’s office is open to the public.

**8‑904.50 Term of Summary Suspension, Reinstatement of Permit.**

(A) A summary suspension shall remain in effect until the conditions cited in the notice of suspension no longer exist and the Department, through re‑inspection, has confirmed their elimination and other means as appropriate.

(B) The suspended permit shall be reinstated if the Department determines that the public health hazard or nuisance no longer exists. A notice of reinstatement shall be provided to the permit holder or person in charge.

**8‑904.110 Suspension of Permits.**

(A) The Department may suspend permits for:

(1) Consecutive priority and priority foundation violations;

(2) Consecutive core violations;

(3) Below seventy (70) inspection scores;

(4) Failure to comply with the terms and conditions of the permit;

(5) Failure to notify the Department of facility changes and to seek amendments to a permit as required by Section 8‑304.11;

(6) Failure to provide the Department access to the retail food establishment for the purpose of conducting an inspection or investigation;

(7) Covering, obscuring, defacing, relocating, or removing the posted grade decal or permit;

(8) Violation of a hold order;

(9) Failure to pay applicable inspection renewal fee or failure to pay a civil penalty required pursuant to a Department order;

(10) Failure to operate as a retail food establishment (serve or sell food) for at least fifteen (15) consecutive days annually or be in operation for at least one day every week for at least fifteen (15) weeks.

(11) As otherwise determined by the Department pursuant to 8‑102.10.

(B) The Department may revoke permits for:

(1) Recurring failure to notify the Department of facility changes or to seek amendments to the permit;

(2) Recurring failure to comply with the Terms and Conditions of the permit;

(3) Recurring priority and priority foundation violations of the regulation;

(4) Recurring failure to provide the Department access to the retail food establishment for the purpose of conducting an inspection or investigation;

(5) Three (3) routine inspections in a two (2) year period that have a rating score of below seventy (70); or

(6) Failure to operate as a retail food establishment (serve or sell food) for at least fifteen (15) consecutive days annually or be in operation for at least one day every week for at least fifteen (15) weeks.

(C) When a facility has a rating score of below seventy (70):

(1) On the second routine inspection, Department staff shall be accompanied by an additional representative for verification of violations.

(2) When the second routine inspection results in a score below seventy (70), the Department shall notify the permit holder, by letter, that if on the next routine inspection the score is less than seventy (70) action will be initiated to revoke the permit.

(3) On the third routine inspection, Department staff shall be accompanied by a standardization officer of the Department.

**8‑904.120 Notification of Permit Suspension and Permit Revocation.**

Except as provided in 8‑904.20, prior to permit suspension or permit revocation, the Department shall notify, in writing, the permit holder, person in charge, or an employee of the specific reasons for which the permit is to be suspended or revoked.

**8‑904.130 Term of Suspension, Reinstatement of Permit.**

A permit suspension shall remain in effect until the conditions cited in the notice of permit suspension no longer exist and their elimination has been confirmed by the Department through re‑inspection and other means as appropriate.

**8‑904.140 Interference with the Department.**

Notwithstanding any other provisions of this regulation, the permit shall be revoked if a permit holder, person in charge, or employee engages in any of the following actions towards Department staff while performing, or as a result of performing, official duties and responsibilities:

(A) Physical or verbal actions that constitute assault, battery, sexual or other harassment, or

(B) Interference, intimidation, threat, or attempted bribery.

**8‑905 Appeals**

**8‑905.10 Appeals.**

A Department decision to deny an application for a permit, deny a request for a variance, impose a penalty, or suspend or revoke a permit may be appealed pursuant to applicable law.

8‑905.40 Hearings and Appeals Procedures.

All appeals and hearings shall be conducted in accordance with applicable law.

**8‑913 Civil Penalties**

**8‑913.10 Penalties.**

Civil penalties for violations of this regulation or an order of the Department may be imposed pursuant to S.C. Code Ann. Section 44‑1‑150.

**Chapter 9 Standards for Additional Retail Food Establishment Operations**

**9‑1 MOBILE FOOD**

This standard shall apply to the construction and operation of mobile food units as part of a retail food establishment.

**(A) Definitions.**

(1) A **mobile food establishment** consists of a commissary and mobile food unit(s) or mobile food pushcart(s).The food service portion of the operation is conducted from a movable driven or propelled vehicle, portable structure, or watercraft that can change location.

(2) A **commissary** is a permitted retail food establishment that is authorized by the Department to provide support of operations, storage, and servicing area for mobile food units or mobile food pushcarts, and is constructed and operated in compliance with the requirements of this regulation and standard. Retail food establishments that prepare and serve food to highly susceptible populations such as those operated by health care facilities that are regulated by the Department shall not be approved as a commissary.

(3) **Mobile food units** are fully enclosed mobile kitchens that may prepare, cook, or serve time/temperature control for safety foods as an extension of the commissary. A mobile food unit must be permitted by the Department in order to operate from a retail food establishment.

(4) **Mobile food pushcarts** are limited food service units that operate as an extension of a commissary. A mobile food pushcart must be permitted by the Department in order to operate from a commissary.

**(B) General.**

(1) A mobile food establishment shall comply with all applicable provisions of this regulation, except as outlined in this standard.

(2) The Department may prohibit the sale of certain time/temperature control for safety foods, and may modify specific requirements for physical facilities when, in the opinion of the Department, no health hazard will result.

(3) For servicing and storage:

(a) A full‑service (self‑contained) mobile food unit must return to the commissary at a frequency necessary to maintain sanitary conditions but in no case may operate for longer than seventy‑two (72) hours of operation without returning to the commissary.

(b) Non‑self‑contained mobile food unit(s) and mobile pushcart(s) must return to the commissary within twenty‑four (24) hours of operation.

(c) Mobile food unit(s) and mobile pushcart(s) that are not stored at the commissary must submit the proposed storage location for Department approval.

**(C) Employees.**

(1) Food employees shall not contact exposed, ready‑to‑eat‑food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single‑use gloves, or dispensing utensils.

(2) Personal clothing and belongings should be stored in a designated place away from food preparation, food service, dry storage areas, utensil and single‑service article storage, and utensil washing areas.

(**D) Food.**

(1) General.

(a) A mobile food establishment shall prepare, hold, and serve food according to Chapter 3, *Food*.

(b) All food items shall be protected from contamination during transportation, storage, cooking, display, and service.

(c) Adequate refrigeration or coolers shall be provided. A temperature measuring device shall be provided for cold holding units.

(d) Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or it’s positioning in the ice or water.

(e) Ice used as a coolant for foods shall not be used for edible ice.

(f) For the purpose of checking temperatures of food, a mobile food establishment shall have at least one temperature measuring device that meets the following requirements:

(i) Able to be calibrated and

(ii) Appropriate for the food density being checked.

(g) Hot held time/temperature control for safety foods on a mobile food unit or mobile pushcart shall be discarded at the end of the day at the commissary.

(h) Food(s) shall be stored, displayed, and served from the mobile food unit(s) and mobile food pushcart(s) only.

(2) Mobile Food Unit.

(a) Preparation of bulk food, including washing, slicing, peeling, and cutting, shall occur at the commissary.

(b) All food, single‑service articles, and other items used for the operation of the mobile food unit shall be stored at the commissary or on the mobile food unit.

(c) Doors on mobile food units shall be kept closed at all times.

(3) Mobile Food Pushcart.

(a) All food, single‑use articles, and other items used for the operation of the mobile food pushcart shall be stored at the commissary.

(b) Other than assembling food items for service, all food preparation, including washing, slicing, peeling, cutting, and cooking, shall occur at the commissary.

(c) Raw animal food shall not be cooked or prepared in any way on a mobile food pushcart.

(d) Door(s) on mobile food pushcarts shall be kept closed when not in use and during transportation.

(**E) Service.**

(1) During operations, food shall be stored, cooked, displayed, and served from the mobile food unit and mobile food pushcart only.

(2) Customer self‑service of unpackaged time/temperature control for safety food is prohibited.

(3) Mobile food units and mobile food pushcarts shall provide only single‑use articles for use by the consumer.

(4) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection or offered in individual packages.

(5) Equipment and utensils shall be adequate in number and where appropriate shall be washed, rinsed, and sanitized as needed.

(6) In‑use wiping cloths must be stored in a clean solution of an approved sanitizer.

(7) A test kit that accurately measures the parts per million concentration of an approved sanitizer shall be accessible and used.

**(F) Construction.**

(1) Mobile food units.

(a) Mobile food units shall have preparation and display areas completely enclosed with a solid material except as specified in (j) of this section.

