

# Summary of Changes in the FDA Food Code

This Summary provides a synopsis of the textual changes from the 2001 FDA Food Code and the Supplement to the 2001 Food Code Chapters and Annexes to the 2005 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 2001 Code and for clarification.
- Section and paragraph numbers listed refer to the 2001 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).

## Preface

### Item 2(B)

Corrected the reference to 21 CFR 5.10 in paragraph 1

### Item 5

Updated reference to CFP meetings

### Item 7

Updated address for the FDA/CFSAN

### Item 8

Added information to assist the reader in understanding Food Code conventions

## Chapter 1 Definitions

### 201.10(B)

The numbering system was removed from the definitions in the 2005 version of this Code. An explanation regarding the rationale can be found in Annex 3, 102.10(B)

Added "Asymptomatic"

Added "Balut"

Added "Conditional Employee"

Replaced defined term “Table-mounted equipment” with “Counter-mounted equipment”

Amended “Eggs” to clarify difference between “egg” (shell egg) and “egg product” (liquid, frozen, or dry egg). Exclusion of baluts and reptile eggs added to clarify that they were not considered when developing the egg-related provisions of the Food Code

Amended “Egg Products” to clarify the difference between “egg” (shell egg) and “egg product” (liquid, frozen, or dry egg)

Amended “Employee” by adding “food employee”

Added “Enterohemorrhagic Escherichia coli”

Amended “Exclude” to clarify that an excluded person may not enter a food establishment as an employee

Amended “Food Processing Plant” subparagraph (b) by deleting the cross reference

Added “Handwashing Sink”

Added “Health Practitioner”

Amended “Juice” to clarify that “juice” does not include liquids, purées, or concentrates that are not used as beverages or ingredient beverages

Added “Major Food Allergen”

Amended “Potentially Hazardous Food” to introduce new term time/temperature control for safety (TCS), and include information and tables from the IFT report (CFP 2004-I-012)

Added “Ratites”

Amended “Reduced Oxygen Packaging” to clarify and expand the definition to address cook/chill and sous vide (CFP 2002-III-039)

Added “Re-Service”

Amended “Shiga toxin-producing *E. coli*” to describe examples

Deleted “Table-mounted equipment” and replaced with “Counter-mounted equipment”

## **Chapter 2**

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

Amended to state that complying with this Code means having no violations of critical items during the current inspection (CFP 2004-I-014)

### **2-102.11(C)(9)**

Added to address knowledge of major food allergens (CFP 2004-III-004)

### **2-102.11(C)(17)**

Added to address knowledge of reporting responsibilities. (CFP 2004-III-030)

### **2-102.20**

Added new section to recognize National Manager Certification (CFP 2004-II-009)

### **2-103.11(K)**

Amended to correct cross reference to 3-301.11(D)

**2-103.11(M)**

Added new paragraph regarding reporting responsibilities

**2-201.11**

Amended employee health section – made major revisions throughout (CFP 2004-III-030)

**2-201.12**

Amended exclusion and restriction section – made major revisions throughout (CFP 2004-III-030)

**2-201.13**

Amended removal of exclusion and restriction section – made major revisions throughout (CFP 2004-III-030)

**2-201.14**

Deleted section

**2-201.15**

Deleted section

**2-301.12**

Amended the excepted cross reference to ¶ (D) in (A) and

Amended to update proper sequence for handwashing procedure and avoiding recontamination of the hands, after handwashing.

**2-301.16**

Amended to eliminate use of the “sanitizer” and “sanitizing” since “sanitization” does not apply to hand antiseptics; replaced the terms “hand sanitizer” with “hand antiseptic.”

**Chapter 3****3-201.11(G)**

Amended language relating to egg and egg products

**3-202.11(C)**

Amended language relating to egg and egg products

**3-202.13**

Amended language relating to egg and egg products; removed small caps from words “restricted” and “consumer”

**3-202.14(A)**

Amended language relating to egg products

**3-202.14(B)**

Amended to clarify existing FDA policy that fluid and dry milk products must be both pasteurized and in conformance with Grade A Standards when received at retail

**3-203.11**

Added new ¶ (D) (CFP 2004-I-017)

**3-203.12(B)**

Revised to clarify that shellstock tags should be held for 90 days from the harvest date rather than the date the container is emptied

**3-203.12(B)(2)(b)**

Amended to clarify the intent of commingling to allow combining containers of shellstock that were harvested in the same growing area on the same harvest date by the same certified shellfish shipper (CFP 2004-I-018)

**3-301.11(B)**

Amended to delete “or when otherwise approved” and replacing with “or as specified in ¶ (D) of this section” (CFP 2004-III-029)

**3-301.11(D)**

Added new ¶ (D) to provide within the codified text the criteria that must be met for approval of an alternative procedure to No Bare Hand Contact with ready-to-eat foods and require prior approval from regulatory authority

**3-301.11(D)(3)**

Added provision to require a written employee health policy

**3-302.12**

Removed insert page with “Clarification of ¶ 3-301.11(B) of the Food Code with respect to the phrase “Except...when otherwise approved”...”

