IMPORTANT - Save this Supplement. It is intended to keep the 2017 Food Code up-to-date. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2017 Food Code effective upon issuance.

Supplement to the 2017 FDA Food Code

The Food Code (and its Supplement) is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents the Food and Drug Administration's (FDA) best advice for a uniform system of provisions that address safety and protection of food offered at retail and in food service.

This model is offered for adoption by local, state, territorial, tribal, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations.

This document is available via the internet in PDF at the following link: www.fda.gov/foodcode
INTRODUCTION

The Food and Drug Administration (FDA) is pleased to issue this Supplement to the 2017 Food Code (hereafter referred to as Supplement). This Supplement updates the 2017 Food Code to address several recommendations made at the 2018 Meeting of the Conference for Food Protection (CFP) with which the FDA, Centers for Disease Control and Prevention (CDC), and United States Department of Agriculture (USDA) concur. The changes contained in this Supplement reflect current science and food safety practices to reduce the incidence of risk factors known to cause foodborne illness.

From 1993 through 2001, the complete Food Code was issued every two years. With the support of the CFP, FDA currently issues a new Food Code every 4 years. The next complete revision of the Food Code will be published in 2021. Until that time, this Supplement provides a means of incorporating into the Food Code several changes with which there is substantial concurrence among the federal agencies and the other stakeholders. The Supplement ensures that the most current food safety provisions are available to agencies planning to initiate rule-making activities prior to 2021. This Supplement provides other users of the Food Code, such as educators, trainers, and the food service, retail food, and vending industries, with up-to-date information of how to best mitigate risk factors that contribute to foodborne illness.

The Supplement has been organized to facilitate the adoption of its provisions by federal, state, local, territorial, and tribal authorities. The Supplement is divided into 3 Parts:

Part 1 - Summary of Changes - a "quick view" of the modifications
Part 2 - Amendments, Additions, Deletions to the Preface, Chapters 1-8 and the Annexes - actual language modifications
Part 3 - New Terms added to the Index to the Food Code

For consistency, drafting conventions used in the Federal Register for announcing proposed changes to federal rules are used to announce changes found in the Supplement to the 2017 Food Code. The standard terms used to describe a change are:

Amend. "Amend" means that an existing Food Code provision has changed. Because it is an introductory term, it is always used with one of the following specific amendatory terms to precisely describe the change to the Food Code provision.
Amendatory Terms

Add - means a new provision has been inserted in the Food Code.
Redesignate - means to modify a Food Code provision by reformatting the text of the provision into a new structural nomenclature designation.
Remove - means an existing provision is being taken out of the Food Code.
Revise - means an existing Food Code provision is replaced in part, or in its entirety.

For example:

Amend Section 4-204.110 to revise subparagraph (B)(1) and to add subparagraph (B)(3) to read as follows: [text of changed subparagraph and newly added subparagraph]

Modifications are organized by Food Code chapter and are identified by Section (§) number and title, and the paragraph (¶), (e.g., ¶9-101.11(A)) or subparagraph (e.g., 9-101.00(A)(1)) to which the change is made. The full text of a Section is provided only if necessary to provide the proper context. Using Chapter 3 as an example, a change is introduced as follows:

Chapter 3 Food

Amend § 3-202.11 to revise paragraph (D) to read as follows:

Specifications for Receiving

3-202.11 Temperature.*

[text of changed paragraph]

The Supplement also contains changes to the informational annexes of the Food Code. Using Annex 3 as an example, a change to the public health reasons for a Food Code provision in Chapter 4 is introduced as follows:

Annex 3 Public Health Reasons/Administrative Guidelines

4-202.15 Can Openers.

Amend Public Health Reason for §4-202.15 to revise to read as follows:

[text of changed paragraph]
We encourage all jurisdictions to examine the level of food safety protection their current rules and implementation strategies provide and take the steps necessary to increase that level in light of the 2017 Food Code and its Supplement. The adoption and implementation of the Food Code in all jurisdictions is an important strategy for achieving uniform national food safety standards and for enhancing the efficiency and effectiveness of our nation's food safety system.

The Department of Health and Human Services (DHHS) and USDA, along with state, local, tribal and other federal government agencies and the food industry, share responsibility for ensuring that our food supply is safe. DHHS and USDA, in partnership with numerous others, will continue to take progressive steps to strengthen our nation’s food safety system. We look forward to achieving uniform and effective standards of food safety for food service, retail stores, and other retail-level establishments nationwide.
**Part 1. Summary of Changes**

The amendments to the 2017 Food Code and its Annexes contained in the Supplement are summarized below. If an amendment relates directly to a recommendation of the Conference for Food Protection (CFP), the CFP issue number is provided in the parenthesis immediately after the summary entry.

**Preface**

No Change.

**Chapter 1  Purpose and Definitions**

Revised the definition of **INTACT MEAT** to clarify that beef products that are vacuum tumbled with solutions are not considered intact meats.

