

Summary of Changes In the FDA Food Code

This Summary provides a synopsis of the textual changes from the 2009 FDA Food Code and the Supplement to the 2009 Food Code Chapters and Annexes to the 2013 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 2009 Code and for clarification.
- Section and paragraph numbers listed refer to the 2009 Code and its Supplement 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.
- Converted several Tables, charts, and images throughout the Code to meet web accessibility requirements under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d). Section 508 mandates that all federal agencies eliminate the barriers in accessing electronic and information technology.

Preface

Amended Preface sections 1, 3, 5, 6, and 8 to add updated information and revise dates to make current.

Chapter 1 Purpose and Definitions

Deleted “**Enterohemorrhagic *Escherichia coli*” (EHEC)** as use of EHEC terminology is outdated.

Amended "**Packaged**" in (1) to delete the term "securely" to avoid undue emphasis on nature of the package; Amended "**Packaged**" in (2) to remove the phrase "or other nondurable container" to clarify when foods packaged at retail need to be labeled so that it reads: "**Packaged**" *does not include wrapped or placed in a carry-out container to protect the FOOD during service or delivery to the CONSUMER, by a FOOD EMPLOYEE, upon CONSUMER request.*

Deleted the term **Potentially Hazardous Food (Time/Temperature Control for Safety Food)** (PHF/TCS) and made a universal change throughout the Code to replace it with the term **"Time/Temperature Control for Safety Food" (TCS)**. The definition remains the same.

Revised "**Reduced Oxygen Packaging**" subparagraph (2)(e), to delete the phrase "placed in a hermetically sealed, impermeable bag" and replace it with "vacuum packaged in an impermeable bag" so it clearly defines the sous vide process as outlined in Annex 6(2)(B)(4)(b). It now reads: "Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens."

Revised "**Shiga toxin-producing *Escherichia coli***" (STEC) to reflect current nomenclature.

Chapter 2 Management and Personnel

2-201.11, 2-201.12, 2-201.13

Amended to add nontyphoidal *Salmonella* (NTS) as one of the reportable illnesses for action by the Person in Charge; Added Code language to address employee health controls for the exclusion and restriction of nontyphoidal *Salmonella*, and removal of exclusion and restriction from NTS.

2-301.14(H)

Amended to clarify that the requirement to wash hands before donning gloves is specific to the beginning of a task involving working with food and not during the task.

2-301.16(A)(2)

Amended to remove (A)(2)(b)(i-ii) and add new subparagraphs (A)(2)(b-e) to clarify and align the codified text with applicable CFR's and the FD&C Act with regard to the use of hand antiseptics as a food additive.

Chapter 3 Food

3-201.16(A)

Amended to remove existing 2009 ¶(A) language in reserve; Added new ¶(A) to recognize a regulatory authority's ability to approve the sale of wild mushrooms within a food establishment and regulate wild mushrooms according to their LAW.

3-301.11(D)

Amended to revise subparagraph (D)(2) to clarify that Paragraph (B) does not apply where a ready-to-eat food is added as an ingredient to another food that does not contain a raw animal food and the combined product will be heated to at least 63°C (145°F).

3-302.11

Amended to remove subparagraph (A)(3) and renumbered the remaining paragraphs as (4) – (8).

3-304.11

Amended to add a new ¶(C) to clarify that food may contact surfaces of linens and napkins as specified in §3-304.13 and added term "Linens" to the tag line.

3-304.13

Amended to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens.

3-304.17

Amended to relocate the requirement regarding the cleaning of returnables into this section from §4-603.17.

Amended ¶3-304.17(A) to clarify conditions under which the re-use of returnables are permitted.

Amended ¶3-304.17(B) to establish conditions under which refilling of returnable take-home containers is permitted.

Amended to relocate the exception for filling a food-specific container with a beverage from ¶4-603.17(B) to ¶3-304.17(C).

Amended to renumber ¶3-304.17(C) as a new ¶3-304.17(D).

