

# Summary of Changes In the FDA Food Code

This Summary provides a synopsis of the textual changes from the 2005 FDA Food Code and the Supplement to the 2005 Food Code Chapters and Annexes to the 2009 edition. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. ***This record should not be relied upon as an absolute comparison that identifies each and every change.***

## General:

- Numerous editing changes were made throughout the document for internal consistency, to correct some errors in the 2005 Code and for clarification.
- Section and paragraph numbers listed refer to the 2009 Code unless otherwise noted. The numbering system was removed from Chapter 1 definitions in the 2005 version of this Code. An explanation regarding the rationale can be found in Annex 3, 1-201.10(B).
- Updated the web links throughout the Code and Annexes
- Throughout the entire Food Code designated Code provisions as:
  - “PRIORITY ITEM”, denoted with a superscript P – <sup>P</sup>; or
  - “PRIORITY FOUNDATION ITEM”, denoted with a superscript Pf – <sup>Pf</sup>; or
  - “CORE ITEM”, a provision in this Code that is not designated as a PRIORITY ITEM or a PRIORITY FOUNDATION ITEM.

## Preface

### Item 1

Updated Healthy People national initiative information to include mention of Healthy People 2020

### Item 3

Updated FDA mission statement

### Item 5

Updated reference to CFP meetings and introduced the revised designation system for Code provisions in 2009

### Item 7

Updated address for the FDA/CFSAN

## **Item 8**

Added information to assist the reader in understanding Food Code conventions

## **Chapter 1 Purpose and Definitions**

### **1-201.10(B)**

Added “Core item”

Added “Cut leafy greens”

Amended definition of “Injected” to remove the public health statement and process where no liquid is introduced.

Added “Mechanically Tenderized”

Added “Non-continuous cooking”

Revised “Potentially Hazardous Food (Time/Temperature Control for Safety Food)” subparagraph (2)(a) by adding, “cut leafy greens”

Added “Priority item”

Added “Priority foundation item”

Revised “Ready-to-Eat Food” subparagraph (1)(b) to correctly cross reference 3-401.11 (D)(1) and (3); Revise subparagraph (1)(c) to update reference to subparagraph 3-401.11(D)(4)

Revised “Reduced oxygen packaging” subparagraph (2)(d) and (2)(e) to correct spelling of “psychrotrophic”

## **Chapter 2 Management and Personnel**

### **2-102.11(A)**

Amended to replace “Critical items” with “Priority items”

### **2-103.11 (L)**

Added “food allergy awareness” as a part of the food safety training of employees by the Person in Charge

## **Chapter 3 Food**

### **3-201.11 (D)**

Amended to correctly cross reference subparagraph 3-401.11 (D)

### **3-302.11(A)(1)**

Amended language to exempt frozen, commercially processed and packaged raw animal foods from separate storage or display from RTE foods; Added new subparagraph (c) that allows this exemption.

**3-401.11(A)(2)**

Added “mechanically tenderized” meats to the list of foods that shall be cooked to heat all parts of the food to 68°C (155°F) for 15 seconds

**3-401.11 (D)**

Amended to add new subparagraph (D)(2) to not allow the sale of undercooked, comminuted meat from a children’s menu

**3-401.11(D)(2)**

Amended to become the new (D)(3)

**3-401.11 (D)(3)**

Amended to become the new (D)(4)

**3-401.14**

Added a new section on Non-continuous cooking of raw animal foods that specifies the criteria for using a non-continuous cooking process

**3-402.11(B)**

Added new subparagraph (4) to exempt fish eggs that have been removed from the skein and rinsed from freezing for parasite destruction

**3-403.11(E)**

Added new ¶ (E) which was missing in 2007 Supplement

**3-404.11(A)**

Amended to correct the reference ¶ 8-201.12 (B) – (E) to ¶ 8-201.14(B) – (E)

**3-501.17(D)(2)**

Amended to correct a typographical error

**3-502.11(D)**

Amended to include *Listeria monocytogenes* controls which are specified under §3-502.12.