Revised the definition of **MECHANICALLY TENDERIZED** to be consistent with the USDA FSIS description of “mechanically tenderized” in the 2015 final rule titled Descriptive Designation of Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Product (80 FR 28153). The rule established labeling requirements for raw or partially cooked mechanically tenderized beef products and clarified that products injected with a marinade or solution are considered mechanically tenderized. (CFP Issue 2018-I-013)

**Chapter 2  Management and Personnel**

2-101.11
Amended Section 2-101.11 to add new ¶(C) to address situations where the REGULATORY AUTHORITY has deemed a FOOD ESTABLISHMENT to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of their operation and extent of FOOD preparation. (CFP Issue 2018-I-003)

**Chapter 3  Food**

3-501.13
Amended ¶¶’s 3-501.13(A)-(C) to re-designate from a Core Item to a Priority Foundation (Pl) Item. (CFP Issue 2016-I-033)

3-501.19
Added new sub-¶¶’s (B)(2)(a), (b), (c), (d) to 3-501.19(B)(2) to address a READY-TO-EAT produce or hermetically sealed FOOD that is rendered TIME/TEMPERATURE CONTROL FOR SAFETY FOOD upon cutting, chopping, or opening of a hermetically sealed container to
begin at 21°C (70°F) or less and remain at 21°C (70°F) or less within a maximum of 4 hours.

Re-designated existing ¶¶’s 3-501.19(B)(2)(3) and (4) as new ¶¶’s 3-501.19(B)(3)(4) and (5) respectively. (CFP Issue 2018-III-019)

3-502.12
Amended to add new sub¶ (e)(iii) to address cook chill/sous vide products cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under §3-501.14 and subsequently cooled to 1°C (34°F) and moved to 5°C (41°F) holding temperature and held for a max of 7 days. (CFP Issue 2018-III-016)

Chapter 4 Equipment, Utensils, and Linens

4-205.10
Amended §4-205.10 to clarify that EQUIPMENT that has been certified for conformance to an appropriate American National Standard is deemed to comply with the EQUIPMENT sanitation provisions contained in Parts 4-1 and 4-2. (CFP Issue 2018-I-007)

4-303.11
Amended §4-303.11 to add the risk designation of PRIORITY FOUNDATION ITEM that was inadvertently left off in the 2017 Food Code.

Chapter 5 Water, Plumbing, and Waste

5-203.11
Amended §5-203.11 to delete “¶(C)” and remove any reference to “¶(C)” in this section. (CFP Issue 2018-III-026)

Chapter 6 Physical Facilities

No Change.

Chapter 7 Poisonous or Toxic Materials

No Change.
Chapter 8 Compliance and Enforcement

8-103.12 Amended §8-103.12 to include new ¶(A) addressing maintenance of APPROVED VARIANCE at the FOOD ESTABLISHMENT; Existing ¶’s (A) and (B) renumbered to ¶’s (B) and (C). (CFP Issue 2018-I-021)

8-201.12 Amended ¶8-201.12(C) as part of the sentence was inadvertently left off in the 2017 Food Code.

8-201.14 Amended §8-201.14 to:
• Delete sub¶ (C)(2) and add as new sub¶ (E)(2) that speaks to significant hazards for each critical control point
• Delete sub¶’s (C)(4-5) and merge into newly revised ¶ (D) to highlight documents that should be submitted as a separate document
• Redesignate existing ¶(D) as the new ¶(E)
• Redesignate existing sub¶(D)(5) as the new sub¶ (E)(5) and switched former ¶(E)(4) to follow, so the sequence in new sub¶(E) now follows the sequence of the HACCP Principles of monitoring, corrective actions and verification, where the subparagraphs are now sequenced as:
  o (E)(4) establish monitoring procedures,
  o (E)(5) establish corrective actions,
  o (E)(6) establish verification procedures.
• Redesignated existing ¶(E) as new ¶(F) and existing ¶(F) as new ¶(G)

8-401.10 Amended sub¶ 8-401.10(B)(1) to reflect updated cross references due to the addition of a new ¶(A) in § 8-103.12.

Annex 1 Compliance and Enforcement

No Change.

Annex 2 References

3-501.19 Amended to add five new references in support of the new exception in §3-501.19. Renumbered references alphabetically to align with existing references.

Supporting Documents
Amended to add new section, W. Minimizing the Risk of Campylobacter and Salmonella Illnesses Associated with Chicken Livers. (CFP Issue 2018-I-029)
Supporting Documents
Amended to add new section, X. Guidance Document for Mail Order Food Companies. (CFP Issue 2018-III-005)

Annex 3 Public Health Reasons

2-101.11
Amended Public Health Reason for §2-101.11 Assignment to add new paragraph 3 that addresses newly added exception for ¶2-101.11(C). (CFP Issue 2018-I-003)

3-501.17
Amended Public Health Reasons for §3-501.17 Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking, to include reference to a fact sheet developed to assist industry and regulatory authorities to better understand the types of information that may be included on a date marking label and what the disposition time of that product looks like based on the information provided. (CFP Issue 2018-I-026)

3-501.19
Amended Public Health Reasons for §3-501.19 Time as a Public Health Control to add new paragraph 16 that addresses newly added exception for ¶3-501.19(B)(2). (CFP Issue 2018-III-019)

3-502.12
Amended Public Health Reasons for §3-502.12, Reduced Oxygen Packaging with One Barrier (Cook-Chill and Sous Vide) to indicate there are “four” options for cooling cook-chill and sous vide TCS foods.

