

Summary of Changes in the FDA Food Code

This Summary provides a synopsis of the textual changes from the 1999 FDA Food Code Chapters and Annexes to the 2001 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 1999 Code and for clarification.
- Section numbers listed refer to the 1999 Code unless otherwise noted. Definition numbers refer to the 2001 Code with the exception of the definitions deleted from the 1999 Code. Renumbering occurred in the 2001 edition, based on the changes made.

Preface

Items 1, 3, & 5

Amended to reflect current CDC data relative to foodborne illness (CFP-2000-I-65)

Items 4 & 6

Amended to recognize USDA/FSIS performance standards that are acceptable, equivalent alternatives that could be implemented in accordance with the Variance and HACCP provisions of the Food Code to allow flexible, but comparable, food safety controls to the command-and-control provisions that now provide specific times and temperatures for processing various products

Chapter 1 Definitions

201.10(B)(8)

Added "Casing" as it relates to cured and processed food

201.10(B)(13)

Added "Commingle" as it relates to combining molluscan shellfish harvested on different days or areas and different shucking dates

201.10(B)(25)

Added definition of "Egg" which includes the shell egg of the domesticated chicken, turkey, duck, goose, or guinea

201.10(B)(29)

Added "Exclude" relating to employees with certain illnesses who may not work as food employees

201.10(B)(30)

Added "FDA"

201.10(B)(36)

Deleted "Group Residence" and any references to term (see § 6-501.115)

201.10(B)(44)

Amended "Highly susceptible population" to clearly identify populations more likely than other people in the general population to experience foodborne illness

201.10(B)(47)

Added "Juice", which when used in the context of food safety, includes the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees, or any concentrates of such liquid or puree

201.10(B)(65)(c)(i)

Amended "Potentially Hazardous Food" to exclude shell eggs that have been treated to destroy all viable *Salmonellae*

201.10(B)(66)(a)(ii)

Amended "Poultry" to include pigeons and squabs

201.10(B)(70)

Amended "Ready-to-Eat" food to provide a comprehensive delineation of foods that are Ready-to-Eat

201.10(B)(74)

Added "Restrict" relating to limiting the activities of a food employee so that there is no RISK of transmitting a disease

201.10(B)(75)

Added "Restricted egg", including terms that apply to a Restricted egg (See also Public Health Reason § 3-202.13)

201.10(B)(77)

Added "Risk" to consider the likelihood that an adverse health effect will occur within a population as a result of a HAZARD in a FOOD

201.10(B)(86)

Added "Shiga toxin-producing *Escherichia coli*" which includes any *E. coli* capable of producing Shiga toxins such as *E. coli* serotype O157:H7, O157:NM, and O157:H-

201.10(B)(97)

Amended definition of "Utensil" to specifically identify temperature sensing probes of food temperature measuring devices

Chapter 2

2-103.11

Amended ¶ (K) by adding "Except when otherwise approved as specified in ¶ 3-301.11(B)..." to be inclusive of the intent of ¶ 3-301.11(B) as it relates to circumstances where bare hand contact with ready-to-eat food may be allowed

2-2

Replaced reference to *E. coli* O157:H7 with defined term: SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and expanded the employee health controls to all Shiga toxin-producing *E. coli* (CFP-2000-I-35)

2-201.11(C)

Deleted existing ¶ (C) and replaced with language to clarify timeframes for the reporting of past illnesses of *S. Typhi*, *Shigella* spp., SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*, or Hepatitis A virus

2-201.11(D)

Added the phrase “and has knowledge about”, relating to employees meeting certain high-risk conditions, to acknowledge that multiple persons may live in the same household, such as in a college sorority or fraternity house, but one person may not have knowledge about another person's health status

2-201.12

Amended subparagraph (B)(1) "Suffering from a symptom ... subparagraph 2-201.11(B)(1)(a), (b), and (e) or..." and (C)(1) "Is experiencing a symptom ... 2-201.11(B)(1)(a), (b), (c), or (e)..." to clarify restriction/exclusion of a food employee with jaundice

2-201.13(B)(1)

Amended subparagraph (a) "Is free of symptoms ... subparagraph 2-201.11(B)(1)(a), (b), (c), or (e) or (2)..." and (a)(i) "Is free ... 2-201.11(B)(1)(a), (b), (c), or (e), and..." to clarify restriction/exclusion of a food employee with jaundice

2-201.13(C)

Amended subparagraph (1) “That specifies ... the infectious agent of concern as specified in § 8-501.40” to clarify restriction/exclusion of a food employee with jaundice

2-301.12(A)

Amended to address ADA concerns relating to persons with prosthetic devices and also to provide greater specificity regarding the cleaning procedure as it applies to hands and arms

2-301.14

Added "(H) Before donning gloves for working with food; and..."

