

Supplement to the 2022 Food Code

U.S. Public Health Service

FDA

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

College Park, MD 20740

IMPORTANT - Save this Supplement. It is intended to keep the 2022 Food Code up-to-date. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2022 Food Code effective upon issuance.

Supplement to the 2022 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

Table of Contents

INTRODUCTION	III
AMENDATORY TERMS	IV
PART 1. SUMMARY OF CHANGES	1
CHAPTER 1 PURPOSE AND DEFINITIONS	1
CHAPTER 2 MANAGEMENT AND PERSONNEL	2
CHAPTER 3 FOOD	2
CHAPTER 4 EQUIPMENT, UTENSILS, AND LINENS	3
CHAPTER 5 WATER, PLUMBING, AND WASTE	4
CHAPTER 6 PHYSICAL FACILITIES	
CHAPTER 7 POISONOUS OR TOXIC MATERIALS	
CHAPTER 8 COMPLIANCE AND ENFORCEMENT	
ANNEX 1 COMPLIANCE AND ENFORCEMENT	
Annex 2 References	
ANNEX 3 PUBLIC HEALTH REASONS	
ANNEX 4 MANAGEMENT OF FOOD SAFETY PRACTICES – ACHIEVING ACTIVE MANAGERI	
FOODBORNE ILLNESS RISK FACTORS	
ANNEX 5 CONDUCTING RISK-BASED INSPECTIONS	
ANNEX 6 FOOD PROCESSING CRITERIA	8
ANNEX 7 MODELS FORMS, GUIDES, AND OTHER AIDS	
PART 2. AMENDMENTS, ADDITIONS, DELETIONS, TO CHAPTERS 1-8 AND TH	E ANNEXES 11
Preface	11
CHAPTERS, PARTS, AND SUBPARTS	11
CHAPTER 1 PURPOSE AND DEFINITIONS	
CHAPTER 2 MANAGEMENT AND PERSONNEL	
CHAPTER 3 FOOD	
CHAPTER 4 EQUIPMENT, UTENSILS, AND LINENS	
CHAPTER 5 WATER, PLUMBING, AND WASTE	
CHAPTER 6 PHYSICAL FACILITIES	
CHAPTER 7 POISONOUS OR TOXIC MATERIALS	
CHAPTER 8 COMPLIANCE AND ENFORCEMENT	
ANNEX 1 COMPLIANCE AND ENFORCEMENT	
ANNEX 2 REFERENCES	
ANNEX 3 PUBLIC HEALTH REASONS/ADMINISTRATIVE GUIDELINES	
ANNEX 4 MANAGEMENT OF FOOD SAFETY PRACTICES — ACHIEVING ACTIVE MANAGERIA	
FOODBORNE ILLNESS RISK FACTORS	
ANNEX 5 CONDUCTING RISK-BASED INSPECTIONS	
ANNEX 6 FOOD PROCESSING CRITERIA	
ANNEX 7 MODEL FORMS, GUIDES, AND OTHER AIDS	
PART 3 NEW TERMS ADDED TO THE INDEX TO THE FOOD CODE	50

Introduction

The Food and Drug Administration (FDA) is pleased to issue this Supplement to the 2022 Food Code (hereafter referred to as Supplement). This Supplement updates the 2022 Food Code to address several recommendations made at the 2023 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 2025. 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 2025. 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 2022 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 (\P), (e.g., \P 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 2022 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.

IMPORTANT. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2022 Food Code effective upon issuance via web posting or hard copy release.

Part 1. Summary of Changes

The amendments to the 2022 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

Amended Preface, Part 3 Public Health and Consumer Expectations to include reference to FOOD DEFENSE.

Chapters, Parts and Subparts

Amended List of Chapters, Parts and Subparts to include new Part 4-10 and Subparts 4-1001, 4-1002, 4-1003 addressing new disinfection provisions.

Chapter 1 Purpose and Definitions

Added a new defined term **ACTIVE MANAGERIAL CONTROL** to clarify and provide consistency in application and understanding of the term. (CFP Issue 2023-II-043)

Added a new defined term **DISINFECTION** to make clear its distinction from sanitizers. (CFP Issue 2023-III-015)

Added new defined term **FOOD DEFENSE** to ensure it is adequately addressed in the Food Code. (CFP Issue 2023-II-039)

Added a new defined term **FOOD SAFETY MANAGEMENT SYSTEM** that promotes a preventative strategy that can help manage and control factors that can contribute to foodborne illness. (CFP-Issue 2023-II-043)

Revised to amend the definition of **Poisonous or Toxic Materials** specifically sub¶¶ 1-201.10(1) and 1-201.10(2) to add the term DISINFECTION to make clear that DISINFECTANTS are indeed POISONOUS OR TOXIC MATERIALS. (CFP Issue 2023-III-015)

Revised to amend the definition of **REDUCED OXYGEN PACKAGING** specifically sub¶ 1-201.10(2)(d) cook chill PACKAGING to replace the term bags with PACKAGING to clarify intent.