Annex 4 Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors

No Change.

Annex 5 Conducting Risk-based Inspections

No Change.

Annex 6 Food Processing Criteria

No Change.
Annex 7 Models Forms, Guides, and Other Aids

Form 3-A Food Establishment Inspection Report
Amended form 3-A Food Establishment Inspection Report, Item #1 Supervision to include an additional compliance status of N/A to address new exception in ¶2-101.11(C). (CFP Issue 2018-I-003)

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item #1
Amended Item 1 to include an additional compliance status of N/A to indicate that the item is not applicable for the facility.

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item #29
Amended Item 29 to reflect marking the inspection report Out of Compliance when the APPROVED VARIANCE in ¶8-103.12(A) is not kept at the food establishment. (CFP Issue 2018-I-021)

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item #35
Amended Item 35 to revise the risk designation from a core item to a priority foundation item under the applicable code section 3-501.13 Thawing. (CFP Issue 2016-I-033)

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item #48
Amended Item 48 to revise the title of §4-501.110 under the applicable code sections, which was incorrectly written in the 2017 Food Code.

Amended Item 48 to include §4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration under the applicable code sections that was inadvertently missing in previous versions of the Food Code.

Chart 4-D FDA Food Code Mobile Food Establishment Matrix
Revised Chart 4-D FDA Food Code Mobile Food Establishment Matrix to delete reference of ¶5-203.11(C) from the following categories: “Personnel”, “Water & Sewage” to reflect the deletion made in §5-203.11. (CFP Issue 2018-III-026)
Preface

No Change.

Chapter 1  Purpose and Definitions

Amend §1-201.10 to revise in paragraph (B) the following defined terms to read as follows:

“Intact Meat” means a cut of whole muscle(s) MEAT that has not undergone COMMINUTION, MECHANICAL TENDERIZATION, vacuum tumbling with solutions, or reconstruction.

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

Chapter 2  Management and Personnel

Amend §2-101.11 to add new paragraph (C) to read as follows:

Responsibility

2-101.11 Assignment.

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

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

(C) This section does not apply to certain types of FOOD ESTABLISHMENTS deemed by the REGULATORY AUTHORITY to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of the FOOD preparation.\textsuperscript{Pl}

Chapter 3 Food

Amend §3-501.13 to re-designate ¶¶'s 3-501.13(A)-(C) from a Core Item to a Priority Foundation (\textsuperscript{Pl}) Item to read as follows:

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 5\textdegree C (41\textdegree F) or less \textsuperscript{Pl}, or

(B) Completely submerged under running water:

(1) At a water temperature of 21\textdegree C (70\textdegree F) or below \textsuperscript{Pl},

(2) With sufficient water velocity to agitate and float off loose particles in an overflow \textsuperscript{Pl}, and

(3) For a period of time that does not allow thawed portions of READY-TO-EAT FOOD to rise above 5\textdegree C (41\textdegree F) \textsuperscript{Pl}, 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 5\textdegree C (41\textdegree F), for more than 4 hours including:

(a) The time the FOOD is exposed to the running water and the time needed for preparation for cooking \textsuperscript{Pl}, or

(b) The time it takes under refrigeration to lower the FOOD temperature to 5\textdegree C (41\textdegree F) \textsuperscript{Pl}.
(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 Pf, or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking EQUIPMENT, with no interruption in the process Pf; 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.

Amend §3-501.19 to add new sub-¶¶’s (B)(2)(a), (b), (c), (d) to 3-501.19(B)(2) and to re-designate existing ¶¶ 3-501.19(B)(2)(3) and (4) as new ¶¶ 3-501.19(B)(3)(4) and (5) respectively to read as follows:

3-501.19 Time as a Public Health Control.

(A) …No Change…

Time – maximum up to 4 hours

(B) If time without temperature control is used as the public health control up to a maximum of 4 hours:

(1) Except as specified in (B)(2), the FOOD shall have an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control; P

(2) The FOOD may have an initial temperature of 21°C (70°F) or less if;
(a) It is a READY-TO-EAT fruit or vegetable that upon cutting is rendered a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD as defined in ¶1-201.10(B), or

(b) It is a READY-TO-EAT hermetically sealed FOOD that upon opening is rendered a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD as defined in ¶1-201.10(B),

(c) The FOOD temperature does not exceed 21°C (70°F) within a maximum time period of 4 hours from the time it was rendered a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD; and

(d) The FOOD is marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is rendered a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD as specified in sub¶¶’s (B)(2)(a) and (b) of this section.