Amended to relocate the exception for filling consumer-owned, personal take-out containers that are not food-specific from ¶4-603.17(C) to ¶3-304.17(E).

3-401.14

Amended to revise ¶(D) to clarify that prior to sale or service, raw animal foods cooked using a non-continuous cooking process shall be cooked to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C).

3-402.11

Amended ¶3-402.11(B) to add a new ¶(2) to clarify that scallop products consisting solely of the shucked adductor muscle are excluded from the requirements for parasite destruction and re-designated existing ¶¶(2)-(4) to be new ¶¶ (3)-(5).

3-403.11

Amended ¶3-403.11(C) to clarify that this provision applies to all commercially processed TCS foods that are ready-to-eat. Previous text suggested that it applied only immediately upon removal of the food from a sealed container.

3-501.13

Amended to add new ¶(E) specifying frozen fish packaged using a ROP method be removed from the ROP environment either prior to initiating thawing procedures under refrigeration as specified in ¶ (A) or prior to, or immediately upon completion of, its thawing using procedures specified in ¶ (B) of this section.

3-501.17

Amended to add new ¶(F) that exempts raw, live in-shell molluscan shellfish from date marking and re-designated former ¶(F) as new ¶(G).

Amended existing subparagraph 3-501.17 (F)(6) to clarify that the exemption from date marking for shelf stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing; Renumbered existing ¶(F)(6) as new ¶(G)(6) as a result of the addition of new ¶ (F).

3-502.11

Amended to revise ¶(D) to make clear that only TCS foods prepared under ROP methods that do not control for growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* require a variance.

3-502.12

Amended ¶¶3-502.12(B), (D), and (E) lead-in paragraphs to reference new ¶ (F) of this section.

Amended ¶3-502.12(B) lead in paragraph and subparagraphs (B)(6)(c), (D)(1), and (E)(2) to reference ¶8-201.14(B) along with existing reference to ¶ (D).

Amended subparagraphs 3-502.12(B)(3)(b) and (B)(4) to delete 14 days and add 30 days.

Amended ¶ 3-502.12(B) to add new subparagraph 7 specifying that a HACCP plan be provided to the regulatory authority prior to implementation.

Amended ¶3-502.12(D) lead in paragraph to delete the word “FOOD” and replace it with the term “Time/Temperature control for safety food” to clarify that this section applies to TCS food.

Amended subparagraph 3-502.12(D)(2)(b) to specify only the cooking parameters in ¶¶ 3-401.11(A), (B) and (C) apply.

Amended subparagraph 3-502.12(D)(2)(e)(ii) to allow for cold holding at 41°F for 7 days after cooling to 41°F.

Amended to delete existing subparagraph 3-502.12(D)(2)(e)(iii) and amended subparagraph 3-502.12(D)(2)(e)(iv) to renumber it as the new subparagraph (D)(2)(e)(iii).

Amended to add new ¶(F) to identify the conditions under which a HACCP Plan is not required for ROP TCS foods.

3-602.11

Amended ¶3-602.11(B)(2),(3),(5), and (7) to clarify the information that a label should include.

Amended subparagraph 3-602.11(B)(2) to clarify what information must be included in the statement of ingredients. The term “sub ingredients” was added to this subparagraph to clarify that individual component ingredients of a main ingredient must be disclosed in the statement of ingredients. This clarification helps to make clear that all individual ingredients in a packaged food will be disclosed in the statement of ingredients.

Amended subparagraph 3-602.11(C)(2) to remove cross reference to subparagraph (B)(5) to correctly refer to what a labeling device such as a card, sign, or other method of notification needs to declare. This change corrects an inadvertent error that was created in the 2005 Food Code when a new subparagraph (B)(5) for food allergens was added and the subparagraph for nutritional labeling was renumbered to (B)(6), but the accompanying cross reference in (C)(2) was not changed to correctly cross reference (B)(1), (2), and (6), nutritional labeling.