(CFP Issue 2023-III-023)

Added a new defined term WATER-BASED FIRE PROTECTION SYSTEMS to be more

encompassing and specific to active fire protection systems that include water-based fire protection, such as standpipes, water mist, and fire sprinklers, as well as other water carrying piping. (CFP Issue 2023-I-024)

Chapter 2 Management and Personnel

2-102.11

Amended \P 2-102.11(C) to add sub \P 2-102.11(C)(18) to include an additional area of knowledge of FOOD DEFENSE as it relates to FOOD ESTABLISHMENTS. (CFP Issue 2023-II-039)

2-103.11

Amended lead in sentence in § 2-103.11 to indicate that the PERSON IN CHARGE has a duty to maintain ACTIVE MANAGERIAL CONTROL by ensuring compliance with the requirements outlined in § 2-103.11. (CFP Issue 2023-II-043)

Amended § 2-103.11 to add a new ¶ 2-103.11(R) that addresses EMPLOYEE training on FOOD DEFENSE. (CFP Issue 2023-II-039)

2-201.13

Amended sub¶ 2-201.13 (E)(1), sub¶ 2-201.13 (F)(1) and sub¶ 2-201.13 (G)(1) to revise the requirement for "2 consecutive negative stool culture tests" with the requirement for "2 consecutive negative laboratory test results from a validated test, using a laboratory accredited or certified to handle clinical specimens". (CFP Issue 2023-III-30). ** Note-This change adds lab methods for reinstating ill food employees. It replaces mandatory use of stool cultures and allows for additionally using culture-independent diagnostic test (CIDTs) results such as molecular or enzyme-based methods for reinstating ill food employees.

2-304.11

Amended § 2-304.11 to fix the convention of the defined terms FOOD, EQUIPMENT, UTENSILS, LINENS and SINGLE-SERVICE and SINGLE-USE ARTICLES into small caps, which was inadvertently left off.

Chapter 3 Food

3-201.11

Amended \P 3-201.11(B) to remove duplicate language from \P 3-201.11(C) that was inadvertently added in the 2022 Food Code and added in the risk designation of Priority foundation in \P 3-201.11(C) that was inadvertently left off.

Amended sub¶ 3-201.11(E)(3)(b) to remove the "and" and correctly place it at the end of sub¶ 3-201.11(E)(3)(a) as it was inadvertently misplaced after removing sub¶ 3-201.11(E)(3)(c). Additionally, fixed spelling error for "received" in sub¶ 3-201.11(E)(3)(a). (CFP Issue 2021-I-032)

3-304.11

Amended ¶ 3-304.11(B) to revise the terms SINGLE-SERVICE and SINGLE-USE ARTICLES as small caps were inadvertently left off.

3-304.17

Amended to re-designate existing \P 3-304.17(A) to be a new \P 3-304.17(C); added new \P 3-304.17(A) to clarify when containers may be refilled with FOOD by a FOOD EMPLOYEE or CONSUMER; revised \P 3-304.17(B) to clarify how containers may be refilled with food to prevent contamination of the FOOD and the PREMISES; and re-designated existing \P 3-304.17(E) to be the new \P 3-304.17(D) which is the exception that nonFOOD containers may be refilled at a water VENDING MACHINE. (CFP Issue 2023-III-012)

3-305.12

Amended ¶ 3-305.12(G) to align with 2024 International Fire Code requirements and new defined term WATER-BASED FIRE PROTECTION SYSTEMS. (CFP Issue 2023-I-024)

3-501.13

Amended \P 3-501.13(E) to align with the risk designation for \P \P 3-501.13 (A), (B), and (C) as an editorial update.

Chapter 4 Equipment, Utensils, and Linens

4-302.14

Amended to add new \P 4-302.14(B) and make existing paragraph a new \P 4-302.14(A) to add in testing kits or other devices to measure disinfecting solution and to revise the tag line (title) to add in the term Disinfecting. (CFP Issue 2023-III-015)

4-401.11

Amended sub¶ 4-401.11(A)(6) to align with 2024 International Fire Code requirements and new defined term WATER-BASED FIRE PROTECTION SYSTEMS. (CFP Issue 2023-I-024)

4-501.116

Amended § 4-501.116 to revise the tag line (title) to include the term "DISINFECTANT" and to make existing paragraph a new paragraph (\P) 4-501.116(A) and add a new paragraph (\P) 4-501.116(B) indicating when a test kit is used to determine the concentration of a Sanitizing solution, it shall be used in accordance with the manufacturer's label instructions. (CFP Issue 2023-I-018)

4-903.12

Amended ¶ 4-903.12 (A) to align with 2024 International Fire Code requirements and new defined term WATER-BASED FIRE PROTECTION SYSTEMS. (CFP Issue 2023-I-024)

4-1001.11

4-1002.11

4-1003.11

Amended Chapter 4 to add a new Part 4-10 Disinfection of Equipment and Utensils to include corresponding subparts and sections.

Chapter 5 Water, Plumbing, and Waste

5-203.11

Amended ¶ 5-203.11(B) to revise text into stylized italics as was inadvertently left off.

Chapter 6 Physical Facilities

No Change.