**3-502.11(E)**

Amended ¶ (E) to replace the word “and” with “or” to clarify that a variance would be required when operating a molluscan shellfish life-support system display tank, regardless of whether the tank was used for storing (back-of-the-house) or displaying (front-of-the-house) shellfish

**3-502.12**

Amended tag line to clarify that no variance is required for Reduced Oxygen Packaging methods listed in this section

**3-502.12(A)**

Amended to clarify that all Reduced Oxygen Packaging methods in this section require controls for growth and/or toxin formation by *Clostridium botulinum* and *Listeria monocytogenes*, not just methods with two barriers

**3-502.12(B)(2)(d)**

Amended to clarify that raw vegetables have high levels of competing organisms

**3-502.12(B)(5)(a)**

Amended to clarify that prohibition only applies to ready-to-eat food to prevent conflict with § 3-301.11

**3-502.12(D)**

Amended to show this paragraph is not optional and remove italics

**3-502.12(D)(1)**

Amended to clarify that implementing a HACCP plan is required

**3-502.12(D)(2)(c)**

Amended to add cross reference to Part 3-3

**3-502.12(D)(2)(d)**

Amended to clarify when bags should be sealed for cook-chill and sous vide

**3-502.12(E)**

Amended to show this paragraph is not optional with no variance and remove italics

**3-502.12(E)(2)and (E)(3)**

Amended to combine (E)(2) with (E)(3)

**3-502.12(E)(4)**

Amended to become the new (E)(3)

**3-502.12(E)(5)**

Amended to become the new (E)(4)

**3-603.11(A)**

Amended cross reference from 3-401.11(D)(3) to 3-401.11(D)(4)

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

**4-204.110(A) and (B)**

Amended to clarify that subparagraphs 4-204.110(A) and (B) applies to molluscan shellfish life support system tanks that are used for either storing or displaying molluscan shellfish

**4-501.114**

Amended lead-in paragraph to change “exposure times” to “contact times” and “manufacturer’s label use instruction or directions” to “EPA-registered label use instructions” to harmonize with EPA terminology (CFP 2008-III-010)

**4-501.114(A)**

Added chlorine concentration ranges and changed “Minimum Concentration” to “Concentration Range” in the chart. (CFP 2008-III-010)

**4-501.114(B)(1)**

Amended to change the minimum temperature requirement for an iodine solution from “24°C (75°F)” to “20°C (68°F)” to be consistent with EPA iodophor registration protocols (CFP 2008-III-010)

**4-501.114(C)(3)**

Amended to change “manufacturer’s label” to “EPA-registered label use instructions” to harmonize with EPA terminology (CFP 2008-III-010)

**4-501.114(E)**

Amended to change “manufacturer’s directions including the labeling” to “EPA-registered label use instructions” to harmonize with EPA terminology (CFP 2008-III-010)

**4-703.11(C)**

Amended to change “exposure time” to “contact time” to harmonize with EPA terminology in (C)(1)(2)(3) and (4) (CFP 2008-III-010); Added sentence to clarify that contact times shall be consistent with EPA-registered labels and to harmonize with EPA terminology

**4-904.13**

Revised the text regarding preset tableware to clarify under what circumstances preset tableware may be exposed and not protected from contamination by wrapping, covering, or inverting

**4-904.14**

Added a new §4-904.14 to allow the application of a post-sanitizing rinse restricted to commercial warewashing machines and the circumstances under which it may be allowed (2008-III-016)

**Chapter 5 Water, Plumbing, and Waste****5-102.12(B)**

Amended to remove “and irrigation”

**5-203.13**

Added a new ¶(B) to address use limitations for toilets and urinals and amended existing paragraph to be new ¶(A)

**5-203.15**

Amended to change “double” check valve to “dual” check valve

**Chapter 6 Physical Facilities****6-301.12**

Added new ¶(D) to allow the use of a high velocity blade of non-heated, pressurized air for hand drying

**6-306.10**

Amended to change the cross reference in the paragraph from §5-203.13 to ¶5-203.13(A). Section 5-203.13 has (A) and (B) paragraphs. The cross reference now only refers to ¶(A)

**6-501.18**

Amended to delete cross reference to §5-205.11 as it pertains to handwashing sinks only and not toilets and urinals.