Clarifies that hands must be washed before putting on gloves to work with food

2-301.15

Amended to include in one location all equipment or facilities in which employees may NOT clean their hands

2-301.16

Deleted reference to the List of Proprietary Substances and Nonfood Compounds since it is no longer published by USDA (CFP 2000-I-60)

2-303.11

Provided clarification, in concert with the ADA, regarding situations that have arisen with food employees wearing medical alert jewelry

Chapter 3

3-201.11(E)

Amended to offer an alternative to the 1999 provision for labeling of whole-muscle intact beef steak (CFP-2000-I-59)

3-201.11(G)

Added a provision relating to labeling that specifies safe handling instructions for raw shell eggs

3-202.11

Added a new provision to address that raw shell eggs must be received in equipment that maintains an ambient air temperature of 7°C (45°F)

3-202.12

Changed the reference to 9 CFR 424.21 (from 9 CFR 318.7) to address both meat **and** poultry

3-202.110

Added provisions relating to packaged juice which address processor HACCP systems, pasteurization or treatments to reduce pathogens, and warning labels

3-203.11(B)

Amended to clarify that shellstock may be removed from the original container for display purposes if identification records are maintained

3-203.12(B)(2)

Amended to eliminate the need for a variance and HACCP plan if a record keeping system is in place to ensure source identification of shellstock (CFP-2000-I-41)

Part 3-4

Added a new subpart “**3-404 Other Methods**” to incorporate issues relating to juice

3-401.11(B)(2)

Revised the Roast Cooking Chart to be consistent with USDA/FSIS criteria for cooking roasts; establishes a microbial lethality of 6.5-log₁₀ reduction of Salmonella (CFP 2000-I-29)

3-404.11

Added a new section to address the criteria for treating juice in a food establishment and to address labeling if not treated

3-501.12

Changed cross-reference in ¶ (A) due to change in § 3-501.16 relating to order of subparagraphs

3-501.13

Changed cross-reference in ¶¶ (A); (B)(3); (B)(4); (B)(4)(b) due to change in § 3-501.16 relating to order of subparagraphs

3-501.14

Changed cross-reference in subparagraph (A)(2); (B); (C); (D) due to change in § 3-501.16 relating to order of subparagraphs

3-501.14

Amended cooling time to clarify cooling provision of subparagraph (A)(2) "... 6 hours from 60°C (140°F) to 5°C (41°F) or less, or to 7°C (45°F) or less [total time for cooling is unchanged]

3-501.14(D)

Amended to clarify that, upon receipt, raw shell eggs must be placed in refrigerated equipment that is capable of maintaining an ambient air temperature of 7°C (45°F) or less

3-501.16

Combined existing paragraphs (A), (B), and (C) into new paragraph (A), added new paragraph (B) to include requirements for the control of the growth of **Salmonella Enteritidis** in refrigerated shell eggs. Amended federal regulations 21 CFR Part 115, Eggs, Refrigeration, issued December 5, 2000 and effective on June 4, 2001, require 45°F maximum ambient air temperature for eggs stored and displayed at retail

3-501.17

Amended to clarify the language with regard to implementation of date marking

3-502.11

Changed from a paragraph to a listing of items requiring a variance; added molluscan shellfish life-support systems, excluded brewing alcoholic beverages

3-502.12(B)(5)

Amended to limit the refrigerated shelf life of Reduced Oxygen Packaged product to 14 days

3-602.11(B)(6)

Added subparagraph (6) relating to any salmonid fish containing canthaxanthin as a color additive to render the Food Code consistent with the CFR

3-801.11

Amended to specify: an age for children in a facility where juice is served; that juices bearing a warning label may not be served; and, a requirement for a HACCP plan if juice is prepared on the premises

Chapter 4**4-204.112(A)**

Amended to allow use of modern technology to measure temperature via substitute food-like products or product mimicking devices (CFP 2000-I-52)

4-204.117

Amended to include automatic dispensing of detergents and sanitizers and clarification of indicators that detergents and sanitizers are properly delivered (CFP 2000-I-53)

4-301.12(D)(2)

Amended to clarify the language relating to limitations on the use of two-compartment sinks and to more clearly present the concept that all kitchenware items must be cleaned

4-302.12

Amended to address the need for a suitable small-diameter probe for measuring the temperature of thin masses of food such as meat patties (CFP 2000-I-30)