Chapter 7 Poisonous or Toxic Materials

Chapter 7 Heading

Amended chapter heading throughout chapter 7 to correctly state Chapter 7. POISONOUS OR TOXIC MATERIALS at the top right margin as it was inadvertently labeled as Chapter 8.

7-102.11

Amended § 7-102.11 Common Name to add the term DISINFECTANTS. (CFP Issue 2023-III-015)

7-201.11

Amended § 7-201.11 as small caps were inadvertently left off the defined terms FOOD, EQUIPMENT, UTENSILS, LINENS and SINGLE-SERVICE and SINGLE-USE ARTICLES in the lead in sentence.

7-202.12

Amended ¶ 7-202.12 (C) as small caps were inadvertently left off the defined term RESTRICTED USE PESTICIDE.

Chapter 8 Compliance and Enforcement

8-103.12

Amended \P 8-103.12(C) to reflect updated cross references due to the redesignations of $\P(E)$ and $\P(F)$ in \S 8-201.14 in the 2022 Food Code.

8-201.12

Amended ¶ 8-201.12(E) to replace the term standard procedures with the term FOOD SAFETY MANAGEMENT SYSTEM. (CFP Issue 2023-II-043)

8-201.15

Amended to add new § 8-201.15 titled When a Food Safety Management System is Required to establish requirements for a FOOD SAFETY MANAGEMENT SYSTEM. (CFP Issue 2023-II-043)

8-201.16

Amended Subpart 8-201 to add new § 8-201.16 as a reserved provision.

8-402.11

Amended § 8-402.11 heading as the number 8 was inadvertently left off the section number and to remove highlighted box designated for Subparts.

Annex 1 Compliance and Enforcement

No Change.

Annex 2 References

3-304.17

Amended to remove outdated reference 1. Food and Drug Administration, 1985. Food Protection – Refilling of take-home beverage containers (8/29/85). Retail Food Protection Program Information Manual.

Supporting Documents

Amended to add new section, **AA. Guidance for Retail Food Establishments in Developing their Food Safety Management Systems**. (CFP 2023-II-043)

Amended to add new section, **BB. Major Food Allergen Framework**. (CFP Issue 2023-II-051)

Amended to add new section, **CC.** Guidance for Safe Use of Reusable Containers. (CFP Issue 2023-III-010)

Amended to add new section, **DD. Guidance Document for Retail Sushi HACCP Standardization**. (CFP Issue 2023-III-006)

Amended to revise **Section 4. Food Defense Guidance from Farm to Table** to fix outdated and broken links and provide the most updated resources from FDA and USDA. (CFP Issue 2023-II-040)

Annex 3 Public Health Reasons

1-201.10

Amended Public Health Reasons for §1-201.10 to revised the CFP Standard Title by deleting the letter "s" to make the word "Standard" singular rather than plural in paragraph 5 under Accredited Program.

Amended Public Health Reasons for §1-201.10 Statement of Application and Listing of Terms to add 3 new paragraphs that address newly defined term "Food Defense". (CFP Issue 2023-II-039)

Amended to add Public Health Reasons for §1-201.10 Statement of Application and Listing of Terms to add 5 new paragraphs that address newly defined term "Food Safety Management System". (CFP Issue 2023-II-043)

2-102.10

Amended Public Health Reason for §2-102.10 Food Protection Manager Certification to replace the term "American National Standards Institute (ANSI)" with new name "ANSI National Accreditation Board (ANAB)" throughout and to revise the CFP Standard Title by deleting the letter "s" to make the word "Standard" singular rather than plural in paragraphs 3-4, 6-10 (including footnote).

2-103.11

Amended Public Health Reason for §2-103.11 Person in Charge to add a new paragraph 1 and make existing paragraph 1 into new paragraph 2 to address the addition of active managerial control. (CFP Issue 2023-II-043)

Amended Public Health Reason for §2-103.11 Person in Charge to add new paragraph 13 that addresses new paragraph R on employee awareness of food defense. (CFP Issue 2023-II-039)

2-201.13

Amended Public Health Reasons for § 2-201.13 to add a new header titled: "Culture-Independent Diagnostic Tests (CIDT) for Medical Clearance" after paragraph 3; add new paragraphs 4 and 5 after existing paragraph 3 to provide rationale for adding the option of using CIDT tests in addition to stool culture tests for reinstatement of food employees diagnosed with STEC, *Shigella* or Non-Typhoidal *Salmonella*; add a new header titled: "Reinstatement of Asymptomatic Food Employees" above new designated paragraph 6 (previous paragraph 4) to provide information to the reader that subsequent paragraphs after the new paragraph 6 return to previous information provided on reinstating asymptomatic diagnosed food employees.