**3-302.13**

Amended language relating to meringue

**3-302.14**

Inserted missing header

**3-304.11**

Amended to add new ¶ (B) specifying that single-service and single-use articles can be used to contact food

**3-304.14**

Amended to clarify use of wiping cloths

**3-306.14**

Amended to correct cross-reference regarding re-service of food in HSP (CFP 2002-I-001)

**3-401.11(A)(1)**

Amended subparagraph (b) to delete the word “pork” since it is included in the definition of meat; updated the language in (a) relating to eggs; added cross-reference to ¶ 3-401.11(C); added exception regarding cooking intact steaks

**3-401.11(B)**

Amended to clarify that lamb and other meat roasts are included

**3-402.11**

Added third option for freezing to control parasites and added exemption for certain fish that are aquacultured

**3-402.12(C)**

Added provision for record keeping for certain aquacultured fish that are exempted from freezing

**3-403.11**

Amended to clarify reheating in 2 hours and changed “beef” to “meat” roasts

**3-501.14(D)**

Amended language relating to eggs

**3-501.16(B)**

Amended language relating to eggs

**3-501.17**

Amended date marking to include cheese exemptions and other exemptions based on the Lm Risk Assessment (CFP 2004-III-006; 2004-III-14; 2004-III-017)

**3-501.19**

Added a provision for longer time out of temperature control when food is removed from cold holding at 41°F (CFP-2004-III-09)

**3-502.11(H)**

Amended the list of items requiring a variance and HACCP plan to include sprouting beans or seeds in a food establishment (CFP 2004-III-012)

**3-502.12**

Amended provisions for ROP to address growth of *Listeria monocytogenes* and added cook/chill and sous vide, added ROP cheese (CFP 2004-III-023)

**3-602.11(B)**

Added labeling requirements for major food allergens as specified in the Food Allergen Labeling and Consumer Protection Act

**3-603.11**

Deleted insert page on “Current Status of Consumer Advisory Language”

**3-801.11(B) & (C)**

Amended language relating to egg and egg products and added meringue

**3-801.11(E)**

Added new cross reference to 3-501.19

**3-801.11(G)**

Added new provision regarding re-service of food (CFP 2002-I-001)

## **Chapter 4**

**4-101.13**

Amended to combine lead, pewter, solder and flux restrictions into one section

**4-101.17 and .18**

Deleted – both provisions and combined with 4-101.13

**4-101.19**

Amended to renumber to 4-101.17

**4-101.110**

Renumbered to 4-101.18

**4-101.111**

Renumbered to 4-101.19

**4-204.16**

Moved exception to beginning

**4-204.122**

“Equipment” to be changed to “apparatus” to be consistent with definition of “equipment”

**4-205.10**

Amended to correct verb to the present tense

**4-402.11(B)**

Amended reference to counter-mounted equipment

**4-402.12(D) & (E)**

Amended reference to counter-mounted equipment

**4-501.114**

Changed opening paragraph to cross-reference to Chapter 7

**4-502.11**

Deleted duplicate paragraph (C)

**4-9**

Amended text box, renamed subpart to “**4-904 Preventing Contamination**”

**4-901.11**

Updated CFR reference in (A)

**4-902.11**

Added cross-reference to § 7-205.11

**4-904.11**

Amended margin note (key words) to “**Preventing Contamination**”

**4-904.13**

Amended to restructure to be internally consistent – list was not in parallel structure

## **Chapter 5**

### **Throughout Chapter 5**

Changed “handwashing facility” to new term “handwashing sink”

**5-402.11**

Amended to clarify that floor drains are allowed in walk-in refrigerators (CFR 2004-I-026)

**5-501.14**

Moved the exception to the beginning of the section

## **Chapter 6**

**6-101.11(B)(1)**

Deleted “suitable” – inherent in “approved”

**6-201.11**

Moved both exceptions to the beginning of the section

**6-202.14**

Moved the exception to the beginning of the section

**6-202.17**

Moved the exception to the beginning of the section

**6-202.18**

Moved the exception to the beginning of the section

**6-303.11(A) and (B)**

The lux (foot candles) level of light intensity was adjusted to more accurately match conversion formulas for light intensity.

