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 Chapter9-9 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.