(b) The serving window opening shall:

(i) Have an area of no more than five hundred seventy‑six (576) square inches, and

(ii) Be covered with solid material or screen. Screening shall be at least sixteen (16) mesh per inch.

(iii) Be self‑closing or free falling type, or covered by an approved air curtain when the serving window is open.

(c) Walls, floors, and ceilings must be smooth, cleanable, durable, and nonabsorbent.

(d) Light bulbs and fluorescent tubes shall be shielded, coated, or otherwise shatter‑resistant and provide twenty (20) foot candles of illumination.

(e) Cooking and reheating equipment shall be installed on the unit, used in accordance with the manufacturer’s instructions, and must meet the provisions of this regulation. Pull behind cookers or smokers are prohibited.

(f) All mobile food unit counters, shelves, and food contact surfaces shall be safe, corrosion resistant, nonabsorbent, smooth, easily cleanable, durable, and free of seams and difficult to clean areas.

(g) It is not the intent for mobile food units to wash, rinse, and sanitize utensils or equipment on the mobile food unit due to hot water demands. If mobile food units are designed to be self sufficient, a utensil washing sink shall:

(i) Have at least three (3) compartments large enough to accommodate two thirds of the largest utensil,

(ii) Have adequate space for air‑drying,

(iii) Be supplied with hot and cold water under pressure, and

(iv) Be equipped with a mixing faucet that is capable of servicing all sink compartments per 4‑301.12.

(h) Mechanical exhaust ventilation equipment shall be provided over all cooking equipment as required to effectively remove cooking odors, smoke, steam, grease, heat, and vapors.

(i) All mechanical exhaust ventilation equipment shall be installed and maintained in accordance to 4‑301.14.

(j) Barbecue pit‑cooking areas on mobile units must comply with 9‑7, *Barbecue Pit And Pit‑Cooking Room Construction.*

(2) Mobile food pushcarts.

(a) Mobile food pushcarts shall have preparation and display areas completely enclosed with a solid material.

(b) Food compartment(s) and food storage compartments must be adequately sized for the intended operation of the mobile food pushcart.

(c) Food compartments must be constructed from materials that are nontoxic, smooth, easily cleanable, durable, and constructed to facilitate the cleaning of the interior and exterior of the compartment.

(d) Food storage compartments shall not contain plumbing of any kind.

(e) All mobile food pushcart counters/shelves and food contact surfaces shall be safe, corrosion resistant, nonabsorbent, smooth, easily cleanable, durable, and free of seams and difficult to clean areas.

**(G) Handwashing Sinks.**

(1) All mobile food units and mobile food pushcarts shall have a separate handwashing sink.

(2) Soap and disposable paper towels shall be provided and adjacent to the handwashing sink.

(3) The handwashing sink shall be:

(a) Equipped with hot and cold water under pressure through a mixing valve or combination faucet. The hot water temperature shall be at least 100 degrees F (37 degrees C) as specified in 5‑202.12; and

(b) Separated from food and food contact surfaces by either a splashguard or a distance of at least 12 inches; and

(c) Unobstructed and accessible to employees at all times.

(4) Gloves and/or hand sanitizers shall not be allowed as a substitute for handwashing facilities.

**(H) Water System.**

(1) All mobile food units and mobile food pushcarts shall have a drinking water system, under pressure, from an approved drinking water supply system.

(2) Mobile food units and mobile food pushcarts water tanks shall comply with 5‑3 of this regulation.

(3) Approved portable drinking water containers shall be stored and handled in a manner that protects the drinking water and equipment from contamination.

(4) The drinking water system tank shall be a minimum of five (5) gallons and of sufficient capacity to furnish hot and cold water for handwashing as specified in 5‑202.12.

(5) If the mobile food unit is designed to be self sufficient, the hot water system shall be sufficient to meet hot water demands of at least 110 degrees F (43 degrees C) to the utensil washing sink and comply with all requirements pursuant to 5‑103.11.

(6) A mobile food unit or mobile pushcart may temporarily use a direct connection to an approved drinking water source at the operating location when the following criteria are met:

(a) The mobile unit is connected to an approved public sewer or onsite wastewater system and

(b) Drinking water and sewage storage tanks remain on the unit at all times.

**(I) Sewage Retention.**

(1) Mobile food units and mobile food pushcarts water tanks shall comply with 5‑3 of this regulation.

(2) Sewage from a mobile pushcart may be stored in a removable retention tank that:

(a) Shall be fifteen (15) percent larger capacity than the drinking water supply tank;

(b) Cannot exceed ten (10) gallons (80 lbs) to be approved as portable;

(c) If sewage retention tanks are removable, they shall be permanently labeled ‘sewage’ to eliminate any confusion;

(d) Permanently installed sewage retention tanks on mobile pushcarts shall meet the same requirements as specified in (1) and (2) of this section.

(3) The mobile food unit and mobile pushcart sewage retention tank shall be thoroughly flushed and drained during the servicing operations at the commissary or approved sewage disposal site, and shall be discharged into a sanitary sewerage disposal system or onsite sewage system approved by the Department.

(4) Flushing and draining shall be done in a manner that does not contaminate floors or any other areas in the commissary or the servicing area.

**(J) Servicing Area.**

The surface of the servicing area shall be constructed of a smooth material, such as concrete or asphalt, and shall be maintained in good repair, kept clean, and be properly drained.

**(K) Exemptions.**

(1) A mobile food pushcart operated inside fully enclosed structures such as, but not limited to, malls or sports arenas may have the requirement for full enclosure waived if in the opinion of the Department, no risk of contamination to the food exists.

(2) Mobile food pushcarts that are used to serve commercially packaged, fully cooked boiled or steamed hot dogs with commercially packaged, fully cooked chili or ice cream may have the requirement for full enclosure waived if in the opinion of the Department, no risk of contamination to the food exists provided those are the only foods served from the unit.

**(L) Compliance.**

(1) No mobile food unit or a mobile food pushcart shall operate that does not have a permit issued by the Department.

(2) Only a mobile food establishment that complies with the requirements of this regulation and this standard shall be entitled to receive and retain a permit.

(3) The permit shall be kept in the mobile food unit or mobile food pushcart and shall be accessible at all times.

(4) No retail food establishment shall operate as a commissary that does not have an authorization issued by the Department.

(5) Only a retail food establishment that complies with the requirements of this regulation and this standard shall be entitled to, receive and retain such an authorization.

(6) The permit and authorization shall be kept in a location in the commissary and shall be accessible at all times as specified in 8‑301.11.

(7) Any person that proposes to operate a mobile food unit or mobile food pushcart must apply to the Department for a permit through the application process.

(8) The following additional documentation shall be submitted as part of the application process:

(a) A proposed menu or list of foods that will be served from the mobile food unit or mobile food pushcart;

(b) A list of all equipment installed on the mobile food unit or mobile food pushcart;

(c) An operations plan that includes:

(i) Information about methods of cooking, if applicable,

(ii) Hot and cold holding of food,

(iii) The mobile food unit or mobile food pushcart operational locations and the hours of operation at those locations,

(iv) The location of the commissary, and the cleaning and servicing operations at the commissary,

(v) A supplemental application form completed by the permit holder for each mobile food unit or mobile food pushcart; and

(vi) Any other information requested by the Department.

(9) Once a mobile food unit or mobile food pushcart has been permitted, the Department shall be notified of any changes to the mobile food unit or mobile food pushcart, such as, but not limited to, operations, menu, or change in commissary in accordance with 8‑304.11.

(10) The mobile food unit or mobile food pushcart shall be available for inspection at the commissary at any reasonable time when requested by the Department.

(11) If a mobile food unit or mobile food pushcart is not presented for inspection at the commissary at the appointed time, the commissary permit and mobile food unit or mobile food pushcart permit shall be suspended in accordance with 8‑904.110.

(12) Each mobile food unit and mobile pushcart shall have its business name and address legibly printed in a contrasting color from the color of the mobile food unit or mobile food pushcart in a manner that is conspicuous to the consumer.

(13) Mobile food units or mobile food pushcarts currently permitted prior to the effective date of this regulation and in compliance with the previous regulation, but which do not fully comply with all the construction, equipment, and physical requirements of this regulation, shall be deemed acceptable provided the facilities and equipment:

(a) Are capable of being maintained in a sanitary condition;

(b) Are not a public health hazard or nuisance; and

(c) Are replaced in the normal course of operation with equipment and facilities that meet the requirements of this standard and regulation.

**9‑2** **MEAT/MEAT PRODUCT AND FISH/FISH PRODUCT SALES**

This standard shall apply to meat/meat products and fish/fish products from source or preparation site to the point of sale.