4-603.12(A)

Deletes the word “scupper”, a nautical term that refers to a drain on the deck of a boat, or a building drain for rainwater

Chapter 5

5-202.12(A)

Amended to decrease the water temperature for handwashing to 100°F based on ASTM Standards for evaluating handwashing formulations (CFP 2000-I-25)

5-203.15

Deletes the word "Reserved" and replaces it with relevant information concerning suitable backflow prevention devices for use with soft drink carbonators (CFP 2000-I-55)

Chapter 6

6-202.15(D)

Amended subparagraph (D)(2) to clarify that air curtains are only effective against flying insects

6-501.115(B)(4)

Deleted the term "group residence" and replaced it with descriptive language of various care facilities

Chapter 7

No changes.

CHAPTER 8

8-201.13(A)

Deleted the need for a variance and HACCP plan if a record keeping system is in place for shellstock and deleted the reference to subparagraph 3-203.12(B)(2)(b) – (when a HACCP plan is required) (CFP 2000-I-41)

8-304.11(D)

Amended to be consistent with Section 2-201.15 by changing "employee" to "food employee"

8-304.11(H)

Changed cross-reference in subparagraph (H) due to change in § 3-501.16 relating to refrigeration equipment

8-501.20 (A) and (B)

Deleted language that no longer is necessary due to new definitions of "exclude" and "restrict"

8-501.40

Replaced reference to *E. coli* O157:H7 to new defined term: SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and expanded the employee health controls to all Shiga toxin-producing *E. coli*

Annex 1

No changes.

Annex 2

3. FDA SUPPORTING DOCUMENTS was added following the end of the existing bibliography with an introductory paragraph and summary of documents A through E:

- A. (Draft) Recommended National Retail Food Regulatory Program Standards
- B. Procedures for Standardization and Certification of Retail food Inspection/Training Officers
- C. (Draft) Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level
- D. Food Establishment Plan Review Guidelines
- E. Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors

2. Bibliography, Preface, reference 2

Reflects source of current CDC data relating to foodborne illness

2-201.11

Added references relating to employee illness

2-301.12

Added 29 references regarding handwashing

3-301.11

Added 10 references concerning potential contamination by bare hand contact of ready-to-eat food

3-501.14

Added new references relating to food cooling parameters

3-501.19

Added new references relative to using time as a public health control

5-202.12

Added references to ASTM Standards related to the temperature of water for evaluation of handwashing formulations

Annex 3

1-201.10

Updated the address for CFP and added updated information regarding manager certification

2-102.11

Amended to reflect updated information regarding manager certification programs

2-103.11

Added a paragraph to address industry developed and implemented operational-specific training programs for food employees

2-201.11,

Added a new sentence to introductory paragraph of List I and List II: "The Lists below include all SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*

2-201.11, (List I)

Changed the title by replacing the word "employees" with "persons" and alphabetized the list (as it is in the Federal Register)

2-201.11, (List II)

Changed the title by replacing the word "employees" with "persons," eliminated pathogen "Rotavirus," added pathogen "*cryptosporidium parvum*," and alphabetized the list (as it is in the Federal Register)

2-201.11

Added new paragraphs after existing paragraph 2 regarding the period of communicability for the four pathogens of concern; *Salmonella Typhi*, *Shigella* spp., Shiga toxin-producing *Escherichia coli*, and hepatitis A virus (source: Control of Communicable Diseases Manual)

2-201.11

Added a paragraph relating to employees with an infected cut and when it is reportable to the person in charge

2-201.12

Added paragraphs to assist in decisions that allow an excluded or restricted food employee to work

2-301.12

Deleted all of the previous language and replaced with information specific to reduction of fecal-oral pathogens from hands

2-301.12

Added a paragraph to address food workers with prosthetic hands/arms

2-301.16

Deleted reference to the List of Proprietary Substances and Nonfood Compounds as it is no longer published by USDA

2-303.11

Added a paragraph related to medical alert jewelry and alternatives as to how it may be displayed

3-201.11

Added information concerning the labeling and safe handling of raw shell eggs and the exclusion from labeling for certain treated eggs

3-201.16

Added several paragraphs regarding wild mushrooms including the issue of buyer specifications (CFP2000-III-09)

3-202.13

Added information that further defines criteria for Restricted Eggs

3-301.11

Added information regarding potential contamination by bare hand contact of ready-to-eat food

3-304.11

Added a paragraph that relates gloves to applicable criteria of utensils

3-304.15

Added information regarding gloves as a utensil; natural rubber latex; use of gloves and handwashing; use of natural rubber latex gloves; and included NIOSH and OSHA recommendations relating to the use of latex gloves