2-301.12

Amended Annex 3 Public Health Reasons for § 2-301.12 to add new paragraphs 3, 5, 8, 9 and shift existing paragraphs 3, 5, 8 to be new paragraphs 4, 5 and 10 respectively to provide more context on hand contamination. (CFP Issue 2023-III-031)

2-301.16

Amended Annex 3 Public Health Reason for § 2-301.16 Hand Antiseptics to revise paragraphs 2 and 3 to clarify the intent of hand antiseptics. (CFP Issue 2023-III-016)

2-501.11

Amended Annex 3 Public Health Reasons for § 2-501.11 Clean-up of Vomiting and Diarrheal Events to revise paragraph 6 to include reference to EPA-registered DISINFECTANTS and to revise paragraph 9 by rearranging bulleted list of items to consider

when developing a written plan to ensure the steps listed reflect the order of actions covered by the plan. (CFP Issue 2023-III-017)

3-201.11

Amended Annex 3 Public Health Reasons for § 3-201.11 to delete the word "not" between "have" and "undergone" in sentence 3 under the section Labeling for Wholemuscle, Intact Beef Steaks. This was a typographical error.

3-301.11

Amended Public Health Reasons for § 3-301.11 to add new paragraphs 3, 4 and 5 to introduce additional control measures, provide more background describing what a double handwash is and to include information on fingernail brushes from the Public Health Reasons found in § 2-301.12. (CFP Issue 2023-I-017)

3-304.17

Amended Annex 3 Public Health Reason for § 3-304.17 Refilling Returnables to add new paragraphs 1-3 and 5-6; revise old paragraph 1 to be new paragraphs 4 and 5 and revise old paragraph 2 to be new paragraphs 7 and 8 to include new language to align with codified text revisions. (CFP Issue 2023-III-010)

3-305.11 Food Storage.

3-305.12 Food Storage, Prohibited Areas.

Amended Annex 3 Public Health Reasons for § 3-305.12 to add pipes, tubes, and hoses to be inclusive of all water carrying piping and correlates to health and plumbing codes. (CFP Issue 2023-I-024)

3-502.11

Amended Annex 3 Public Health Reasons for § 3-502.11 Variance Requirement to add new paragraph 8 that addresses food preservation techniques as it relates to variance requests, (CFP Issue 2023-III-027)

4-302.14

Amended Annex 3 Public Health Reasons for § 4-302.14 Sanitizing Solutions, Testing Devices to revise the section title to add the term "Disinfecting" and revise the paragraph to include language regarding disinfectants and testing devices. (CFP Issue 2023-III-015)

4-501.116

Amended Annex 3 Public Health Reason for § 4-501.116 to revise the section tag line (title) to include the term "Disinfectant" and to update language to include the term disinfectant throughout the paragraph. (CFP Issue 2023-III-015)

4-601.11

Amended Annex 3 Public Health Reasons for § 4-601.11 to revise the term nonfood contact to nonfood-contact to make it grammatically consistent throughout the Food Code.

4-602.13

Amended Annex 3 Public Health Reasons for § 4-602.13 to revise the term nonfood contact to nonfood-contact to make it grammatically consistent throughout the Food Code.

4-1001.11

4-1002.11

4-1003.11

Added new Annex 3 Public Health Reasons for §§ 4-1001.11, 4.1002.11, 4-1003.11 to address new codified provisions added under new Part 4-10 addressing disinfection. (CFP Issue 2023-III-015)

6-202.15

Amended Public Health Reasons for § 6-202.15 to reference the newest edition of the National Fire Protection Association's NFPA 101, Life Safety Code within paragraph two.

7-102.11

Amended Annex 3 Public Health Reasons for § 7-102.11 Common Name to include the term disinfectants after the term sanitizers in sentence 1. (CFP Issue 2023-III-015)

8-201.12

8-203.10

Amended Annex 3 Public Health Reasons for §§ 8-201.12 and 8-203.10 to add a new header § 8-201.15 When a Food Safety Management System is Required and revise existing paragraphs 2-4 to reflect new codified language in § 8-201.15. (CFP 2023-II-043)

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

Section 2. Reduced Oxygen Packaging

Amended Annex 6 Section 2. Reduced Oxygen Packaging, Part (B) Definitions to reflect the revised definition of Reduced Oxygen Packaging and to align with codified text. (CFP 2023-III-023)

Section 4. Acidification (Sushi Rice) - New

Amended Annex 6 Food Processing Criteria to add new Section 4 Acidification (Sushi Rice) to include further explanation in critical limits associated with sushi rice.

(CFP Issue 2023-III-008)

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 Guide 3B, Section C, Supervision, Item #1, to add new paragraphs for inclusion in B(3) and under applicable code sections §2-102.11 and §2-103.11.

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item 6

Amended Guide 3B, Section C, Proper eating, tasting, drinking, or tobacco products use, Item #6, to revise the term nonfood contact to nonfood-contact to make it grammatically consistent throughout the Food Code in sentence #2.

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item 16

Amended Guide 3B, Section C Item #16 Food-contact surfaces, cleaned and sanitized to revise the title of the section, update the marking instructions and include new applicable Code sections. (CFP Issue 2023-III-015)

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item 28

Amended Guide 3B, Section C. Toxic Substances properly identified, stored, and used; held for retail sale, properly stored, Item #28 to include disinfectant as a toxic substance. (CFP Issue 2023-III-015)

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item 35

Amended Guide 3B, Section D, Approved Thawing Methods Used, Item #35, to add new risk designation to 3-305.13 in the applicable code section.