**(A) General.**

(1) Meat/meat products and fish/fish products shall be protected from contamination by use of packaging or covered containers while being transported.

(2) Meat/meat products and fish/fish products being transported shall meet the requirements and sections of this regulation relating to approved source, food supplies, food protection, food storage, and sanitary control of liquid waste.

(3) Acceptable products for meat/meat products and fish/fish products sales under this standard are as follows:

(a) Prepackaged frozen meat and fish/fish products which are processed and packaged in an approved food processing plant and are sold by the package or case,

(b) Fresh unprocessed fish/fish products from an approved source which are whole, or

(c) Fresh unprocessed shrimp with either the heads on or heads removed.

**(B) Employees.**

Meat/meat products and seafood and freshwater fish shall be delivered by persons with clean hands and wearing clean clothing.

**(C) Food.**

(1) All food/ice shall be obtained from sources approved by the Department.

(2) Meat/meat products and fish/fish products shall be protected from contamination when transported with other products.

(3) All food employees shall hold and display food according to all applicable sections of Chapter 3, *Food*.

(4) Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container, or its positioning in the ice or water.

(5) Whole unpackaged fish/fish products may be stored in ice made from drinking water or obtained from an approved source.

(6) Ice used as a coolant for foods shall not be used for edible ice.

(7) During transport of meat/meat products and fish/fish products, there shall be at least one temperature measuring device for checking temperatures of food that meets the following requirements:

(a) Able to be calibrated; and

(b) Appropriate for the food density being checked.

(8) All fresh meat/meat products and fish/fish products shall be transported so as to maintain a temperature of 41 degrees F (5 degrees C) or below during the transportation period.

**(D) Cleanliness/ Maintenance.**

(1) If meat/meat products and fish/fish products reach their destination at 41 degrees F (5 degrees C) or below, vehicles need not be refrigerated.

(2) The storage portion of each vehicle shall be washed and cleaned.

**9‑3 OUTDOOR PET DINING**

This standard shall apply to outdoor dining areas where table service of food is provided and shall not apply to customer pick up take out service with picnic type dining areas that may be provided by a retail food establishment

**(A) Definition.**

A **pet** is defined as domesticated cats, dogs, and ferrets.

**(B) General.**

(1) A retail food service establishment may allow customers to be accompanied by pets in an outdoor dining area provided the retail food service establishment complies with the requirements of this section and all other applicable sections of this regulation.

(2) Pets at retail food establishments shall also comply with the South Carolina Rabies Control Act Section 47‑5‑60.

**(C) Employees.**

Employees shall wash hands after any contact with pets, pet supplies, and pet waste.

**(D) Service.**

(1) All tableware used for the pets shall be restricted to single‑service or single‑use articles.

(2) Tables and chairs located in the outdoor pet dining area shall be easily cleanable.

(3) Cleaning supplies and sanitizers shall be provided and stored in the outdoor pet dining area. These items shall be exclusively used for outdoor pet dining purposes only and stored outside.

(4) Cleaning equipment necessary for the removal of pet waste shall be provided. These items shall be exclusively used for outdoor pet dining purposes only and stored outside.

(5) Pet waste shall be removed immediately and the area shall be cleaned and sanitized.

(6) A covered refuse container shall be located in the outdoor pet dining area and shall be used exclusively to store all pet waste generated by the outdoor pet dining area.

**(E) Construction.**

(1) The retail food establishment shall post signs at the entrance of all dining areas stating the facility is pet dining friendly and has an outdoor pet dining area.

(2) The retail food establishment shall post signs stating pets are only allowed in the outdoor pet dining area.

(3) Outdoor pet dining areas shall have an outside entrance.

(4) Pets shall be restricted to the outdoor pet dining area and shall not be allowed in the retail food establishment.

(5) All pets shall be restrained and under control of the owners.

(6) No pets are allowed on a table, countertop, or any other food contact surfaces within the outdoor pet dining area.

**(F) Compliance.**

(1) Retail food establishments that have pets on the premises and do not comply with this standard shall be cited for violations under Sections 2‑403.11 and 6‑501.115 as applicable.

(2) This standard shall not apply to service animals in outdoor or indoor dining areas.

**9‑4 WILD MUSHROOM FORAGING**

Wild foraged mushrooms species must be individually inspected and found to be safe by an approved mushroom identification expert that:

(A) Has met the requirements of knowledge and passed an exam given by a 3rd party certifier that has been approved by the Department; and

(B) Will harvest only those mushrooms species listed below:

Pink Chanterelles (Cantharellus cinnabarinus)

Golden Chanterelles (Cantharellus cibarius, C.lateritius, C. Appalachiensis)

Yellow Morel (Morchella esculenta)

Tulip Morel (Morchella deliciosa)

Black morel (Morchella elata)

Black Trumpet (Craterellus fallax)

Lobster (Hypomyces lactifluorum)

Wood Ears (Auricula auricularia, A. Fuscosuccinea)

Chicken of the Woods (Laetiporus sulphureus, L.cincinnatus, L.perscinus)

Beefsteak (Fistulina hepatica)

Hedgehog (Hydnum repandum)

Lions Mane or Pom Pom (Hericium erinaceus, H.ramosum)

White Oyster Mushroom (Pleurotus ostreatus, P. pulmonarius, P. populinus, P.floridanus)

Cauliflower (Sparassis crispa, S.herbstii, S.spathulata)\

Maitake (Grifola frondosa)

Blewits (Clitocybe nuda)

Honey (Armillaria ostoyae, A.mellea, A.tabescens)

Blue Milky (Lactarius indigo)

Golden Milkies (Lactarius corrugis, L.volemus)

Pecan Truffle (Tuber lyonii).

**9‑5 SHARED USE OPERATIONS**

This standard shall apply to retail food establishments designed and operated for use by multiple permit holders.

**(A) Definitions.**

(1) **Shared use operation** means a facility designed for multiple and individually permitted retail food establishment(s) or other food processing plant(s) operating at different times using the same area and equipment for cooking, processing, or preparing food that is provided to the consumer. The purpose of a shared use operation is to provide farmers, caterers, gourmet food producers, and others interested in the production of food items, a facility to prepare food products. A shared use operation provides a licensed South Carolina Department of Agriculture or permitted retail food establishment the equipment and individual spaces necessary to prepare, package, store, and label their products. A shared use operation may also serve as a commissary for mobile food establishments provided it meets the requirements as per section 9‑1, *Mobile Food*. Retail food establishments that prepare and serve food to highly susceptible populations such as those operated by health care facilities that are regulated by the Department shall not be approved as a shared use operation.

(2) **Facilitator** means the person responsible for all facility structural requirements, equipment, maintenance, and scheduling of a shared use operation.

**(B) General.**

(1) The facilitator shall obtain a retail food establishment permit and shall be responsible for the facility and equipment maintenance, utilities, refuse removal, and other common use services.

(2) A shared use operation and the associated retail food establishments shall comply with all applicable provisions of this regulation, except as outlined in this standard.

(3) The Department may prohibit the distribution of certain time/temperature control for safety food, and may modify specific requirements for physical facilities when, in the opinion of the Department, no health hazard will result.

**(C) Compliance**

(1) Facilitator.

(a) The facilitator shall provide to the Department the number of associated retail food establishments and/or licensed SCDA operators that the shared use kitchen can accommodate. The shared use operation shall not exceed this number of operators without first notifying the Department.

(b) The facilitator shall maintain a schedule of the associated retail food establishment(s) days and hours of operation. This information shall be provided to the Department weekly for purposes of inspections and foodborne outbreak or complaint investigations.

(c) Only those retail food establishment(s) that are scheduled to use the kitchen for a particular day and time will be allowed in the shared areas.

(d) The facilitator shall ensure that deliveries that are received are from approved sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unadulterated and accurately presented.

(e) The facilitator shall provide notice to the Department prior to the addition or deletion of associated retail food establishments.

(2) Associated retail food establishments.

(a) Each proposed operator shall obtain a retail food establishment permit.

(b) Each associated retail food establishment shall be responsible for its own operation and shall be required to comply with all applicable sections of the regulation.

(c) Each associated retail food establishments shall have a secured dry storage area(s), and designated space in walk‑in coolers and freezers for items exclusive to their operation.

(3) No person shall operate a shared use operation that does not have a permit issued by the Department pursuant to 8‑301.11.

(4) Only a person who complies with the requirements of this regulation and standard shall be entitled to receive and retain such a permit.