Chapter 4 Equipment, Utensils, and Linens

4-302.13

Amended the tag line to add “mechanical warewashing”

Amended to redesignate the existing section into ¶(A) and new ¶(B) to require the availability of irreversible registering temperature indicators.

4-602.11

Amended ¶ 4-602.11(B) to change the cleaning and sanitizing frequency for food contact surfaces or utensils that are in contact with a raw animal food that is a major food allergen such as fish, followed by other types of raw animal foods. With this change, the exception to existing subparagraph (A)(1) found in ¶(B) now applies only to raw meat and poultry.

4-603.17

Amended to delete §4-603.17 and relocate its requirements into §3-304.17.

4-802.11

Amended ¶4-802.11(C) to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens as mentioned in ¶3-304.11(C) and §3-304.13.

Chapter 5 Water, Plumbing, and Waste

No Changes.

Chapter 6 Physical Facilities

No Changes.

Chapter 7 Poisonous or Toxic Materials

7-204.12

Amended ¶7-204.12(A) to redesignate ¶(A) into a lead-in paragraph with four new subparagraphs: Added 21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption as new subparagraph (A)(1); Added GRAS ingredients as new subparagraph (A)(2); Added effective food contact notifications as new subparagraph (A)(3); Added 40 CFR 156 Labeling Requirements for Pesticides and Devices as new subparagraph (A)(4) to allow the use of other antimicrobial agents allowed under the food contact notification program for washing fruits and vegetables as well as GRAS ingredients permitted as antimicrobials or for general food use.

Chapter 8 Compliance and Enforcement

8-201.13

Amended ¶8-201.13(B) to add new language to have the food establishment notify the Regulatory Authority through submission of a HACCP plan that they will be conducting ROP operations that conform with procedures in § 3-502.12.

8-304.11

Amended to add new ¶(K) to include a requirement for the permit holder to post a sign or placard notifying the public that inspectional information is available for review.

Annex 1 Compliance and Enforcement

No Changes.

Annex 2 References

Preface

Amended to redesignate numbers and alphabetize.

2-201.12 and 2-201.13

Amended to update three references and add twenty new references in support of including public health controls for the control of nontyphoidal *Salmonella* (NTS) in retail food establishments; references renumbered to keep alphabetical format.

3-401.11

Amended to redesignate numbers and alphabetize.

3-402.11

Amended to add one new reference (#6), the Fish and Fishery Products Hazards and Controls Guidance, 4th Edition, April 2011, and renumbered remaining references.

3-502.12

Amended to add two new references (#24, and #28) and renumbered the remaining references. The new references are regarding time to formation of *C. botulinum* toxin. These references provide support of the pH of 5 limit for the psychrotrophic strains of *C. botulinum* due to Code changes to allow a 7-day storage for ROP at 41°F and a 30-day hold for vacuum packaging and Cook-Chill/Sous Vide of foods with a pH of 5 or less.

4-603.17

Amended to move reference for deleted §4-603.17 to be under §3-304.17 since the two sections were merged into §3-304.17.

6-501.111

Amended to add new reference in support of this section on controlling pests.

7-204.12

Amended to add new reference to include 21 CFR 173.405, Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate.

3. Supporting Documents

Amended section **K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information**, to update with current USDA/FSIS information and documents. The update includes deleting existing paragraphs 5 and 6 and adding new paragraphs 5 and 6; Updated other existing paragraphs with editorial changes.

Amended to add new section, **S. CIFOR The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response**

Amended to add new section, **T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)**

Annex 3 Public Health Reasons/Administrative Guidelines

1-201.10

Packaged.

Amended to add a section on “Packaged” to clarify when foods packaged at retail need not be labeled and placed the text after the “Food Establishment and a food processing plant located within the same premises of a food establishment” section and before the “TCS” section.

2-2 Employee Health

Amended to add a description of nontyphoidal *Salmonella* between the descriptions of Norovirus and *Salmonella* Typhi.