(3) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control; PT

(4) The FOOD shall be cooked and served, served at any temperature if READY-TO-EAT, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control; P and

(5) The FOOD in unmarked containers or PACKAGES, or marked to exceed a 4-hour limit shall be discarded. P

….No further change….

Amend §3-502.12 to add new sub¶ 3-502.12(e)(iii) and re-number existing sub¶ 3-502.12(e)(iii) as new sub¶ 3-502.12(e)(iv) to read as follows:

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

Cook-Chill or Sous Vide

(D) Except as specified under ¶ (C) and ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a cook-chill or sous vide process shall:
(1) Provide to the REGULATORY AUTHORITY prior to implementation, a HACCP PLAN that contains the information as specified under ¶¶ 8-201.14 (C) and (D); 

(2) Ensure the FOOD is:

(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER, 

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under ¶¶ 3-401.11 (A), (B), and (C),

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,

(d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F),

(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and:

   (i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;

   (ii) Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded; or

   (iii) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) FOOD temperature and then held at 5°C (41°F) or less for no more than 7 days, not to exceed 30 days from its date of PACKAGING, at which time the FOOD must be consumed or discarded; or

   (iv) Held frozen with no shelf life restriction while frozen until consumed or used.

…No Change…
Amend §4-205.10 to clarify that equipment that has been certified for conformance to an appropriate American National Standard is deemed to comply with the equipment sanitation provisions contained in Parts 4-1 and 4-2 to read as follows:

Acceptability

4-205.10 Food Equipment, Certification and Classification.

FOOD EQUIPMENT that is certified or classified for sanitation in conformance to a recognized American National Standard by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.

Amend §4-303.11 to add the Priority Foundation item risk designation that was inadvertently left off to read as follows:

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 Part 4-6, shall be provided and available for use during all hours of operation. Pf

(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 Part 4-7, shall be provided and available for use during all hours of operation. Pf

Chapter 5 Water, Plumbing, and Waste

Amend §5-203.11 to delete ¶5-203.11(C) to read as follows:

Numbers and Capacities

5-203.11 Handwashing Sinks.

(A) Except as specified in ¶ (B) of this section, at least 1 HANDWASHING SINK, a number of HANDWASHING SINKS necessary for
their convenient use by EMPLOYEES in areas specified under § 5-204.11, and not fewer than the number of HANDWASHING SINKS required by LAW shall be provided.\textsuperscript{Pf}

(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 FOOD ESTABLISHMENT that has at least 1 HANDWASHING SINK.

Chapter 6  Physical Facilities

No Change.

Chapter 7  Poisonous or Toxic Materials

No Change.

Chapter 8  Compliance and Enforcement

Amend §8-103.12 to add new ¶8-103.12(A) and renumber existing ¶¶’s (A) and (B) to new ¶¶’s (B) and (C) to read as follows:

8-103.12 Conformance with Approved Procedures.

If the REGULATORY AUTHORITY 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) Maintain the APPROVED VARIANCE at the FOOD ESTABLISHMENT;\textsuperscript{Pf} and

(B) 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;\textsuperscript{P} and

(C) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under § 8-201.14 (D) and (E)(3) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring the CRITICAL CONTROL POINTS,\textsuperscript{Pf}

(2) Monitoring of the CRITICAL CONTROL POINTS,\textsuperscript{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

**Amend ¶8-201.12(C) to add part of the sentence inadvertently left off in the 2017 Food Code Edition to read as follows:**

**8-201.12 Contents of the Plans and Specifications.**

The plans and specifications for a FOOD ESTABLISHMENT, including a FOOD ESTABLISHMENT specified § 8-201.13, shall include, as required by the REGULATORY AUTHORITY based on the type of operation, type of FOOD preparation, and FOODS prepared, the following information to demonstrate conformance with Code provisions:

(A) Intended menu;

(B) Anticipated volume of FOOD to be stored, prepared, and sold or served;

(C) Proposed layout, mechanical schematics, construction materials, and finish schedules;

…No Change…

**Amend §8-201.14 to:**

- Delete sub¶(C)(2) and add as new sub¶(E)(2) that speaks to significant hazards for each critical control point
- Delete sub¶¶’s (C)(4-5) and merge into newly revised ¶(D) to highlight documents that should be submitted as a separate document
- Redesignate existing ¶(D) as the new ¶(E)
- Redesignate existing sub¶(D)(5) as the new sub¶(E)(5) and switched former ¶(E)(4) to follow, so the sequence in new sub¶(E) now follows the sequence of the HACCP Principles of monitoring, corrective actions and verification, where the sub¶s are now sequenced as:
  - (E)(4) establish monitoring procedures,
  - (E)(5) establish corrective actions,
  - (E)(6) establish verification procedures.
- Redesignated existing ¶(E) as new ¶(F) and existing ¶(F) as new ¶(G)
8-201.14  Contents of a HACCP Plan.