(5) Any person who proposes to operate a shared use operation must apply to the Department for a permit on the application form provided by the Department pursuant to 8‑302.

(6) The Department shall be notified of any changes to the shared use operation or associated retail food establishment, such as, but not limited to, operations, equipment, or menu, in accordance with 8‑304.11.

**9‑6 IMMEDIATE OUTDOOR COOKING**

This standard shall apply to retail food establishments that provide food by outdoor cooking, grilling, or roasting of the food on their premises.

**(A) Definition.**

**Immediate outdoor cooking (IOC)** is defined as the outdoor cooking, grilling, or roasting of food on the physical premises of a permitted retail food establishment. Immediate outdoor cooking activities shall not be associated with a mobile food unit, mobile food pushcart, farmer’s market, or seasonal series.

**(B) General.**

(1) A retail food establishment that conducts IOC shall comply with all applicable provisions of this regulation, except as outlined in this standard.

(2) The Department may prohibit the distribution of certain time/temperature control for safety food, and may modify specific requirements for physical facilities when, in the opinion of the Department, no health hazard will result.

(3) The retail food establishment shall be in operation at all times during any IOC activities.

(4) The retail food establishment is solely responsible for all IOC provisions, including, but not limited to, employees, person in charge, food supplies, and preparations.

(5) The Department must approve the location that is to be considered the IOC area.

(6) The Department may have additional requirements due to environmental conditions that may pose a risk for contamination of food products. Under such conditions, the Department may limit or cease the use of the outdoor cooking and service areas.

**(C) Employees.**

Food employees shall not contact exposed, ready‑to‑eat‑food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single‑use gloves, or dispensing utensils.

**(D) Food.**

(1) All food preparation shall be completed inside the permitted retail food establishment.

(2) All food items shall be protected from contamination during transportation, storage, cooking, display, and service.

(3) All food employees shall prepare, hold, and serve food according to all applicable sections of Chapter 3, *Food*.

(4) IOC shall have at least one temperature measuring device for checking temperatures of food that meets the following requirements:

(a) Able to be calibrated; and

(b) Appropriate for the food density being checked.

(5) Leftover portions of food cooked during IOC shall be discarded immediately. No food shall be stored for future service.

**(E) Service.**

(1) Equipment used for IOC shall be limited to grills, steam pots and pizza ovens designed for outdoor use.

(2) The Department shall authorize IOC operations based on the following:

(a) The permitted retail food establishment must be of sufficient size and capability to support the same operations inside as well as IOC.

(b) The same or similar size or type of equipment used for cooking inside the permitted retail food establishment may be authorized for IOC.

(c) The same or similar type foods that are cooked inside the permitted retail food establishment may be authorized for IOC.

(3) Only the cooking and immediate service of food will be allowed during IOC operations, except that the serving of displayed food in the immediate cooking area must be completed within four (4) hours for any single function or activity.

(4) Food shall be kept covered, except during times of continuous serving or display.

(5) Covers or lids may be removed only for monitoring, stirring, or adding additional ingredients.

(6) Condiments must be dispensed in individual single‑service type packets, pump dispensers, squeeze bottles, shakers, or similar dispensers which minimize contamination of food items by food employees, patrons, vermin, environmental conditions, or other sources.

(7) Equipment and utensils shall be adequate in number to conduct the IOC activities.

(8) In‑use wiping cloths shall be stored in a clean solution of an approved sanitizer.

(9) The IOC area shall be effectively separated from the public.

**(F) Construction.**

(1) Floors shall be constructed of concrete, asphalt, tight wood, or other similarly cleanable material and shall be kept clean and in good repair.

(2) Light bulbs and fluorescent tubes shall be shielded, coated, or otherwise shatter‑resistant and provide 20‑foot candles of illumination.

(3) All IOC equipment, including tables, shall be safe, corrosion resistant, nonabsorbent, smooth, easily cleanable, durable, and free of seams and difficult to clean areas.

(4) Warewashing is not permitted outside. All utensils/equipment used in outdoor cooking/serving of food shall be returned to the permitted retail food establishment for proper cleaning; except that, in‑place cleaning may be allowed for grills and similar equipment.

**(G) Handwashing Sinks.**

If IOC exceeds four (4) times per calendar year, the following handwashing sink requirement shall be met:

(1) A permanently installed exterior handwashing sink shall be provided pursuant to 5‑202.12, 5‑203.11 and 5‑204.11.

(2) If using a portable handwashing sink, it shall have a minimum five (5) gallon potable water‑dispensing tank and a minimum seven‑point five (7.5) gallon waste water holding tank.

(3) The handwashing sink shall be provided with soap and disposable paper towels.

(4) When a permanently installed exterior handwashing sink is not required, a container of water with a spigot, soap, disposable towels and a catch bucket shall be provided.

(5) Gloves and/or hand sanitizers shall not be allowed as a substitute for handwashing facilities.

**(H) Authorization.**

(1) No retail food establishment shall conduct IOC operations that does not have an authorization issued by the Department.

(2) Any retail food establishment that operates or proposes to conduct IOC operations must apply to the Department for an authorization thru the application process.

(3) Only a retail food establishment who complies with the requirements of this regulation and this standard shall be entitled to, receive and retain such an authorization.

(4) Once IOC has been authorized, the retail food establishment shall notify the Department of any changes to the authorized IOC operation, such as, but not limited to, operations, procedures, menus, or changes in the retail food establishment in accordance with 8‑304.11(B).

**9‑7 BARBECUE PIT AND PIT‑COOKING ROOM CONSTRUCTION**

This standard shall apply to the construction and operation of a barbeque pit or smokehouse room as part of a retail food establishment.

**(A) Definition.**

**Barbecue** is defined as a single process method of cooking by which meat, poultry, or fish (either whole or in pieces) is covered and slow cooked in a pit or on a spit using an indirect or direct heat source.

**(B) General.**

Barbecue pit rooms shall be located on the physical premises of the permitted retail food establishment.

**(C) Employees.**

(1) Food employees shall not contact exposed, ready‑to‑eat‑food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single‑use gloves, or dispensing utensils.

(2) Personal clothing and belongings shall be stored in a designated place away from food preparation, food service, dry storage areas, utensil and single‑service article storage, and utensil washing areas.

**(D) Food.**

(1) All food items shall be protected from contamination during transportation, storage, cooking, display, and service.

(2) All food employees shall prepare, hold, and serve food according to all applicable sections of Chapter 3 , *Food*.

(3) Pit rooms shall have at least one temperature measuring device for checking temperatures of food that meets the following requirements:

(a) Able to be calibrated and

(b) Appropriate for the food density being checked.

(4) Adequate refrigeration shall be provided to support the cooking activity conducted in the pit room at the permitted retail food establishment.

**(E) Pit‑Cooking Room Restrictions.**

(1) Pit‑cooking rooms built according to these minimum construction requirements shall be restricted to barbecue cooking equipment and the single process of cooking.

(2) No additional food preparation or processing activities shall be permitted in the pit room unless there is full compliance with all construction requirements pursuant to Chapter 6 of this regulation.

**(F) Construction.**

(1) All sides and the ceiling of the pit room shall be completely enclosed.

(2) Screening may be used above wainscot height, four (4) feet on walls, and must be at least sixteen (16) mesh per inch.

(3) All outside openings shall be protected against insects by tight‑fitting, self‑closing doors, closed windows, screening, approved fly fans, or other means.

(4) Canvas flaps or other effective devices may be required to protect against blowing contamination.

(5) A large tight‑fitting garage door may be allowed without a self‑closer but shall remain closed during cooking operations.

(6) Floors of pit‑cooking rooms, excluding pit floors, shall be constructed of smooth, durable materials such as sealed concrete, quarry tile, vinyl floor covering, or other approved material.

(7) Floors shall be maintained in good repair.

(8) Floors approved for water flushing, such as quarry tile or sealed concrete, shall be graded to floor drains and shall have junctures between walls and floors sealed.

(9) Interior walls shall have smooth, easily cleanable, and washable surfaces to at least wainscot height (4 feet).

(10) If screening is used above wainscot, studs and other exposed bracing shall be sealed or painted.

(11) Concrete blocks or other masonry products used for wall construction shall be trowelled, skim‑coated, or receive sufficient coats of full strength block filler to render a smooth surface prior to the application of a washable paint.

(12) Ceilings shall be finished to provide a smooth, nonabsorbent, and easily cleanable surface.

(13) Trusses and rafters shall not be exposed.

(14) Ceiling joists shall be properly sealed.