Amended Part 2-2 and its related subparts and Tables/Decision Trees to be consistent with the changes in Chapter 2; Tables and Decision trees were revised to meet accessibility requirements for web posting.

Amended to update the list of *Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens* from CDC, effective November 30, 2012.

Amended the pathogen descriptions in subpart 2-201.11 to be consistent with the Bad Bug Book, 2nd Edition, 2012.

2-301.14

Amended to clarify that subparagraph ¶2-301.14(H) requires handwashing immediately before, during, and immediately after, the activities listed.

2-301.16

Amended the “As a Food Additive” Section to add a new paragraph 4 to elaborate on the prior sanction requirements under the food additive provision in the Federal Food, Drug and Cosmetic Act as it relates to the substances in a hand antiseptic reasonably expected to become a component of food based upon the product’s intended use; Renumbered the existing paragraph 4 as a new paragraph 5.

3-201.11

Amended to relocate information about safe food handling label instructions from Annex 3, §3-602.11 to Annex 3 §3-201.11.

3-201.16

Amended to delete last sentence in paragraph 2; revise paragraph 3; add new paragraphs 4-5; and delete existing paragraphs 4-8.

3-302.11

Amended to remove paragraph 3 to be consistent with change to delete subparagraph 3-302.11(A)(3).

3-304.17

Amended to describe the public health reasons for inclusion of an exception for reusing and refilling returned take-home containers with TCS- or non-TCS food; Relocated PHR text from §4-603.17 to §3-304.17.

3-401.14

Amended to revise paragraph 6 to clarify that during the final cooking step, raw animal FOODS cooked using a NON-CONTINUOUS COOKING process shall be cooked to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C).

3-402.11

Amended to update paragraph 6 to be consistent with the Fish and Fisheries Products Hazards and Controls Guidance, Fourth edition.

Amended to add new paragraph 8 to explain why the requirements for parasite destruction do not apply to molluscan shellfish and scallop products consisting solely of the shucked adductor muscle.

3-403.11

Amended to add a new paragraph 4 to provide the public health reason for requiring a reheating temperature for commercially processed foods that is lower than that for foods prepared in the food establishment.

3-501.13

Amended to add three new paragraphs to address the removal of ROP frozen fish from its packaging before thawing to prevent *C. botulinum* toxin formation.

3-501.17

Amended to remove “PHF” from the Tagline so it references only TCS food.

Amended to add a new paragraph #13 under a new subheading “Shellstock” as public health rationale for exempting shellstock from date marking.

Amended paragraph 4 under subheading of USDA-regulated products to clarify that the exemption from date marking for shelf stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing.

3-502.11

Amended with an editorial change to make a correction in the title of Chart 1 to accurately cross reference §3-502.11 rather than §3-501.11.

3-502.12

Amended the entire annex section to reorganize the information according to different concepts presented in the Annex, added sub-headings, and revised certain text within the existing paragraphs, such that changes are:

- In the introductory paragraphs,
 - amended paragraph 1 to add information about safety concerns when spoilage organisms are inhibited, and
 - amended paragraph 2 to delete information about oxygen transfer rate and add information about other ways oxygen is restricted not just by the packaging.
- Amended text under the new subheading, ROP with Two Barriers,
 - in paragraph 2, to provide examples of foods that have high levels of competing organisms and explained why the refrigerated shelf life time was increased from 14 calendar days to 30 calendar days for vacuum packaged ROP food, and
 - in paragraph 3, to address non-time/temperature control for safety food explaining why these foods do not require a variance or HACCP Plan for ROP.
- Amended the first sentence in paragraph 1 under the new subheading, ROP and Cheese, to remove “Naturally fermented” at the start of the sentence.
- Amended text under the new subheading, ROP with One Barrier (Cook-Chill and Sous Vide),
 - in paragraph 1 to change the four options to three options for inhibiting growth for cook/chill, sous vide processing, and

- in paragraph 2, to change the 38°F cold holding temperature noted to 41°F, to be consistent with the changes made in subparagraph 3-502.12(D)(2)(e).
- Amended text under the new subheading, The Relationship Between Time and ROP, to add new text that provides information regarding short-term ROP storage and exemption from a HACCP Plan.
- Amended text under the new subheading, HACCP Plans with ROP,
 - in paragraph 1 to add information on submitting a HACCP Plan to the regulatory authority, and
 - in paragraph 2 to clarify information for when an operator submits an application for a variance.
- Amended text under the new subheading, ROP with Fish, for internal consistency.