**6-501.12(B)**

Moved the exception to the beginning of the section

## **Chapter 7**

### **7-204.11**

Amended to correct CFR reference to 40 CFR 180.940

### **7-207.11(A)**

Moved the exception to beginning of section

## **CHAPTER 8**

### **8-304.11**

Amended to correct cross-reference in ¶ (D) to §2-201.11

### **8-403.10**

Amended to correct cross-reference in subparagraph (B)(2) to §2-201.11

### **8-501.10**

Amended opening phrase

### **8-501.20**

Added conditional employee

### **8-501.40**

Amended entire section to reflect reinstatement of excluded or restricted food employee or conditional employee consistent with new Part 2-2

## **Annex 1**

### **8-801.10(D)**

Added reference to conditional employee

## **Annex 2**

### **1. USC and CFR**

Amended (A) and (B) contact names and addresses

### **2. Bibliography**

#### **Preface**

Amended reference to DFSSR list of state officials

#### **1-201.10**

Added new reference for the Food Allergen Labeling and Consumer Protection Act

Amended references to the NSSP and PMO

Added new reference to the IFT Report Evaluation and Definition of Potentially Hazardous Foods (CFP 2004-I-012)

Added new reference relating to egg and egg products

#### **2-102.11**

Deleted reference #5 – outdated CFP Report

#### **2-201.11-.13**

Deleted 1 and added 23 references relating to employee health; amended others (CFP 2004-III-030)

**2-301.16**

Added 8 references regarding hand antiseptics and changed title

**3-201.13**

Updated reference to the PMO

**3-201.14**

Added 3 references for recreationally caught fish and 3 for labeling requirements

**3-201.15**

Updated reference to NSSP

**3-201.17**

Added 2 CFR references on exotic animals, voluntary inspection of rabbits

**3-202.12**

Added 3 references to food and color additives

**3-202.13**

Amended CFR reference related to egg and egg products; deleted 1 CFR reference

**3-202.14**

Added 2 new CFR references on cheese and frozen desserts

**3-202.18 and .19**

Updated reference to NSSP

**3-202.17**

Added 1 CFR reference on molluscan shellfish shipment; updated reference to NSSP

**3-202.110**

Added 3 references for treated juice

**3-203.11**

Added reference for repacking shellfish

**3-203.12**

Updated reference to NSSP

**3-501.16**

Added 23 references relating to PHF (TCS food) hot and cold holding

**3-501.17 and .18**

Added references relating to date marking (CFP 2004-III-007); amended USDA/ARS PMP

**3-501.19**

Added information regarding CFP report on using time/temperature for 6 hours; amended USDA/ARS PMP

**3-502.11**

Added 3 references relating to sprouting beans or seeds

**3-502.12**

Added 14 new references relating to ROP (CFP 2004-III-023)

**3-601.11 – 3-603.11**

Added 4 references on labeling and on the FD&C Act

**3-801.11**

Added new reference to the Juice HACCP Regulations

**4-101.13**

Added 3 references related to lead in ceramic ware



**4-101.17**

Deleted outdated reference to ASTM

**4-101.19**

Added CFR reference regarding preservatives for wood

**4-501.13**

Added new CFR reference on microwave ovens

**4-501.114**

Added reference to CFR Title 40, Part 180.940; added 2 new references and deleted four existing references

**4-901.11**

Added new CFR reference on food-contact sanitizing solutions

**5-202.12**

Amended 4 references

**6-202.15**

Amended 2 references

**6-303.11**

Amended the lighting handbook reference

**Chapter 7**

Added all new references

**3. Supporting Documents**

Deleted FDA from the title

Amended opening statement

Added (G) Growing Sprouts in a Retail Food Establishment (CFP Issue 2004-III-012)

Added (H) Advisories for Retail Processing with Proper Controls and Variances for Product Safety (CFP 2004-I-009; 2004-I-010)

Added (I) Evaluation and Definition of Potentially Hazardous Foods (CFP 2004-I-012)

Added (J) The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers"

Added (K) Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information (CFP Issue 2004-I-029)

Added (L) Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003 (CFP Issue 2004-I-006)

Added (M) Comprehensive Guidelines for Food Recovery Programs

**4. Food Defense Guidance From Farm to Table**

Added new Part 4. Defense Guidance from Farm to Table (CFP 2004-II-013)

## **Annex 3**

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

Added an explanation regarding the rationale for removing the numbering system from the definitions in the 2005 version of this Code

Deleted outdated reference to National Commission for Certifying Agencies' Standards for Accreditation of National Certification Organizations

Added information about the new definition of PHF/TCS food and guidance on using new Tables A and B (CFP 2004-I-012)

Added information about the new definition of egg and egg products

### **2-102.11**

Added information regarding the CFP Food Protection Manager Certification program