(15) Pit‑cooking rooms shall be ventilated and kept reasonably free of excessive heat, vapors, smoke, and fumes by ventilating the pit itself or by ventilating the room. Pit ventilation can be achieved by a chimney or duct using dampers, pit doors, or other devices to control airflow. Pit‑cooking rooms may be ventilated by a cathedral ceiling with screened roof‑ridge vents, mechanical exhaust fans, or other effective methods approved by the Department when pits are not directly vented to the outside.

(16) At least twenty (20) foot‑candles of light shall be provided at all working surfaces, including the handwashing sink.

**(G) Cooking Pit and Cooker Construction.**

(1) Cooking pit floors may consist of a solid base of compacted clay with a top layer of clean sand to absorb grease drippings. Sand shall be replaced as necessary to maintain a safe and sanitary condition.

(2) Pit floors may also be constructed of concrete, firebrick, or other material that can be cleaned and maintained.

(3) Cooking pit walls (exterior sides only) shall be smooth, easily cleanable, and washable.

(4) Concrete blocks or other masonry products used for pit construction shall be trowelled, skim coated, or receive sufficient coats of full strength block filler applied to the exterior wall prior to the application of a washable paint.

(5) Pit grills, grates, and other supports shall be constructed of smooth, easily cleanable, nonabsorbent, non‑toxic material, and shall be in sections that are easily removable for cleaning.

(6) Hog wire, chicken wire, hardware cloth, and similar materials, that are not galvanized or have welded joints, are permitted for single‑use only and shall be discarded after each cooking period. Expanded metal and cast iron grating are recommended materials that can be cleaned and maintained.

(7) Pit covers shall be single‑use or shall be constructed of a smooth, easily cleanable, nonabsorbent, and non‑toxic material.

(8) The use of cookers and mobile cookers in lieu of a barbeque pit shall require the prior approval of the Department. These units shall be located in the pit room.

**(H) Handwashing Sinks.**

(1) Handwashing sinks shall be provided pursuant to 5‑202.12, 5‑203.11, and 5‑204.11.

(2) The handwashing sink shall be provided with soap and disposable paper towels.

(3) Gloves and/or hand sanitizers shall not be allowed as a substitute for handwashing facilities.

**(I) Authorization.**

(1) No retail food establishment shall operate a barbecue pit that does not have an authorization issued by the Department.

(2) Any retail food establishment that operates or proposes to operate a barbecue pit must apply to the Department for an authorization through the application process.

(3) The following additional documentation shall be submitted as part of the application process:

(a) Information about food prepared in the barbecue pit room and

(b) Any other information requested by the Department.

(4) Only a retail food establishment that complies with the requirements of this regulation and standard shall be entitled to receive and retain such an authorization.

(5) Once a barbecue pit has been authorized, the Department shall be notified of any changes to the barbecue pit, such as, but not limited to, operational changes, menu changes, or changes in the barbecue pit in accordance with 8‑304.11(B).

**9‑8 TEMPORARY FOOD SERVICE ESTABLISHMENTS**

This standard shall apply to the construction and operation of a temporary food establishment.

**(A) Definitions.**

A **temporary food service establishment** is defined as an establishment that may be authorized by the Department to operate at a fixed location for a period of time not to exceed fourteen (14) consecutive days in connection with a fair, carnival, circus, trade show, movie or filming location, golf or other national sporting events, and other transitory gatherings organized by the community. This standard also applies to retail food service establishments that operate in an area affected by a natural or man‑made disaster and where a state of emergency or a public health emergency has been declared.

**(B) General.**

(1) Temporary food service establishments shall comply with all applicable sections of this regulation except as outlined in this standard.

(2) The Department may prohibit the distribution of certain time/temperature control for safety food, and may modify specific requirements for physical facilities when, in the opinion of the Department, no health hazard will result.

**(C) Employees.**

(1) Food vendors and/or employees shall not contact exposed, ready‑to‑eat‑food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single‑use gloves, or dispensing utensils.

(2) Personal clothing and belongings shall be stored in a designated place away from food preparation, food service, dry storage areas, utensil and single‑use article storage, and utensil washing areas.

**(D) Food.**

(1) All food/ice shall be obtained from sources approved by the Department.

(2) All food items shall be protected from contamination during transportation, storage, cooking, display, and service.

(3) All food vendors shall prepare, hold, and serve food according to all applicable sections of Chapter 3, *Food*.

(4) All time/temperature for safety food cooked offsite shall be provided by a retail food establishment or mobile food establishment permitted under this regulation.

(5) Time/temperature for safety foods that have been cooked or are in hot holding at any point during the daily operating hours shall be discarded at the end of the day.

(6) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection or offered in individual packages.

(7) Cakes, breads, and cookies that are not made at a permitted retail food establishment may be offered for sale only if they are not a time/temperature for safety food.

(8) Ice shall be obtained in closed single‑service bags or approved covered containers and shall be protected from contamination. Ice used as a coolant for foods shall not be used for edible ice.

(9) Each temporary food service establishment shall have at least one temperature measuring device for checking temperatures of food that meets the following requirements:

(a) Able to be calibrated; and

(b) Appropriate for the food density being checked.

**(E) Service.**

(1) During operations, food shall be stored, cooked, displayed, and served from the temporary food service establishment only.

(2) Customer self‑service of unpackaged time/temperature control for safety foods is prohibited.

(3) Temporary food service establishments shall provide only single‑service articles for use by the consumer.

(4) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection or offered in individual packages.

(5) In use wiping cloths must be stored in clean solution of an approved sanitizer.

(6) A test kit that accurately measures the parts per million concentration of an approved sanitizer shall be accessible and used.

(7) Food shall be kept covered except during times of continuous serving or display.

(8) Covers or lids may be removed only for monitoring, stirring, or adding additional ingredients.

**(F) Construction.**

(1) Floors shall be constructed of concrete, asphalt, tight wood, or other similar cleanable material.

(2) Floors shall be kept clean and in good repair.

(3) Walls shall be constructed of a solid, easily cleanable material.

(4) Screening may be used above wainscot height, four (4) feet, on walls and must be at least sixteen (16) mesh per inch.

(5) Studs and joists may be exposed, provided they are sealed.

(6) Ceilings shall be constructed of a solid, easily cleanable material.

(7) Exposed ceiling joists and rafters may be allowed, provided they are sealed.

(8) Light bulbs and fluorescent tubes shall be shielded, coated, or otherwise shatter‑resistant and provide at least twenty (20) foot candles of illumination.

(9) All outside openings shall be protected against insects by tight‑fitting, self‑closing doors, closed windows, screening, approved air curtains, or other means.

(10) Canvas flaps or other effective devices may be required to protect against blowing contamination where screening is used.

(11) Counterservice openings shall be equipped with approved air curtains, self‑closing windows, or free‑falling windows or screens that must be at least sixteen (16) mesh per inch. Where air curtains are used, the size of the openings shall be limited so that the fans effectively prevent the entrance of flying insects.

(12) A temporary food establishment shall be equipped with a warewashing sink with at least three (3) compartments large enough to accommodate two thirds of the largest utensil. This requirement shall not apply to temporary food establishments engaged only in the dispensing of prepackaged food.

(13) The warewashing sink shall be supplied with hot and cold water under pressure, equipped with a mixing faucet that is capable of servicing all sink compartments.

(14) Adequate refrigeration shall be provided.

(15) A temperature measuring device shall be provided for each refrigeration unit.

(16) Equipment shall be installed in a manner that allows it to be maintained in a sanitary condition.

(17) Ice and beverages may be dispensed in the serving area if protected from contamination. This area must be sheltered but is not required to be screened or enclosed.

**(G) Handwashing Sinks.**

(1) All temporary food service establishments shall have a separate handwashing sink, equipped with hot and cold water under pressure through a mixing valve or combination faucet.

(2) The handwashing sink shall be separated from food and food contact surfaces by either a splashguard or a distance of at least twelve (12) inches.

(3) Soap and disposable paper towels must be provided and be adjacent to the handwashing sink.

(4) Gloves and/or hand sanitizers shall not be allowed as a substitute for handwashing facilities.

**(H) Water system.**

(1) Drinking water hoses shall be made from food grade materials and shall be a different color from hoses used for sewage.

(2) Drinking water hoses shall be capped or covered when not in use and shall be stored separately from sewage hoses.

(3) When attached to a drinking water system, the temporary food service establishment shall be equipped with an approved backflow prevention device.

(4) Connections to the drinking water and sewage tanks shall be different types or sizes to eliminate contamination of the drinking water supply.

(5) Sewage and drinking water hose connections shall not be interchangeable.