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item 47

Amended Guide 3B, Section D, Food and nonfood-contact surfaces cleanable, properly designed, constructed and used, Item #47, to remove hyphen between the word nonfood throughout; add new marking instructions and add new risk designation of Core to 3-304.17 in the Applicable Code Section.

(CFP Issue 2023-III-012)

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Item 48

Amended Guide 3B, Section D, Warewashing Facilities, Installed, Maintained, Used, Test Strips, Item #48 to revise the title of §§ 4-302.14 and 4-501.116 to include the word "disinfecting" under the applicable code sections and to revise the marking instructions to include guidance on when to mark out of compliance when testing solution concentrations. (CFP Issue 2023-I-018)

Part 2. Amendments, Additions, Deletions, to Chapters 1-8 and the Annexes

Preface

Amended Preface, Part 3 Public Health and Consumer Expectations to include reference to food defense to read as follows:

3. Public Health and Consumer Expectations

It is a shared responsibility of the food industry and the government to ensure that food provided to the consumer is safe and does not become a vehicle in a disease outbreak, in the transmission of a communicable disease or part of an intentional act of adulteration or tampering. This shared responsibility extends to ensuring that consumer expectations are met, and that food is safe, unadulterated, prepared in a clean environment, and honestly presented.

Under FDA's Mission Statement the agency is responsible for protecting the public health by ensuring the safety of our nation's food supply...and for advancing the public health by helping the public get accurate, science-based information they need about foods to maintain and improve their health.

Accordingly, the provisions of the Food Code provide a system of prevention and overlapping safeguards designed to minimize foodborne illness; ensure employee health, industry manager knowledge, safe food, nontoxic and cleanable equipment, and acceptable levels of sanitation on food establishment premises; and promote fair dealings with the consumer.

Chapters, Parts, and Subparts

Amended List of Chapters, Parts and Subparts to include new Part 4-10 and subparts 4-1001, 4-1002, 4-1003 addressing new disinfection provisions to read as follows:

- ...NO CHANGE...
- 4-10 Disinfection of Equipment and Utensils
 - 4-1001 Objectives
 - 4-1002 Frequency
 - 4-1003 Methods

Chapter 1 Purpose and Definitions

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

"Active Managerial Control" means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness RISK factors. It embodies a preventive rather than reactive approach to FOOD safety through a continuous system of monitoring and verification.

"Disinfection" means the application of a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi, and viruses, but not necessarily bacterial spores.

"Food Defense" is the effort to protect FOOD from acts of intentional ADULTERATION or tampering.

Food Safety Management System

- (1) "FOOD SAFETY MANAGEMENT SYSTEM" means a specific set of actions taken by the EMPLOYEE to prevent the occurrence of foodborne illness RISK factors based on the type of operation, type of FOOD preparation, and FOODS prepared within the FOOD ESTABLISHMENT.
- (2) "FOOD SAFETY MANAGEMENT SYSTEM" includes written procedures, training plans, and monitoring records to control specific operational steps in a FOOD ESTABLISHMENT that contribute to foodborne illness.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 5 categories:

- (1) Cleaners, SANITIZERS and DISINFECTANTS, which include cleaning, SANITIZING and DISINFECTING agents and agents such as caustics, acids, drying agents, polishes, and other chemicals:
- (2) Pesticides, except SANITIZERS and DISINFECTANTS, which include substances such as insecticides and rodenticides;
- (3) (5) NO CHANGE

Reduced Oxygen Packaging

- (2) "Reduced oxygen packaging" includes:
 - (a) (c) NO CHANGE
 - (d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable PACKAGING (such as a bag or film on trays) that is then sealed or crimped closed. The PACKAGED FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotropic pathogens; or
 - (e) NO CHANGE

"Water-based fire protection systems" means automatic or manual fire systems using water as a primary agent, which are used to detect, extinguish, or control a fire.

Chapter 2 Management and Personnel

Amend \P 2-102.11(C) to add new sub \P (C)(18) to read as follows:

2-102.11 Demonstration.

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

- (A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection; Pf
- (B) Being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM;^{Pf} or
- (C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:
- ...NO CHANGE...
 - (18) Explaining steps that are taken to prevent intentional ADULTERATION by CONSUMERS, EMPLOYEES, or other PERSONS including monitoring operations, ingredients, supplies, and finished products for unusual or suspicious activities, or other FOOD DEFENSE activities. Pf

Amend §2-103.11 to revise the lead in sentence and to add new \P (R) to read as follows:

2-103.11 Person in Charge.

The Person in Charge shall maintain active managerial control of foodborne illness risk factors by ensuring that:

...NO CHANGE...

(R) EMPLOYEES are aware of FOOD DEFENSE, such as signs of intentional acts of ADULTERATION as it relates to their assigned duties, and report suspicious activity to the PERSON IN CHARGE. Pf

Amend sub- $\P\P\P$ 2-201.13 (E)(1) and 2-201.13 (F)(1) and 2-201.13 (G)(1) to replace the requirement for 2 consecutive negative stool culture tests with: 2 consecutive negative laboratory test results from a validated test, using a laboratory

accredited or certified to handle clinical specimens as an additional option to allow for the use of culture-independent diagnostic test results to read as follows:

Managing Exclusions and Restrictions

2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions. The person in charge shall adhere to the following conditions when removing, adjusting, or retaining the exclusion or restriction of a food employee: ...NO CHANGE...