**6-501.111**

Amended the lead-in paragraph to clarify that establishments are expected to be free of pests

**Chapter 7 Poisonous or Toxic Materials****7-204.12**

Added a new ¶(B) that allows the use of ozone on fruits and vegetables according to 21 CFR 173.368

**Chapter 8 Compliance and Enforcement****8-201.13(A)(2)**

Amended cross reference from subparagraph 3-401.11(D)(3) to subparagraph 3-401.11(D)(4)

**8-304.11(G)**

Amended to remove reference to deleted ¶8-304.11(H)

**8-304.11(H)**

Deleted ¶(H) as it references subparagraph 3-501.16(A)(2) that was deleted from the Code in the Supplement to the 2005 Food Code; renumbered remaining paragraphs

**8-304.11(I)**

Amended to become new ¶(H)

**8-304.11(J)**

Amended to become new ¶ (I)

**8-304.11(K)**

Amended to become new ¶ (J)

**8-401.20(A)**

Amended to change “critical” to “priority items or priority foundation items”

**8-401.20(B)**

Amended to change “noncritical” to “core items”

**8-403.10(B)(3)**

Amended to change “critical items” to “priority items or priority foundation items”

**8-405.11(A) and (B)**

Amended to change “critical item” to “priority item or priority foundation item”

**8-405.20 (A) and (B)**

Amended to change “critical item” to “priority item or priority foundation item”

**8-406.11(A)**

Amended to change “noncritical violations” to “core items”

**Annex 1 Compliance and Enforcement**

Added new Part 8-7 Authority, Subpart 8-701 Legal Authority, and §§8-701.10, 8-701.11, and 8-701.20

Re-numbered existing Parts such that the existing Part 8-7 Notices, becomes new Part 8-8 Notices, and existing Part 8-8 Remedies, becomes new Part 8-9 Remedies, respectively

**Annex 2 References****1. USC and CFR**

Amended (A) and (B) contact addresses

**2. Bibliography****Preface**

Amended reference to DFSSR list of state officials

**1-201.10**

Added 8 new references to support the addition of cut leafy greens to the definition of “Potentially Hazardous Food (Time/Temperature Control for Safety Food)”

Added 2 new references regarding injected and mechanically tenderized beef steaks

**3-202.12**

Added 3 CFR references regarding food additives

**3-401.11**

Added 3 new references regarding ground beef and foodborne illness in children

**3-502.12**

Amended tag line to be consistent with change in coded text

**5-102.12**

Added new §5-102.12 and 2 new references in support of removing irrigation from the list of nonculinary purposes for nondrinking water use

**5-203.13**

Added new §5-203.13 with 6 new references regarding foodborne illness transmission via environmental surfaces

**5-203.15**

Added new §5-203.15 with 1 new reference regarding American Society of Sanitary Engineering standards

**6-202.15**

Updated web link to the most recent version of the Life Safety Code

**6-301.12**

Added new §6-301.12 with 1 new reference regarding hand drying

**6-501.18**

Added new §6-501.18 with 5 new references regarding foodborne illness transmission via environmental surfaces

**3. Supporting Documents**

Added (O) “Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut leafy Greens”

Added (P) “Employee Health and Personal Hygiene Handbook”

Added (Q) “Risk Assessment Process and Spreadsheet to Redesignate Food Code Provisions”

Added (R) the NACMCF report, “Parameters for Determining Inoculated Pack/Challenge Study Protocols”

**Annex 3 Public Health Reasons/Administrative Guidelines****1-201.10(B)****Potentially Hazardous Food (Time/Temperature Control for Safety Food)**

Added information to explain why cut leafy greens was added to the definition

**Accredited Program**

Added cross reference to the definition of “Accredited Program” in ¶1-201.10(B)(3) to provide greater clarification of the defined term

**2-102.20**

Added double asterisks at the end of paragraph 5, subparagraph 5 (Accredited program.\*\*\*) and a footnote to the double asterisks

**2-103.11**

Amended paragraph 2 to break text into paragraph 2 and new paragraph 4; Added new paragraph 3 on food allergies

**2-201.11**

Amended paragraph 9 under Title I of the Americans with Disabilities Act of 1990 to the most recent Federal Register notice for the CDC List of Infectious and Communicable Diseases Which are Transmitted Through the Food Supply

Amended Decision Tree 1, Decision Tree 2, Table 1a, Table 1b, Table 2, Table 3, and Table 4 with editorial changes

**2-201.13**

Amended to reverse the order of paragraphs 9 and 10 for improved flow of information provided; Added a sentence in paragraph 11 for clarification of protection afforded to immune-suppressed populations in highly susceptible population food establishments

**3-101.11 and 3-201.11**

Amended paragraph to add a clarification regarding exceptions to freezing of fish before consumption

**3-302.11**

Added information in paragraph 1 regarding storage of frozen, commercially processed and packaged raw animal foods