(6) Water heaters with sufficient capacity shall be provided in facilities that prepare and serve time/temperature for safety food.

**(I) Sewage Retention.**

(1) Sewage that is not directly discharged into an approved sewage system shall be kept in closed containers adequate in number and capacity to prevent spillage and must be discharged into an approved sewage disposal system as often as needed.

(2) All sewage lines shall be connected to sewage tanks with watertight seals.

(3) Used cooking oil shall be disposed of in an approved manner.

(4) Adequate and approved toilet facilities shall be provided.

(5) Adequate trash cans and other sanitary facilities, as deemed necessary by the Department, shall be provided to support the temporary food service establishments operating at the event.

**(J) Specific Exemptions.**

(1) Temporary food service establishments are exempt from the requirements for training certification in 2‑102.12(B).

(2) Temporary food service establishments that provide foods pursuant to 8‑301.12(A)(11),(12),(19) and (20) of this regulation are exempt from the requirements of this standard.

**(K) Authorization.**

(1) No person, retail food establishment, or mobile food unit may serve time/temperature for safety food at a temporary food service establishment unless the sponsoring entity obtains authorization from the Department.

(2) The sponsoring entity of an event where temporary food service establishments will operate shall appoint an Event Coordinator as a point of contact.

(3) Any sponsoring entity that operates or proposes to operate an event where temporary food service establishments will operate shall apply for authorization on the form provided by the Department prior to commencement of the event. The following information shall be submitted with the application:

(a) Event Coordinator name and contact information;

(b) The dates of the fourteen (14) consecutive days of operation;

(c) A list of temporary food service establishments, with contact information, that will operate at the event; and

(d) The time that all temporary food service establishments are required to be ready for operation.

(4) Each temporary food service establishment shall be authorized by the Department prior to serving food to the public at the event.

(5) The Department may require a sponsoring entity or a temporary food service establishment to submit information sufficient to determine if the definition and requirements of this standard or regulation are met. This information may include, but is not limited to, information defining the fair, carnival, circus, or organized event, event schedule(s), hours of food vendor operations, vendor list and foods specific to those vendors, and vendor contact information.

(6) All food vendors shall meet the requirements for temporary food service establishment.

(7) Food vendors shall not be allowed to operate under the requirements of Sections 9‑9, *Community Festivals*, 9‑10, *Special Promotions*, or 9‑11, *Retail Food Establishment – South Carolina Farmers Markets, Seasonal Series, and Remote Service*, of this regulation.

(8) When the Department determines that a sponsoring entity or a temporary food service establishment has violated applicable provisions of this standard or regulation, the Department may issue a written notice directing any or all temporary food service establishments to cease operations until the violations are corrected as determined by the Department.

(9) Any temporary food service establishment that proposes to operate at one event and location for more than fourteen (14) days, either by remaining in operation for additional consecutive days, or by reopening after a short period of closure, shall comply with the requirements for, and be permitted as, a retail food establishment or a mobile food establishment.

(10) If a retail food service establishment is operating as a temporary food service establishment in an area affected by a natural or man‑made disaster after a state of emergency or a public health emergency has been declared, it may be allowed to exceed fourteen (14) consecutive days of operation if approved by the Department.

**9‑9 COMMUNITY FESTIVALS**

This standard shall apply to the service of food and the requirements of food vendors at community festivals.

**(A) Definitions.**

**Community festivals** are defined as events sponsored by a community group, city/county/state organization, as a community celebration, that are generally theme related, and have multiple food vendors recruited to provide food to the public for a time period not to exceed three (3) consecutive days or no more than seventy‑two (72) continuous hours. Each community festival is unique and will not be held more frequently than annually, although a sponsoring organization or group might have multiple but differently themed community festivals in a year.

**(B) General.**

(1) Community festival food vendors shall comply with all applicable sections of this regulation except as outlined in this standard.

(2) The Department may prohibit the distribution of certain time/temperature control for safety food and may modify specific requirements for physical facilities when, in the opinion of the Department, no health hazard will result.

**(C) Employees.**

(1) Food vendor employees shall not contact exposed, ready‑to‑eat‑food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single‑use gloves, or dispensing utensils.

(2) Personal clothing and belongings shall be stored in a designated place away from food preparation, food service, dry storage areas, utensils, single‑use article storage, and utensil washing areas.

**(D) Food.**

(1) All food/ice shall be obtained from sources approved by the Department.

(2) All food items must be protected from contamination during transportation, storage, cooking, display, and service.

(3) All food vendors shall prepare, hold, and serve food according to all applicable sections of Chapter 3, *Food*.

(4) Time/temperature for safety foods, such as raw meat products, shall be ready to be cooked.

(5) All time/temperature for safety food fully prepared or cooked offsite shall be provided by a retail food establishment or mobile food establishment permitted under the regulation.

(6) Only quantities of meat, such as barbecue, may be pulled, chopped, or cut for same day service in the food vendor’s preparation area.

(7) No mechanical chopping equipment will be allowed in unenclosed preparation areas.

(8) Time/temperature for safety foods that have been cooked or in hot holding at any point during the daily operating hours shall be discarded at the end of the day.

(9) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection or offered in individual packages.

(10) Cakes, breads, and cookies that are not made at a permitted retail food establishment may be offered for sale only if they are not a time/temperature for safety food.

(11) Ice shall be obtained in closed single‑service bags or approved covered containers and shall be protected from contamination. Ice used as a coolant for foods shall not be used for edible ice.

(12) Each community festival food vendor shall have at least one temperature measuring device for checking temperatures of food that meets the following requirements:

(a) Able to be calibrated; and

(b) Appropriate for the food density being checked.

(13) Food shall be kept covered except during times of continuous serving or display.

(14) Covers or lids may be removed only for monitoring, stirring, or adding additional ingredients.

**(E) Construction.**

(1) Food preparation areas shall have overhead protection and adequate barriers (e.g., tables or equipment) to prevent the access to the area by the public.

(2) Equipment shall arrive clean and ready to use.

(3) Utensils and single use articles shall be clean, protected during storage, and in sufficient quantities to conduct the activity.

**(F) Handwashing Sinks.**

(1) When a handwashing sink is not available, a container of water with a spigot, soap, disposable towels, and a catch bucket shall be provided.

(2) Gloves and/or hand sanitizers shall not be allowed as a substitute for handwashing facilities.

**(G) Water system.**

(1) Drinking water hoses shall be made from food grade materials and shall be a different color from hoses used for sewage.

(2) Drinking water hoses shall be capped or covered when not in use and shall be stored separately from sewage hoses.

(3) When attached to a drinking water system, the hose shall be equipped with an approved backflow prevention device.

**(H) Sewage Retention.**

(1) Sewage that is not directly discharged into an approved sewage system shall be kept in closed containers with adequate capacity or adequate in number to prevent spillage and must be discharged into an approved sewage disposal system as often as needed.

(2) All sewage lines shall be connected to sewage tanks with watertight seals.

(3) Used cooking oil shall be disposed of in an approved manner.

(4) Adequate toilet facilities shall be provided.

(5) Adequate trash cans and other sanitary facilities, as deemed necessary by the Department, shall be provided to support the community festival food vendors.

(**I) Specific Exemptions.**

(1) Community festival food vendors are exempt from the requirements for training certification in 2‑102.20.

(2) Community festival food vendors that provide food pursuant to 8‑301.12(A)(11),(12),(19) and (20) are exempt from the requirements of this standard.

(3) Hot water requirements are waived for food vendors at community festivals.

**(J) Authorization.**

(1) No person, retail food establishment, or mobile food unit may serve time/temperature control for safety food at a community festival unless the sponsoring entity obtains authorization from the Department.

(2) The sponsoring entity of a community festivals shall appoint an Event Coordinator as a point of contact.

(3) Any sponsoring entity that operates or proposes to operate a community festival where time/temperature for safety food will be served shall apply for authorization on the form provided by the Department prior to commencement of the festival. The following information must be submitted with the application:

(a) The Event Coordinator’s name and contact information;

(b) The dates of the seventy‑two (72) continuous hour period in which all food vendors will be in operation;

(c) A list of food vendors, with contact information, that will operate at the event; and

(d) The time that all food vendors are required to be ready for operation.

(4) Each community festival food vendor shall be authorized by the Department prior to serving food to the public at the festival.

(5) The Department may require a sponsoring entity or a food vendor to submit information sufficient to determine if the definition and requirements of this standard or regulation are met. This information may include, but is not limited to, information defining the community group, city/county/state organization, event schedule(s), hours of food vendor operations, vendor list and foods specific to those vendors, and vendor contact information.