### **2-102.20**

Added new section for updated information regarding Accredited Programs for food manager certification

### **2-201**

Added supporting information about the change in approach to controlling ill employees

### **2-201.11 - .13**

Amended the entire discussion on employee health, exclusions and restrictions; and amended Lists I and II

### **2-301.12**

Added information on use of brushes, soap, and recontamination of hands after washing

### **2-301.16**

Added and updated information on hand antiseptics; changed title to Hand Antiseptics; updated address for OTC Drugs

### **3-201.11**

Updated the information about egg labeling; labeling irradiated raw meat (CFP 2004-I-028)

### **3-201.14**

Added information about recreationally caught fish

### **3-202.13**

Updated information related to egg labeling

### **3-203.11**

Added information related to repacking shellfish (CFP 2004-I-017)

### **3-301.11**

Amended entire section to reflect new provisions in ¶3-301.11(D); deleted "clarification of ¶ 3-301.11(B) of the Food Code with respect to the phrase "Except ... when otherwise approved;" replaced "Norwalk-like virus" with "Norovirus"

### **3-302.11**

Amended to clarify storage of raw animal food

### **3-401.11**

Amended to clarify that formed roasts are cooked the same as whole roasts; added information about roasts that are cooked slowly

**3-402.11**

Added information related to freezing for parasites and information on exemptions from freezing

**3-402.12**

Added information related to record keeping for freezing for parasites for aquacultured fish

**3-501.16**

Added information related to the Lm Risk Assessment

**3-501.17**

Added several paragraphs regarding the FDA/FSIS/CDC *Listeria monocytogenes* Risk Assessment and the justification for the additional exemptions to the date marking provision (CFP 2004-III-006; 2004-III-014; 2004-II-017)

**3-501.19**

Added information regarding using 6 hours to hold food without temperature control (CFP 2004-III-009)

**3-502.12**

Updated information regarding ROP, cook/chill, and sous vide (CFP 2004-III-023)

**3-602.11-.12**

Added information on the labeling of food allergens

**3-603.11**

Added information regarding consumption/sale of raw milk

**3-801.11**

Amended to clarify that pureed fruits and vegetables used as food for highly susceptible populations do not require preparation under a HACCP plan or compliance with 21 CFR Part 120

**3-801.11(G)**

Added information about re-service of food

**4-101.13**

Amended to combine lead, pewter, solder and flux restrictions into one section; deleted sections 4-101.17 and .18

**4-501.14**

Updated CFR cross-reference and information

**4-501.114**

Updated CFR cross-reference and information

**4-502.14**

Amended to clarify use limitations of mollusk shells

**5-402.11**

Added information about floor drains

**Annex 4**

Rewritten and renamed; old Annex 5 (HACCP) is now renumbered as new Annex 4 and retitled (Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors); deleted the entire old Annex 5 (HACCP) and replaced it with new Annex 4

Updated allergen information

## **Annex 5**

Rewritten and renamed; old Annex 4 (Food Establishment Inspection) is now renumbered as new Annex 5 and retitled (Conducting Risk-based Inspections); deleted the entire old Annex 4 (Food Establishment Inspection) and replaced it with new Annex 5

## **Annex 6**

Made editorial corrections throughout the Annex

## **Annex 7**

### **Forms, Guides, List & Charts**

Introductory Cover page – Updated listing of new forms

Forms – 1A, 1-B, and 1-C – Updated to reflect changes to Subpart 2-2

New Form 1-D, Bare Hand Contact application – Added form to apply for alternative procedure to touch RTE food with bare hands

Guides 1-D, 1-E – Deleted entirely

List 1-F – Deleted entirely

Previous Form 3-A – Deleted HACCP Inspection Data Form entirely

New Form 3-A – Added new Inspection Report Form (CFP 2004-II-019; 2004-II-021)

Guide 3-B – Added Food Code references for the new Inspection Report Form; deleted previous Inspection Form 3-B (CFP 2004-II-019; 2004-II-021)

New Guide 3-C – Added Inspection Report Marking Instructions; deleted previous Inspectional Guide 3-C

Chart 4-A – Added ratites to list of foods requiring 155°F for 15 seconds minimum cooking temperature; added baluts, stuffed ratites, stuffing containing ratites to list of foods requiring 165°F for 15 seconds minimum cooking temperature

Chart 4-C – Summary Chart for Date Marking – Corrected the symbol to  $\leq 45^{\circ}\text{F}$  and specified that this summary can be used for foods described in 3-501.17(A) - (E)

Chart 4-D – Mobile Food Establishment Matrix – Added ¶ 5-203.11(C); deleted ¶ 5-203.11(B) in the rows for Personnel and Water & Sewage

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