For a food establishment that is required under § 8-201.13 to have a HACCP PLAN, the PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY a properly prepared HACCP PLAN that includes:

(A) General information such as the name of the PERMIT applicant or PERMIT HOLDER, the 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;

(C) A flow diagram or chart for each specific FOOD or category type that identifies:
   (1) Each step in the process; and
   (2) The steps that are CRITICAL CONTROL POINTS;

(D) The ingredients, recipes or formulations, materials and equipment used in the preparation of each specific FOOD or category type and methods and procedural control measures that address the FOOD safety concerns involved;

(E) A CRITICAL CONTROL POINTS summary for each specific FOOD or category type that clearly identifies:
   (1) Each CRITICAL CONTROL POINT,
   (2) The significant HAZARDS for each CRITICAL CONTROL POINT,
   (3) The CRITICAL LIMITS for each CRITICAL CONTROL POINT,
   (4) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the designated FOOD EMPLOYEE or the PERSON IN CHARGE,
   (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,
   (6) The method and frequency for the PERSON IN CHARGE
to routinely verify that the FOOD EMPLOYEE is following standard operating procedures and monitoring CRITICAL CONTROL POINTS, Pf and

(7) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed; Pf

(F) Supporting documents such as:

(1) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern; Pf

(2) Copies of blank records forms that are necessary to implement the HACCP PLAN; Pf

(3) Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal. Pf

(G) Any other information required by the REGULATORY AUTHORITY.

Amend sub¶8-401.10(B)(1) to reflect updated cross references due to the addition of a new ¶(A) in §8-103.12 to read as follows:

Frequency

8-401.10 Establishing Inspection Interval.

(A) Except as specified in ¶¶ (B) and (C) of this section, the REGULATORY AUTHORITY shall inspect a FOOD ESTABLISHMENT at least once every 6 months.

(B) The REGULATORY AUTHORITY may increase the interval between inspections beyond 6 months if:

(1) The FOOD ESTABLISHMENT is fully operating under an APPROVED and validated HACCP PLAN as specified under § 8-201.14 and ¶¶ 8-103.12(B) and (C);

…No Change…
Annex 1  Compliance and Enforcement

No Change.

Annex 2  References

Amend 2. Bibliography to add five new references in support of the new exception in §3-501.19 and renumbered references alphabetically to read as follows:

3-501.19  Using Time as a Public Health Control.


Amend 3. Supporting Documents to add the following new sections W and X to read as follows:

3. SUPPORTING DOCUMENTS

FDA is providing the following guidance documents for reference. A brief summary for each document is provided.

…No Change…

W. Minimizing the Risk of *Campylobacter* and *Salmonella* Illnesses Associated with Chicken Liver

USDA-FSIS has found that from 2000 to 2015, chicken livers were associated with 22 outbreaks most commonly due to undercooking. USDA-FSIS' Compliance Guideline, Minimizing the Risk of *Campylobacter* and *Salmonella* Illnesses Associated with Chicken Liver provides additional guidance that retailers and others can use to reduce or eliminate pathogens, thereby decreasing the likelihood of foodborne illness outbreaks from this product. The guidance document explains why searing the outside of the liver is not adequate for pathogen elimination in chicken livers and emphasizes appropriate cooking to an internal temperature of 165°F to avoid illnesses. Thorough cooking is the only method to eliminate pathogens. This guidance also provides other recommendations to minimize (but not eliminate) pathogen contamination associated with undercooked chicken liver dishes.

This document is available for download at:

X. Guidance Document for Mail Order Food Companies

This guidance document is intended for retail food establishments delivering perishable foods to the consumer by mail order. The intent of the guide is primarily to provide best practices for preventing biological, physical and chemical contamination, as well as the growth of harmful bacteria and/or the formation of toxins within the food being shipped. Foodborne illness may occur if products are not prepared, packed and shipped using sanitary conditions and proper temperature controls. It is the result of a joint effort by the FDA and the Conference for Food Protection.

This document is available for download at:
http://www.foodprotect.org/media/site/cfp-mail-order-committee-draft-document-per-2018-iii-004.pdf
Annex 3  Public Health Reasons/Administrative Guidelines

Amend Public Health Reasons §2-101.11 to add new paragraphs 3 and 4 to follow existing paragraph 2 to read as follows:

Responsibility  2-101.11  Assignment.