(6) When the Department determines that a sponsoring entity or a food vendor has violated applicable provisions of this standard or regulation, the Department may issue a written notice directing any or all food vendors to cease operations until the violations are corrected as determined by the Department.

**9‑10 SPECIAL PROMOTIONS**

This standard shall apply to the service of food and the requirements of food vendors at special promotions.

**(A) Special promotions** are defined as events sponsored by businesses or city/county organizations that may be authorized by the Department to prepare and dispense food for the purpose of promoting a product or service. Preparation and dispensing food at special promotions are limited to one (1) day in duration at four (4) separate times per year. Special promotions do not include regularly occurring sporting events, such as, but not limited to, school ballgames.

**(B) General.**

(1) Food preparation and service areas shall comply with all applicable sections of this regulation except as outlined in this standard.

(2) The Department may prohibit the distribution of certain time/temperature control for safety foods, and may modify specific requirements for physical facilities when, in the opinion of the Department, no health hazard will result.

**(C) Employees.**

(1) Food vendor employees shall not contact exposed, ready‑to‑eat‑food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single‑use gloves, or dispensing utensils.

(2) Personal clothing and belongings shall be stored in a designated place away from food preparation, food service, dry storage areas, utensil and single‑use article storage, and utensil washing areas.

**(D) Food.**

(1) All food/ice shall be obtained from sources approved by the Department.

(2) All food items must be protected from contamination during transportation, storage, cooking, display, and service.

(3) All food vendors shall prepare, hold, and serve food according to all applicable sections of Chapter 3, *Food*.

(4) Time/temperature for safety foods, such as raw meat products, shall be ready to be cooked.

(5) All time/temperature for safety food cooked offsite shall be provided by a retail food establishment or mobile food establishment permitted under this regulation.

(6) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection or offered in individual packages.

(7) Cakes, breads, and cookies that are not made at a permitted retail food establishment may be offered for sale only if they are not a time/temperature for safety food.

(8) Ice shall be obtained in closed single‑service bags or approved covered containers and shall be protected from contamination.

(9) Ice used as a coolant for foods shall not be used for edible ice.

(10) Each food vendor shall have at least one temperature measuring device for checking temperatures of food that meets the following requirements:

(a) Able to be calibrated; and

(b) Appropriate for the food density being checked.

**(E) Construction.**

(1) Food preparation areas shall have overhead protection and adequate barriers (e.g., tables or equipment) to prevent the access to the area by the public.

(2) Equipment shall arrive clean and ready to use.

(3) Utensils and single‑service articles shall be clean, protected during storage, and in sufficient quantities to conduct the activity.

**(F) Handwashing Sinks.**

(1) When a handwashing sink is not available, a container of water with a spigot, soap, disposable towels, and a catch bucket shall be provided.

(2) Gloves and/or hand sanitizers shall not be allowed as a substitute for handwashing facilities.

**(G) Water system.**

(1) Drinking water hoses shall be made from food grade materials and shall be a different color from hoses used for sewage.

(2) Drinking water hoses shall be capped or covered when not in use and shall be stored separately from sewage hoses.

(3) When attached to a drinking water system, the hose shall be equipped with an approved backflow prevention device.

**(H) Sewage Retention.**

(1) Sewage that is not directly discharged into an approved sewage system shall be kept in closed containers with adequate capacity to prevent spillage and must be discharged into an approved sewage disposal system as often as needed.

(2) All sewage lines shall be connected to sewage tanks with watertight seals.

(3) Used cooking oil shall be disposed of in an approved manner.

**(I) Specific Exemptions.**

(1) Special promotions are exempt from the requirements for training certification in 2‑102.20.

(2) Special promotions that provide food pursuant to 8‑301.12(A)(11),(12),(19) and (20)are exempt from the requirements of this standard.

(3) Hot water requirements are waived for special promotions.

(4) Toilet and service sink facilities are not required for special promotions.

**(J) Authorization.**

(1) The Department may require a sponsoring entity to submit information sufficient to determine if a special promotion complies with this standard and regulation. This information may include, but is not limited to, information defining the businesses, or city/county organizations, event schedule(s), hours of food vendor operations, vendor list and foods specific to those vendors, and vendor contact information.

(2) When the Department determines that a sponsoring entity has violated applicable provisions of this standard or regulation, the Department may issue a written order directing the special promotion to cease operations.

**9‑11 RETAIL FOOD ESTABLISHMENT – SOUTH CAROLINA FARMER**’**S MARKETS, SEASONAL SERIES, AND REMOTE SERVICE**

This standard shall apply to the service of food and the requirements of food vendors participating in SC Farmers Markets, Seasonal Series, Remote Service Operations, or other events as approved by the Department.

(**A) Definitions.**

(1) **Community‑based farmers market** means a market sponsored by a community or governmental organization either having been Certified by the South Carolina Department of Agriculture as a SC Certified Farmer’s Market or a farmers market that meets the definition of the Farmers Market Coalition which states, “A farmers market operates multiple times per year and is organized for the purpose of facilitating personal connections that create mutual benefits for local farmers, shoppers, and communities and implements rule or guidelines of operation that ensure that the farmers market consists principally of farms selling directly to the public products that the farms have produced.”

(2) **Seasonal series** means a regularly occurring event sponsored by a community or governmental organization for promoting local business, culture, or other local specialties.

(3) **Remote service operation** means a permitted retail food establishment providing food to individual consumers at an indoor location by food employees of the retail establishment who maintain control of the food service.

**(B) General.**

(1) Retail food establishments at a seasonal series or community‑based farmers market or remote service site shall comply with all applicable sections of this regulation except as outlined in this standard.

(2) The Department may prohibit the distribution of certain time/temperature control for safety foods and may modify specific requirements for physical facilities when, in the opinion of the Department, no health hazard will result.

(3) Permitted retail food establishments may be authorized by the Department to cook and serve food to the public at community farmers markets and/or seasonal series only two (2) days per week during one continuous period of time not to exceed six (6) hours.

(4) Community‑based farmers market and seasonal series shall designate the days of the week food vendors are allowed to operate.

(5) Roadside produce stands and flea markets are not defined as community‑based farmers markets or seasonal series, and this standard shall not apply to those locations.

**(C) Employees.**

(1) Retail food establishment employees shall not contact exposed, ready‑to‑eat‑food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single‑use gloves, or dispensing utensils.

(2) Personal clothing and belongings shall be stored in a designated place away from food preparation, food service, dry storage areas, utensils and single‑use article storage, and utensil washing areas.

**(D) Food.**

(1) Preparation of bulk food, including washing, slicing, peeling, and cutting, shall occur at the permitted retail food establishment.

(2) All food items shall be protected from contamination during transportation, storage, cooking, display, and service.

(3) All food vendors shall prepare, hold, and serve food according to all applicable sections of Chapter 3, *Food*.

(4) Time/temperature for safety foods that have been cooked or are in hot holding at any point during the daily operating hours shall be discarded at the end of the day.

(5) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection or offered in individual packages.

(6) Ice shall be obtained from an approved source, in closed single‑service bags or approved covered containers and shall be protected from contamination.

(7) Ice used as a coolant for foods shall not be used for edible ice.

(8) Each retail food establishment shall have at least one temperature measuring device for checking temperatures of food that meets the following requirements:

(a) Able to be calibrated; and

(b) Appropriate for the food density being checked.

(9) Food shall be kept covered except during times of continuous serving or display.

(10) Covers or lids shall not be removed other than for monitoring, stirring, or adding additional ingredients.

**(E) Construction.**

(1) Food preparation areas shall be provided with overhead protection and have adequate barriers (e.g., tables or equipment) to prevent the access to the area by the public.

(2) Equipment and utensils shall arrive clean, ready to use, and in sufficient quantities to conduct the activity.

(3) Equipment and utensils shall only be cleaned at the permitted retail food establishment.

(4) Only single‑service articles shall be provided for use by the consumer.

**(F) Handwashing Sinks.**

(1) Each food vendor shall have at least one (1) handwashing facility located at the individual vendor location that may be either:

(a) A portable handsink that provides water under pressure or

(b) A container of water with a spigot and catch bucket.

(2) All handwashing facilities must have adequate water dispensing storage capacity to meet the demand for handwashing. The wastewater storage capacity must be larger than the water storage container.

(3) Handwashing facilities must include soap and disposable towels.

(4) Gloves and/or hand sanitizers shall not be allowed as a substitute for handwashing facilities.

**(G) Water System.**

(1) Drinking water hoses shall be made from food grade materials and shall be a different color from hoses used for sewage.