Shigella spp. Diagnosis - Removing Exclusion or Restriction

- (E) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2201.12(A)(2) or (E)(1) or who was RESTRICTED under Subparagraph 2201.12(E)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:
 - (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Shigella* spp. infection based on 2 consecutive negative laboratory test results from a validated test, using a laboratory accredited or certified to handle clinical specimens and obtained from stool specimens that are taken:
 - (a) Not earlier than 48 hours after discontinuance of antibiotics, P and
 - (b) At least 24 hours apart; P
 - (2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC: P or
 - (3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 7 calendar days have passed since the FOOD EMPLOYEE was diagnosed. P

STEC Diagnosis - Removing Exclusion or Restriction

- (F) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(A)(2) or (F)(1) or who was RESTRICTED under Subparagraph 2-201.12(F)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:
 - (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of an infection from SHIGA TOXIN-PRODUCING ESCHERICHIA COLI based on 2 consecutive negative laboratory test results from a validated test, using a laboratory accredited or certified to handle clinical specimens, and obtained from stool specimens that are taken:

- (a) Not earlier than 48 hours after discontinuance of antibiotics; P and
- (b) At least 24 hours apart; P
- (2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC: P or
- (3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 7 days have passed since the FOOD EMPLOYEE was diagnosed. P

Nontyphoidal Salmonella - Removing Exclusion or Restriction

- (G) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(2) or who was RESTRICTED as specified under ¶ 2-201.12(G) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:
 - (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Salmonella* (nontyphoidal) infection based on test results showing 2 consecutive negative laboratory test results from a validated test, using a laboratory accredited or certified to handle clinical specimens and obtained from stool specimens that are taken:
 - (a) Not earlier than 48 hours after discontinuance of antibiotics, P and
 - (b) At least 24 hours apart; P
 - (2) The FOOD EMPLOYEE was RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC: P or
 - (3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 30 days have passed since the FOOD EMPLOYEE was diagnosed. P

...NO CHANGE...

Amend §2-304.11 to revise convention of defined terms into small caps to read as follows:

2-304.11 Clean Condition.

FOOD employees shall wear clean outer clothing to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

Chapter 3 Food

Amend ¶ 3-201.11 (B) to remove duplicate language and add in the risk designation of Priority foundation in ¶ 3-201.11(C) and amend sub¶ 3-201.11(E)(3)(b) to remove the "and" and correctly place it at the end of sub¶ 3-201.11(E)(3)(a) and fix spelling error for "received" in sub¶ 3-201.11(E)(3)(a) to read as follows:

3-201.11 Compliance with Food Law.

- (A) FOOD shall be obtained from sources that comply with LAW. P
- (B) FOOD prepared in a private home may not be used or offered for human consumption in a FOOD ESTABLISHMENT. P
- (C) PACKAGED FOOD shall be labeled as specified in LAW, including 21 CFR 101 FOOD Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under § 3-202.18. Pf

...NO CHANGE...

- (E) WHOLE-MUSCLE, INTACT BEEF steaks that are intended for consumption in an undercooked form without a CONSUMER advisory as specified in ¶ 3-401.11(C) shall be:
 - (1) Obtained from a FOOD PROCESSING PLANT that does not MECHANICALLY TENDERIZE, vacuum tumble with solutions, reconstruct, cube or pound these WHOLE-MUSCLE, INTACT BEEF STEAKS, Pf or
 - (2) Deemed acceptable by the REGULATORY AUTHORITY based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of WHOLE-MUSCLE, INTACT BEEF, Pf and
 - (3) If individually cut in a FOOD ESTABLISHMENT:
 - (a) Cut from WHOLE-MUSCLE INTACT BEEF that is received from a FOOD PROCESSING PLANT as specified in Subparagraph (E)(1) of this section or identified as specified in Subparagraph (E)(2) of this section, P and
 - (b) Prepared so they remain intact. Pf

...NO CHANGE...

Amend ¶ 3-304.11(B) as small caps were inadvertently left off the defined terms SINGLE-SERVICE and SINGLE-USE ARTICLES to read as follows:

3-304.11 Food Contact with Equipment and Utensils.

Food shall only contact surfaces of:

- (A) EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code; P
- (B) SINGLE-SERVICE and SINGLE-USE ARTICLES; P or
- (C) LINENS, such as cloth napkins, as specified under § 3-304.13 that are laundered as specified under Part 4-8 of this Code. P

Amend to re-designate existing \P 3-304.17(A) to be a new \P 3-304.17(C); added new \P 3-304.17(A); revised \P 3-304.17(B); and re-designated existing \P 3-304.17(E) to be the new \P 3-304.17(D) to read as follows:

3-304.17 Refilling Returnables.