…No Change…

The concept of an unmanned food establishment that is typically located in an office building or restricted break area is a recent innovation. While a wide variety of food items may be provided, these operations are intended to offer packaged TCS and non-TCS food products that are displayed via refrigeration units, food racks, baskets and/or countertop display units. There are a number of state and local agencies that mandate the permit holder be the person in charge or designate a person in charge present at the food establishment during all hours of operation. It is appropriate for State and local agencies, by way of codes and ordinances or by policy to establish criteria for what types of permitted establishments could be exempt from designating a person in charge present at all times during operation. Factors to consider when establishing such criteria include:

• Types of food served or offered
• Public access to the food establishment
• Cleaning frequency of equipment and food contact surfaces
• Surveillance operations
• Types of cold and hot holding equipment
• Contact information for management personnel of the food establishment

Regulatory Agencies are encouraged to review guidance issued thru the Conference for Food Protection (CFP) that addresses unmanned food establishments. The CFP posted Unattended Food Establishment Guidance Document can be found at the following link: (http://www.foodprotect.org/media/site/guidance-document-for-unattended-food-establishments.pdf)
Amend Public Health Reasons §3-501.17 to add new paragraph 6 to follow existing paragraph 5 to read as follows:

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-501.17</td>
<td>Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking.</td>
</tr>
<tr>
<td>3-501.18</td>
<td>Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.</td>
</tr>
</tbody>
</table>

...No Change...

As part of the effort to enhance understanding by industry and regulators regarding the proper labeling and disposition of time/temperature control for safety (TCS) food prepared in a retail food establishment and held longer than 24 hours, the FDA developed a fact sheet to visually display examples of some date marking systems. This fact sheet is intended for retail food establishments and regulatory authorities to better understand the types of information that may be included on a date marking label and what the disposition time of that product looks like based on the information provided.

This document is available for download at:
https://www.fda.gov/media/127796/download

Amend Public Health Reasons §3-501.19 to add new paragraph 16 to follow existing paragraph 15 to read as follows:

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-501.19</td>
<td>Using Time as a Public Health Control.</td>
</tr>
</tbody>
</table>

...No Change...

At the 2018 meeting of the CFP it was recommended that Section 3-501.19 be amended to allow raw agricultural commodities (RACs) that are cut on-site (such as tomatoes, melons, or leafy greens) or shelf-stable hermetically sealed containers (such as canned tuna) opened on-site have an initial temperature of 21°C (70°F) or less when time without temperature control is used as a public health control for a maximum of 4 hours. Peer-reviewed scientific literature and the above-mentioned pathogen modeling has shown *Salmonella spp.* and *L. monocytogenes* will not exceed a 1-log increase in growth when started and maintained at 21°C (70°F) or less for up to 4 hours.
Amend Public Health Reasons §3-502.12 to revise paragraph 8 to read as follows:

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

...No Change...

Some foods may not have secondary barriers to prevent the growth of *C. botulinum* and *L. monocytogenes*, such as aw, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses. When these foods are packaged using a reduced oxygen packaging process, time/temperature becomes the critical controlling factor for growth of *C. botulinum* and *L. monocytogenes*. Non-proteolytic *C. botulinum* spores are able to germinate and produce toxin at temperatures down to 3ºC (38ºF). Therefore, holding ROP foods at 3ºC (38ºF) or less should prevent the formation of *C. botulinum* toxin. *L. monocytogenes* is able to grow, although very slowly, at temperatures down to -1ºC (30ºF). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Four separate options are provided in subparagraphs (D)(2)(e).

Amend Public Health Reasons §4-205.10 to add new paragraphs 1 and 2 to read as follows:

Acceptability 4-205.10 Food Equipment, Certification and Classification.

Commercial food equipment standards that are designated as American National Standards have been developed by a Standards Developing Organization (SDO) that is accredited by the American National Standards Institute (ANSI). Accreditation by ANSI signifies that the procedures used by the SDO in the development of American National Standards meet the Institute’s essential requirements for openness, balance, consensus and due process.

Refer to the following link ([https://www.fda.gov/media/133482/download](https://www.fda.gov/media/133482/download)) for a listing of the American National Standards that address the sanitary materials, design and construction of commercial food equipment commonly used in retail and foodservice establishments.

...No Change...
Annex 4 Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors

No Change in Annex 4.

Annex 5 Conducting Risk-based Inspections

No Change in Annex 5.

Annex 6 Food Processing Criteria

No Change in Annex 6.
Annex 7 Model Forms, Guides, and Other Aids

Amend Form 3-A Food Establishment Inspection Report Item #1 compliance status to read as follows:

FORM 3-A

Food Establishment Inspection Report

<table>
<thead>
<tr>
<th>Compliance Status</th>
<th>Item #</th>
<th>Description</th>
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<tbody>
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<td>Supervision</td>
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<td></td>
<td>2</td>
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</tr>
<tr>
<td></td>
<td>3</td>
<td>IN OUT N/A</td>
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<td>4</td>
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<tr>
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<td>16</td>
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</tr>
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<td>18</td>
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<td></td>
<td>28</td>
<td>IN OUT N/A</td>
</tr>
<tr>
<td></td>
<td>29</td>
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</tr>
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</table>