(2) Drinking water hoses shall be capped or covered when not in use and shall be stored separately from sewage hoses.

(3) When attached to a drinking water system, the hose shall be equipped with an approved backflow prevention device.

**(H) Sewage Retention and Refuse Removal.**

(1) Sewage that is not directly discharged into an approved sewage system shall be kept in closed containers adequate in number and capacity to prevent spillage and must be discharged into an approved sewage disposal system as often as needed.

(2) All sewage lines shall be connected to sewage tanks with watertight seals.

(3) Used cooking oil shall be disposed of in an approved manner.

(4) Adequate toilet facilities shall be provided.

(5) Adequate trash cans, as deemed necessary by the Department, shall be provided to support the retail food establishment.

**(I) Specific Exemptions.**

Seasonal series or community‑based farmers markets that provide foods pursuant to 8‑301.12(A)(11),(12),(19) and (20) are exempt from authorization based on the requirements of this standard.

**(J) Authorization.**

(1) No retail food establishment, or mobile food unit may serve time/temperature control for safety foods at a seasonal series or community‑based farmers market unless the sponsoring entity obtains authorization from the Department. Pre‑approval is not required for remote service operations.

(2) The sponsoring entity of a seasonal series or community‑based farmers market shall appoint an Event Coordinator as a point of contact.

(3) Any sponsoring entity that operates or proposes to operate a seasonal series or community‑based farmers market where time/temperature control for safety foods will be served by retail food establishments shall apply for authorization from the Department. The following information shall be submitted:

(a) The Event Coordinator name and contact information;

(b) The one day of the week and hours of operation for food service; and

(c) A list of retail food establishments, with contact information, that will operate at the event.

(4) Each retail food establishment at a seasonal series or community‑based farmers market shall be authorized by the Department prior to serving food to the public at the event.

(5) The Department may require a sponsoring entity or a retail food establishment to submit information sufficient to determine if the definition and requirements of this standard or regulation are met. This information may include, but is not limited to, information defining the community group, governmental organization, SC Certified Farmer’s Market certification, association to Farmers Market Coalition, event schedule(s), hours of food vendor operations, vendor list and foods specific to those vendors, and vendor contact information.

(6) When the Department determines that a sponsoring entity or a retail food establishment has violated applicable provisions of this standard or regulation, the Department may issue a written notice directing any or all retail food establishment vendors to cease operations until the violations are corrected as determined by the Department.

61‑37. [Repealed].

**Fiscal Impact Statement:**

There are no anticipated new costs to the state or its political subdivisions associated with the implementation of this regulation.

**Statement of Need and Reasonableness:**

The following presents an analysis of the factors listed in 1976 Code Section 1‑23‑115(C)(1)‑(3) and (9)‑(11):

DESCRIPTION OF REGULATION: 61‑25, Retail Food Establishments; and 61‑37, Retail Food Establishment Inspection Fees.

Purpose: The Department repeals R.61‑37, Retail Food Establishment Inspection Fees, in total and amends R.61‑25, Retail Food Establishments, to incorporate revised fee schedules currently residing in R.61‑37. Furthermore, the Department amends R.61-25 to meet the current standards of the 2017 United States Food and Drug Administration (“FDA”) Food Code. The FDA Food Code is the national standard for state, local, and tribal food protection programs. The FDA Food Code offers a practical, scientifically‑sound technical and legal basis for regulating the retail food establishment segment of the food industry by addressing the risk factors known to cause foodborne illness outbreaks in retail food establishment settings. The amendments also include revisions to selected sections of R.61‑25 to reflect the current business models of the food service industry and incorporate comments and suggestions from the regulated community. The amendments also include other changes as deemed necessary by the Department to improve the overall clarity, organization, and quality of the regulation. These changes include, but are not limited to, stylistic changes, updates to definitions and exemptions, corrections for clarity, readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

Legal Authority: 1976 Code Sections 44‑1‑140(2), 44‑1‑150, and 44‑1‑180.

Plan for Implementation: The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to this amendment and repeal. Additionally, printed copies are available for a fee from the Department’s Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendment/repeal and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments will allow the Department, through regulation, to meet the current standards of the 2017 United States Food and Drug Administration (“FDA”) Food Code. The FDA Food Code is the national standard for state, local, and tribal food protection programs. The FDA Food Code offers practical, science‑based guidance that addresses the risk factors known to cause foodborne illness outbreaks in retail food establishment settings. It is amended every two (2) years and published in full every four (4) years via the Conference for Food Protection, a national conference of food safety regulators, food scientists, industry representatives, and members of academia.

The amendments also revise the regulation to reflect current business models within the food service industry not addressed by the FDA Food Code.

The amendments also incorporate an increase in inspection fees, which will provide necessary program support. The amendments merge R.61‑37 into R.61‑25 to provide the retail food industry with one streamlined regulation.

The amendments also include other changes as deemed necessary by the Department to improve the overall clarity, organization, and quality of the regulation.

DETERMINATION OF COSTS AND BENEFITS:

The amendments seek to benefit food safety in South Carolina and the health of South Carolina’s citizens, as the intent of this regulation is to provide consumers with safe, unadulterated food and food products at the retail level. The amendment of R.61‑25 will allow the regulation to conform to the current national standard set by the 2017 FDA Food Code. For the food service industry, including many establishments associated with national chains, the current edition of the FDA Food Code provides a needed uniformity and consistency with food safety rules nationally. Other changes to the regulation improve the overall clarity, organization, quality, and consistency of the regulation, which benefits the public and regulated community by facilitating improved understanding and implementation of the regulation.

The increase in fees will benefit the Bureau of Environmental Health Services (“Bureau”) and ease the burden on the general public by facilitating additional program support through increasing existing fees instead of requesting additional state taxpayer funding. The additional funds will generate more resources to fund Department development and provision of compliance assistance tools and training for the regulated community to support facilities in developing practical food safety systems for their operations.

The fee increase is based on the Bureau’s review of comparable regional food safety programs and evaluation of program needs due to retail food service industry growth. Existing program fees were established in 2000 and have not increased since such time. The following fee changes will both ensure fees for South Carolina facilities remain in keeping with fees charged by other southeastern states and also generate much needed funds for the Bureau’s permit and inspection programs. Under the amended regulation, the base annual inspection fee of sixty dollars ($60.00) will be increased to one hundred dollars ($100.00). The annual inspection fee increases by increments of fifty dollars ($50.00) per tier up to a maximum inspection fee of four hundred and fifty dollars ($450.00), as compared to increments of thirty dollars ($30.00) per tier up to a maximum inspection fee of two hundred and seventy dollars ($270.00) under the preexisting regulation. To meet the growing demands for service and inspection, the Department also is increasing the initial permitting fee to include a one‑time fee of one hundred dollars ($100.00) in addition to the applicable tiered annual inspection fee. This increased fee will support the cost of conducting pre‑operational and permit inspections.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Implementation of this regulation will not compromise the protection of the environment or the public health. The regulation will help to ensure that consumers are receiving safe, unadulterated food and food products at the retail level. The amendment of R.61‑25 to conform to the most recent edition of the FDA Food Code also provides effective means of reducing the risks of foodborne illnesses within retail food establishments, thus protecting consumers and industry from potentially devastating public health consequences and financial losses.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There will be no adverse effect on the environment if the regulations are not implemented. Not implementing these regulations could have detrimental effect on public health. Not implementing these regulations will prevent the implementation of the latest sanitary standards and will impede the comprehensive approach to food safety management needed in addressing food protection in the retail food industry. This could have a detrimental effect on the health of South Carolina’s citizens and visitors. Failure to provide the necessary fee funding for the program may result in a decrease in effectiveness of the food safety oversight program as the industry continues to expand in size. The lack of increased fee funding also reduces Department compliance assistance resources for the regulated industry.

**Statement of Rationale:**

These amendments provide the retail food industry the regulatory framework to meet the latest sanitation requirements for providing safe, unadulterated food and food products to consumers. The FDA Food Code offers proven scientific reasons behind regulation and actively seeks input from the scientific and academic communities as their understanding of foodborne pathogens increases. The amendment of R.61‑25 to conform to the most recent edition of the FDA Food Code provides a comprehensive approach to food safety management, superior supporting documents and training, and is consistent with the national integrated food safety management system. Furthermore, the R.61‑25 amendments and R.61‑37 repeal provide the retail food industry with one streamlined regulation while allowing for necessary program support through an increase in inspection fees. Other revisions are intended to better reflect current business models within the food service industry. Other changes to the regulation improve the overall clarity, organization, and quality, of the regulation.