- (A) Containers may be refilled with FOOD either by a FOOD EMPLOYEE or the CONSUMER, if:
 - (1) The container is designed and constructed for multiuse in accordance with the requirements specified under § 4-101.11, § 4-201.11, and 4-202.11 of this Code, and
 - (2) The container is cleaned and SANITIZED following procedures as specified under § 4-601.11, § 4-602.11, § 4-701.10, § 4-702.11 and §4-703.11 of this Code prior to refilling, and,
 - (3) The container is visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified prior to use. Pf
- (B) Except as specified in ¶ (D) of this section, containers refilled in a FOOD ESTABLISHMENT shall be refilled so that:
 - (1) The container is refilled in a contamination-free transfer process; Pf
 - (2) The container is handled to prevent direct contact with FOOD-CONTACT SURFACES: and Pf
 - (3) FOOD-CONTACT SURFACES are cleaned as specified under Part 4-6 and SANITIZED as specified under Part 4-7 of this Code by a FOOD EMPLOYEE. Pf
- (C) Containers returned to a FOOD ESTABLISHMENT for cleaning and refilling in a regulated FOOD PROCESSING PLANT shall not be refilled at a FOOD ESTABLISHMENT.
- (D) CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE or system.

Amend ¶ 3-305.12 (G) to align with 2024 International Fire Code requirements and new defined term WATER-BASED FIRE PROTECTION SYSTEMS to read as follows:

3-305.12 Food Storage, Prohibited Areas.

FOOD may not be stored:

- (A) In locker rooms;
- (B) In toilet rooms; Pf
- (C) In dressing rooms;
- (D) In garbage rooms;
- (E) In mechanical rooms;
- (F) Under sewer lines that are not shielded to intercept potential drips;
- (G)Under leaking or where water is condensed on pipes, tubes, or hoses, including plumbing, heating, air conditioning and WATER-BASED FIRE PROTECTION SYSTEMS.
- (H) Under open stairwells; or
- (I) Under other sources of contamination.

Amend \P 3-501.13 (E) to align with the risk designation for \P \P 3-501.13 (A), (B), and (C) as an editorial update to read as follows:

3-501.13 Thawing.

Except as specified in \P (D) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be thawed:

...NO CHANGE...

- (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 $\P(A)$ of this section; Pf or
 - (2) Prior to, or immediately upon completion of, its thawing using procedures specified in \P (B) of this section. Pf

Chapter 4 Equipment, Utensils, and Linens

Amend § 4-302.14 to add new ¶ 4-302.14(B) and make existing paragraph into new \P 4-302.14(A) and to add in the term Disinfecting to the Tag line (title) to read as follows:

4-302.14 Sanitizing and Disinfecting Solutions, Testing Devices.

(A) A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided. Pf

(B) A test kit of other device that accurately measures the concentration of DISINFECTING solutions shall be provided. Pf

Amend ¶ 4-401.11(A) to align with 2024 International Fire Code requirements and new defined term WATER-BASED FIRE PROTECTION SYSTEMS to read as follows:

4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

- (A) Except as specified in ¶ (B) of this section, EQUIPMENT, a cabinet used for the storage of FOOD, or a cabinet that is used to store cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be located:
 - (1) In locker rooms;
 - (2) In toilet rooms; Pf
 - (3) In garbage rooms;
 - (4) In mechanical rooms;
 - (5) Under sewer lines that are not shielded to intercept potential drips;
 - (6) Under leaking or where water is condensed on pipes, tubes, or hoses, including plumbing, heating, air conditioning and WATER-BASED FIRE PROTECTION SYSTEMS;

...NO CHANGE...

Amend § 4-501.116 to revise the tag line (title) to include the term "DISINFECTANT" and to make existing paragraph a new paragraph (\P) (A) and add a new paragraph (\P) (B) to read as follows:

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer or Disinfectant Concentration.

- (A) Concentration of the SANITIZING or DISINFECTING solution shall be accurately determined by using a test kit or other device. Pf
- (B) A test kit, used to determine the concentration of a SANITIZING or DISINFECTING solution shall be used in accordance with the manufacturer's label instructions.

Amend ¶ 4-903.12 (A) to align with 2024 International Fire Code requirements and new defined term WATER-BASED FIRE PROTECTION SYSTEMS to read as follows:

4-903.12 Prohibitions.

- (A) Except as specified in ¶ (B) of this section, cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be stored:
 - (1) In locker rooms;

- (2) In toilet rooms; Pf
- (3) In garbage rooms;
- (4) In mechanical rooms;
- (5) Under sewer lines that are not shielded to intercept potential drips;
- (6) Under leaking or where water is condensed on pipes, tubes, or hoses, including plumbing, heating, air conditioning and WATER-BASED FIRE PROTECTION SYSTEMS.

...NO CHANGE...

Amend Chapter 4 to add a new Part 4-10 Disinfection of Equipment and Utensils to include corresponding subparts and sections to read as follows:

CHAPTER 4 EQUIPMENT, UTENSILS, AND LINENS

Parts:

- 4-1 Materials for Construction and Repair
- 4-2 Design and Construction
- 4-3 Numbers and Capacities
- 4-4 Location and Installation
- 4-5 Maintenance and Operation
- 4-6 Cleaning of Equipment and Utensils
- 4-7 Sanitization of Equipment and Utensils
- 4-8 Laundering
- 4-9 Protection of Clean Items
- 4-10 Disinfection of Equipment and Utensils
- ...NO CHANGE...