GOOD RETAIL PRACTICES

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<tr>
<th>Item #</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>30</td>
<td>Pasteurized eggs used where required</td>
</tr>
<tr>
<td>31</td>
<td>Water &amp; ice from approved source</td>
</tr>
<tr>
<td>32</td>
<td>Variance obtained for specialized processing methods</td>
</tr>
<tr>
<td>33</td>
<td>Proper cooling methods used; adequate equipment for temperature control</td>
</tr>
<tr>
<td>34</td>
<td>Plant food properly cooled for hot holding</td>
</tr>
<tr>
<td>35</td>
<td>Approved thawing methods used</td>
</tr>
<tr>
<td>36</td>
<td>Thermometers provided &amp; accurate</td>
</tr>
<tr>
<td>37</td>
<td>Food properly labeled, original container</td>
</tr>
<tr>
<td>38</td>
<td>Insents, rodents, &amp; animals not present</td>
</tr>
<tr>
<td>39</td>
<td>Contamination prevented during food preparation, storage &amp; display</td>
</tr>
<tr>
<td>40</td>
<td>Personal cleanliness</td>
</tr>
<tr>
<td>41</td>
<td>Wiping cloths: properly used &amp; stored</td>
</tr>
<tr>
<td>42</td>
<td>Washing fruits &amp; vegetables</td>
</tr>
</tbody>
</table>

Person in Charge (Signature)

Supplement to the 2017 Food Code

24
Amend Guide 3B, Section C, Supervision, Item #1, to add new Compliance Status to read as follows:

Guide 3B

Instructions for Making the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices

Supervision

1. PIC present, demonstrates knowledge, and performs duties

IN/OUT This item must be marked IN or OUT of compliance. The person in charge (PIC) has three assigned responsibilities – Presence; Demonstration of Knowledge; and Duties. This item is marked OUT of compliance if any one of the responsibilities is not met.

A. **Person in charge** is present. This item is marked OUT of compliance if there is no PIC per 2-101.11(A) and (B).

B. Demonstration of Knowledge. The PIC has three options for demonstrating knowledge. This item is marked IN compliance if the PIC meets at least one of the options. The three options for demonstration of knowledge allowed by the Food Code are:
   2. Complying with this Code by having no violations of priority items during the current inspection; or
   3. Correct responses to the inspector’s questions regarding public health practices and principles applicable to the operation. The inspector should assess this item by asking open-ended questions that would evaluate the PIC’s knowledge in each of the areas enumerated in ¶ 2-102.11(C)(1), (4)-(16). Questions can be asked during the initial interview, menu review, or throughout the inspection as appropriate. The Inspector should ask a sufficient number of questions to enable the inspector to make an informed decision concerning the PIC's knowledge of the Code requirements and public health principles as they apply to the operation. The dialogue should be extensive enough to reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

C. Duties of the **PIC**. This item must be marked IN or OUT of compliance based on the interaction and observation with the PIC and food employee. The inspector needs to determine the systems or controls the PIC has put into practice regarding oversight and/or routine monitoring of the Duties listed in § 2-103.11. This is accomplished by 1) discussion with the PIC, and 2) verified through observation that the systems or controls are actually being implemented. This concept is commonly referred to as Active Managerial Control. This item must be marked OUT of compliance when there is a pattern of non-compliance and obvious failure by the PIC to ensure employees are complying with the duties listed in § 2-103.11. Since marking this item out of compliance requires judgment, it is important that this item not be marked for an isolated incident, but rather for an overall evaluation of the PIC’s ability to ensure compliance with the duties described in § 2-103.11.

**N.A.** This item may be marked N.A. if the establishment is deemed by the Regulatory Authority to not apply due to the minimal risk of causing, or contributing to foodborne illness based on the nature
Amend Guide 3B, Section C, Supervision, Item #29, to add new marking instructions to read as follows:

Conformance with Approved Procedures

29. Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan

NOTE Except for fish a HACCP plan is not required when a TCS food is packaged using a reduced oxygen packaging method and is labeled with production time and date, held at required cold holding temperature, and removed from ROP packaging within 48 hours after packaging at the food establishment.

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food preparation and storage, a discussion with the PIC to determine if there are specialized food processes [i.e. smoking food, curing food, reduced oxygen packaging, using food additives to render a food so that it is not TCS food, cook chill, sous vide, etc.] and the record review of standard operating procedures and HACCP documentation. This item should be marked IN compliance when observations of food operations and review of available records indicate compliance is being met with regards to specialized food processes and HACCP plans were submitted to the regulatory authority prior to conducting a ROP operation that conforms to procedures within §3-502.12. This item should be marked OUT of compliance if the inspection reveals specialized food processes that are not approved by the regulatory authority are performed or not conducted in accordance with the approved variance or a HACCP plan was not submitted to the regulatory authority prior to engaging in a ROP operation without a variance or the approved variance is not retained in the food establishment.