3-401.11, 12, & 13

Amended to reflect current USDA/FSIS time/temperature criteria for cooking roasts

3-403.11

Modified wording relating to reheating for hot holding with no change in content

3-501.14

Added a position paper regarding the cooling parameters (CFP 2000-III-05), and added information relative to air-cooled hard-boiled eggs, ionizing radiation of shell eggs, and updated information regarding the egg safety rule

3-501.16

Expanded this Reason to include information relative to control of the growth of *Listeria monocytogenes* in refrigerated food and *Salmonella Enteritidis* in refrigerated shell eggs

3-501.17 and .18

Rewritten to address date marking concerns relative to the growth of *Listeria monocytogenes*, when processed foods need to be date marked, date marking methods, shelf-stable products, and manufacturer's use-by and sell-by dates

3-501.19

Added a position paper regarding the rationale for using time alone as a public health control (CFP 2000-III-03)

3-502.11

Added information to assist in implementing variances, a Model Flow Process for State Regulators to Address Variances, and Model Administrative Procedures for Regulators to Address Variances (CFP 2000-I-33)

3-502.12

Clarified the difference in refrigerated shelf life requirements between ¶ 3-501.16(B) [refrigerated food] and § 3-502.12 [refrigerated reduced oxygen packaged food] and explained that there is a difference between food that is held at refrigeration temperatures versus food held frozen

3-602.11

Edited labeling issues so the Food Code is consistent with the CFR regarding labeling of food

3-801.11

Added information relative to safeguards for highly susceptible populations relating to the risk of contracting foodborne illness from juice

4-101.12

Deleted existing paragraph relating to the use limitation for cast iron and replaced with appropriate language addressing surface characteristics of cast iron

4-101.13

Provided additional explanation relative to the limits of lead in ceramicware

4-204.112

Added information regarding the use of modern technology to measure temperature via substitute food-like products or product mimicking devices

4-204.117

Added public health reasons regarding the automatic dispensing of detergents and sanitizers, and clarified the meaning of a sanitizer indicator or alert

4-302.12

Added information regarding the use of small-diameter probes for temperature measurement of thin foods such as meat patties

4-501.111

Corrected an error in the temperature for the hot water sanitizing step - 77°C (171°F).

4-501.112

Clarified the difference between sanitizing water temperature at the manifold and at the surface of utensils in warewashers

4-501.114

Added information to clarify the confusion caused by separating the provision about the sanitizing solution strength from the provision relating to exposure time

4-602.11

Added information regarding adulteration from one species to another to reflect current information from USDA/FSIS

5-202.12

Added information relating to the water temperature for handwashing and the ASTM Standards for testing the efficacy of handwashing formulations

5-203.15

Added information relating to the concerns for copper poisoning when carbon dioxide is mixed with water in copper plumbing or tubes

6-501.115

Changed the words "support animals" to "service animals" to make the provision consistent with the ADA language

Annex 4**1. (A)**

Added reference to the guidance document, "FDA's Recommended National Retail Food Regulatory Program Standards"

4. (E)

Incorporated and referenced FDA's guidance documents (see **Annex 2, 3. FDA SUPPORTING DOCUMENTS** above)

4. (J)(1)(a)

Amended Annex 4 to be consistent with the roast cooking chart in paragraph 3-401.11(B) of the codified language

9. (A)

Amended language to distinguish accuracy with calibration of a Celsius vs. a Fahrenheit thermometer

Annex 5

1.

Added a note that Annex 5 is currently under review and modified the text for the Introduction

2 (A) and 2(B)

Replaced text to reflect current FDA thinking and incorporated and referenced FDA's guidance documents into the Food Code Annexes

Changed the order of Principles #6 and #7 to be consistent with the NACMCF

Annex 6

No changes

Annex 7

Forms, Guides, List & Charts

Replaced each reference to *E. coli* 0157:H7 to read: "Shiga toxin-producing *Escherichia coli*"

Expanded the employee health controls to all Shiga toxin-producing *E. coli*

Renumbered all forms and guides and organized them so that related topics are together

Chart 3 [summary chart for date marking]

Corrected an error in the example and provided a revised chart to reflect revised date marking criteria

ADA = Americans with Disabilities Act

ASTM = American Society for Testing and Materials

CDC = Centers for Disease Control and Prevention

CFR = Code of Federal Regulations

HACCP = Hazard Analysis and Critical Control Point

NACMCF = National Advisory Committee on Microbiological Criteria for Foods

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