**3-302.15**

Added and updated information on washing of fruits and vegetables

**3-401.11, 3-401.12, 3-401.13**

Added new information on Children's menu

**3-401.14**

Added new information on non-continuous cooking of raw animal foods

**3-402.11**

Added new paragraph 6 regarding parasite hazards in fish

**3-502.12**

Amended the tag line to be consistent with change in coded text; Amended to explain that all ROP methods in this section control for the growth and/or toxin production of *Clostridium botulinum* and *Listeria monocytogenes*

**3-603.11**

Amended to update contact information for FDA/CFSAN

**4-501.14**

Deleted paragraphs 1 and 3-7, leaving only paragraph 2 to eliminate duplicate language found also in §4-501.114 where language is appropriately applied to sanitizing (CFP 2008-III-010)

**4-501.114**

Amended to update all six paragraphs with new language to be consistent with changes made in §4-501.114 (CFP 2008-III-011-011)



**5-102.12**

Added a new paragraph to explain why use of irrigation water as nondrinking water was removed

**5-203.11**

Amended to make section title consistent with the Code; Added 2 new paragraphs regarding the importance of handwashing and having hand sinks for handwashing

**5-203.12**

Deleted paragraph 2; Relocated paragraph 2 to §6-501.18 because it addresses the cleaning of toilets and urinals and not numbers and capacities

**6-301.12**

Added 3 new paragraphs regarding hand drying

**6-501.18**

Amended the tag line to match §6-501.18 in the Food Code; Relocated second paragraph from §5-203.12 because it addresses the cleaning of toilets and urinals; Added 3 new paragraphs containing supporting information to address the reason to clean toilets and urinals

**6-501.111**

Revised to clarify that establishments are expected to be free of pests

**Annex 4 Management of Food Practices-Achieving Active Managerial Control of Foodborne Illness Risk Factors**

Updated web links web pages throughout the Annex

**Annex 5 Conducting Risk-Based Inspection**

3. B. Amended to change pressure range to be consistent with that in 4-501.113

4. G. 1. Amended to change “critical item” to “priority item”

4. H. Amended to change “noncritical” to “core item” in the Examples of concerns list for the listing “food protection”

5. A. Amended to change “critical violations” to “priority item and priority foundation item violations”

**Annex 6 Food Processing Criteria****2. Reduced Oxygen Packaging**

Revised and updated the Reduced Oxygen Packaging section following changes to the definition of Reduced Oxygen Packaging and to §3-502.12 Reduced Oxygen Packaging, Criteria

## **Annex 7      Models Forms, Guides, and Other Aids**

Introductory Cover page – Updated listing of new forms

Forms – 1-A, 1-B, 1-C, 1-D – Updated with editorial changes

Forms – 2-A, 2-B updated Section 2, Insertions and Changes, to reflect change from Part 8-8 to Part 8-9 in Annex 1

Form 3-A – Inspection Report Form - Updated to reflect changes in the Supplement to the 2005 Food Code

Guides - 3-B and 3-C merged and explanatory paragraphs added regarding the merge  
Previous Guide 3-B deleted after merge with Guide 3-C

New Guide 3-B – Added new *“Instructions for Marking the Food Establishment Inspection Report with Food Code References for Risk Factors/Interventions and Good Retail Practices Specified on the Food Establishment Inspection Report”* and included marking instructions for good retail practices #28 - #54

Chart 4-A – Summary Chart for Minimum Cooking Food Temperatures and Holding Times Required by Chapter 3 - Added “mechanically tenderized meats” to the list of foods cooked to a minimum cooking temperature of 68°C (155°F)

Chart 4-C – Summary Chart for Date Marking – Corrected to remove reference to date marking at  $> 41 - \leq 45^{\circ}\text{F}$  for  $\leq 4$  days

ADA = Americans with Disabilities Act

ASTM = American Society for Testing and Materials

CDC = Centers for Disease Control and Prevention

CFP = Conference for Food Protection

CFR = Code of Federal Regulations

HACCP = Hazard Analysis and Critical Control Point

IFT = Institute of Food Technologists

Lm = *Listeria monocytogenes*

NACMCF = National Advisory Committee on Microbiological Criteria for Foods

NSSP = National Shellfish Sanitation Program

OTC = Over The Counter

PMO = Pasteurized Milk Ordinance

PMP = Pathogen Modeling Program

ROP = Reduced Oxygen Packaging

USDA/FSIS = United States Department of Agriculture/Food Safety & Inspection Service