N.A. This item may be marked N.A. if the establishment is not required by the regulatory authority to have a variance or HACCP plan, juice is not packaged or reduced oxygen packaging is not done on the premises.

N.O. Do Not Mark this item N.O.

Applicable Code Sections:
3-404.11 Treating Juice (P, Pf)
3-502.11 Variance Requirement (Pf)
3-502.12 Reduced Oxygen Packaging, Criteria (P, Pf)
4-204.110(B) Molluscan Shellfish Tanks (Pf)
8-103.12 Conformance with Approved Procedures (P, Pf)
8-201.13 When a HACCP Plan is Required (C)
8-201.14 Contents of a HACCP Plan (Pf)

Amend Guide 3B, Section D, Approved thawing methods used, Item #35, to revise risk designation under the applicable code sections to read as follows:

Food Temperature Control

35. Approved thawing methods used
Observing and then gaining an understanding of the establishment’s thawing method(s) will help in determining whether a violation exists from the approved thawing methods found under § 3-501.13 as
well as the level of risk imposed. Keep in mind that various food products especially those destined for
deep-fat frying are often slacked (not thawed) prior to cooking.

**Applicable Code Sections:**

3-501.12 Time/Temperature Control for Safety Food, Slacking (C)
3-501.13 Thawing (Pf)

**Amend Guide 3B, Section D, Warewashing facilities, installed, maintained, used, test strips, Item #48, to revise the Applicable Code Sections to read as follows:**

48. Warewashing facilities, installed, maintained, used, test strips
Adequate warewashing facilities must be available and used for the cleaning and sanitization of food-
contact surfaces, including the availability of means to monitor its use and the effectiveness of
sanitization. For example, an irreversible registering temperature indicator is provided and readily
accessible for measuring the utensil surface temperature for establishments that have a hot water
mechanical warewashing operation. Observation of manual and mechanical warewashing methods are
made to assess the procedure for cleaning and sanitizing equipment and utensils. This item is marked
OUT of compliance when cleaners and sanitizers are not available for use within the food establishment.

**Applicable Code Sections:**

...No Change....
4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature (Pf)
4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration (Pf)
...No Change...
Amend Chart 4-D FDA Food Code Mobile Food Establishment Matrix to remove reference to ¶5-203.11(C) within the chart to read as follows:

**FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX**

<table>
<thead>
<tr>
<th>Food Code</th>
<th>Time/Temperature for Safety Food (TCS) Menu</th>
<th>Time/Temperature for Safety Food (TCS) Menu</th>
<th>Not TCS Food Menu</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Areas/Chapter</strong></td>
<td><strong>Food Preparation</strong></td>
<td><strong>Prepackaged</strong></td>
<td><strong>Food Preparation</strong></td>
</tr>
<tr>
<td><strong>Personnel</strong></td>
<td>Applicable Sections of Parts 2-2 - 2-4</td>
<td>Applicable Sections of Parts 2-2 - 2-4</td>
<td>Applicable Sections of Parts 2-2 - 2-4</td>
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<td><strong>Food</strong></td>
<td>3-101.11</td>
<td>3-101.11</td>
<td>3-101.11; 3-201.11</td>
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<td></td>
<td>3-201.11 - .16</td>
<td>3-201.11 - .16</td>
<td>3-201.11</td>
</tr>
<tr>
<td></td>
<td>3-202.16; Applicable Sections of Part 3-3; 3-501.16</td>
<td>3-303.12(A)</td>
<td>3-201.11; 3-202.16; Applicable Sections of Part 3-3</td>
</tr>
<tr>
<td></td>
<td>3-501.16</td>
<td>3-501.16</td>
<td>3-201.11</td>
</tr>
<tr>
<td></td>
<td>3-305.11; 3-305.12 (Applicable to Service Area or Commissary)</td>
<td>3-305.11; 3-305.12</td>
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</tr>
<tr>
<td><strong>Temperature Requirements</strong></td>
<td>3-202.11; Applicable Sections of Parts 3-4 &amp; 3-5</td>
<td>3-202.11</td>
<td>NONE</td>
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<tr>
<td><strong>Equipment Requirements</strong></td>
<td>Applicable Sections of Parts 4-1 - 4-9 and 5-5</td>
<td>Applicable Sections of Parts 4-1 - 4-2; 4-6 and 5-5</td>
<td>Applicable Sections of Parts 4-1 - 4-2; 4-5 - 4-6 and 5-5</td>
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<td><strong>Water &amp; Sewage</strong></td>
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</tr>
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<td><strong>Servicing</strong></td>
<td>6-202.18 / As necessary to comply with the Food Code</td>
<td>6-202.18 / As necessary to comply with the Food Code</td>
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<tr>
<td><strong>Compliance and Enforcement</strong></td>
<td>Applicable Sections of Chapter 8 and Annex 1</td>
<td>Applicable Sections of Chapter 8 and Annex 1</td>
<td>Applicable Sections of Chapter 8 and Annex 1</td>
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