3-602.11

Amended to reorganize the entire public health reasons and include new subheading titles; removed outdated information from the food allergen labeling subsection; included information about astaxanthin, a color additive used in salmonid fish under its new subheading; New cross-reference created in §3-602.11 to direct the reader to §3-201.11 under the new safe handling instructions subheading.

Amended to clarify why food held under the direct control of the operator is exempt from the labeling requirements in 3-602.11, while food enclosed in a container or wrapping and placed on display for consumer self service is subject to the labeling requirements under §3-602.11.

Added public health rationale to explain the importance of having an accurate list of food ingredients on the label. Two examples were provided to illustrate the method that food establishments may use to list the ingredients on the label.

4-101.15

Amended paragraph 1 and added new paragraph 2 to add information about zinc and zinc poisoning

4-302.13

Amended to change the tag line and to add a new paragraph 2 with the public health rationale for the new ¶4-302.13(B).

4-602.11

Amended to add new paragraphs 5 and 6 to clarify that food contact surfaces of equipment and utensils that have contacted a raw animal food that is a major food allergen such as raw fish must be cleaned and sanitized prior to contacting different types of raw animal foods.

4-603.17

Removed Annex 3, §4-603.17 and relocated the public health reasons text from §4-603.17 to §3-304.17.

7-204.12

Amended to update web link in paragraph 1, revise paragraph 3 and add a new paragraph 4 that speaks to allowing food additives and food contact substances as well as substances generally recognized as safe (GRAS) that are permitted under FDA's regulations for washing fruits and vegetables.

8-304.11

Amended to add new public health reasons to explain the intent of adding in new ¶(K) a requirement to post a sign/placard notifying the public that inspectional information is available for review.

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

Amended to convert Table 1 through Table 4 and the CCP Decision Tree 1 to meet web accessibility requirements.

Amended section **9. Resources and References (C) FDA Publications** to update the list of resources and references to also reference the Fourth Edition of the Fish & Fishery Products Hazards and Controls Guidance, April 2011.

Annex 5 Conducting Risk-Based Inspection

No Changes.

Annex 6 Food Processing Criteria

Amended Section 2, Reduced Oxygen Packaging, (B) Definitions, (1) through (5) to revise the ROP definitions to be consistent with the ROP definition in Chapter 1 (1-201.10).

Annex 7 Models Forms, Guides, and Other Aids

Amended the Tables and Charts throughout to be consistent with web accessibility requirements.

Amended Forms 1-A, 1-B, and 1-C to revise the forms to be consistent with the changes in Chapter 2 in regards to the use of the term STEC and not EHEC and NTS, as applicable.

Amended Forms 2-A and 2-B to change use of term “Potentially hazardous food (time/temperature control for safety food)” to “time/temperature control for safety food”.

Amended Form 3-A, *Food Establishment Inspection Report* form, for consistency with changes made in the Supplement with the 2009 Food Code to add two new entries and renumber the subsequent items. This change added in a new item #2 Certified Food Protection Manager, renumbered existing #2-3 as new items #3-4; added in a new item #5 Procedures for responding to vomiting and diarrheal events, renumbered existing items #4-54 as new #6-56.

Amended Guide 3-B, *Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices* to add the risk designations (Priority^(P), Priority Foundation^(Pf) and Core^(C)) to each applicable code section for reference when recording observations in the inspection report.

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