4-10 Disinfection of Equipment and Utensils

4-1001 Objective

4-1001.11 Food-Contact, nonFood-Contact Surfaces and Utensils

EQUIPMENT, FOOD-CONTACT SURFACES, nonFOOD-CONTACT SURFACES, and UTENSILS shall be DISINFECTED when pathogens of concern are not controlled by available SANITIZERS.^P

4-1002 Frequency

4-1002.11 Disinfectant Use

When pathogens of concern are not controlled by available SANITIZERS, EQUIPMENT, FOOD-CONTACT SURFACES, nonFOOD-CONTACT SURFACES, and UTENSILS shall be DISINFECTED:

- (A) When contaminated with vomitus, fecal matter, blood, or any other bodily fluid that can lead to disease transmission; or
- (B) During a FOODBORNE DISEASE OUTBREAK OR IMMINENT HEALTH HAZARD. P

4-1003 Methods

4-1003.11 Chemical

- (A) FOOD-CONTACT SURFACES and nonFOOD-CONTACT SURFACES shall be DISINFECTED in accordance with the EPA-registered label use directions. P
- (B) DISINFECTANTS applied to a FOOD-CONTACT SURFACE shall be rinsed with potable water, unless otherwise specified on the EPA-registered label use directions. P

Chapter 5 Water, Plumbing, and Waste

Amend ¶5-203.11(B) to revise text into stylized italics to read as follows:

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. 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

Amend Chapter 7 Chapter heading at the top right margin throughout Chapter 7 to read as follows:

Chapter 7. Poisonous or Toxic Materials

Amend § 7-102.11 to add the term DISINFECTANTS to read as follows:

7-102.11 Common Name.

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners, SANITIZERS and DISINFECTANTS taken from bulk supplies shall be clearly and individually identified with the common name of the material. Pf

Amend § 7-201.11 as small caps were inadvertently left off the defined terms to read as follows:

7-201.11 Separation.

POISONOUS OR TOXIC MATERIALS shall be stored so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

...NO CHANGE...

Amend ¶ 7-202.12 (C) as small caps were inadvertently left off the defined term RESTRICTED USE PESTICIDE to read as follows:

7-202.12 Conditions of Use.

Poisonous or toxic material's shall be:

...NO CHANGE...

(C) A RESTRICTED USE PESTICIDE shall be applied only by an applicator certified as defined in 7 USC 136 Definitions, (e) Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act, or a PERSON under the direct supervision of a certified applicator. Pf

Chapter 8 Compliance and Enforcement

Amend \P 8-103.12(C) to reflect updated cross references due to the redesignations of $\P(E)$ and $\P(F)$ in \S 8-201.14 in the 2022 Food Code to read as follows:

8-103.12 Conformance with Approved Procedures.

...NO CHANGE...

- (C) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶ 8-201.14(E) and sub¶ 8-201.14(F)(3) that demonstrate that the following are routinely employed;
 - (1) Procedures for monitoring the CRITICAL CONTROL POINTS, Pf
 - (2) Monitoring of the CRITICAL CONTROL POINTS, 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(E) to replace the term standard procedures with the term food safety management system 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 under § 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:

...NO CHANGE...

(E) Evidence that a FOOD SAFETY MANAGEMENT SYSTEM that ensures compliance with the requirements of this Code are developed or are being developed; and

...NO CHANGE...

Amend to add new § 8-201.15 titled When a Food Safety Management System is Required to establish requirements for a food safety management system to read as follows:

8-201.15 When a Food Safety Management System is Required.

- (A) Within 4 years of the REGULATORY AUTHORITY'S adoption of this Code, a written FOOD SAFETY MANAGEMENT SYSTEM shall be:
 - (1) Developed and maintained to ensure compliance with requirements of this Code as specified in 2-103.11.
 - (2) Implemented in the FOOD ESTABLISHMENT during all hours of operation, and
 - (3) Made available to the REGULATORY AUTHORITY upon request.
- (B) 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.

Amend Subpart 8-201 to add new § 8-201.16 as a reserved provision to read as follows:

8-201.16 Contents of a food safety management system.

RESERVED.

Amended § 8-402.11 heading as the number 8 was inadvertently left off the section number and to remove highlighted box designated for Subparts to read as follows:

8-402.11 Allowed at Reasonable Times after Due Notice.

...NO CHANGE...

Annex 1 Compliance and Enforcement

No Change.

Annex 2 References

Amend 2. Bibliography to remove outdated reference 1. Food and Drug Administration, 1985. Food Protection – Refilling of take-home beverage containers (8/29/85)-Retail Food Protection Program Information Manual to read as follows:

**Reference outdated, removed and no longer available

Amend 3. Supporting Documents to add the following new sections AA., BB., CC., DD. 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...

AA. Guidance for Retail Food Establishments in Developing their Food Safety Management Systems

USDA Food Nutrition Service (FNS) in partnership with the Institute of Child Nutrition (ICN) developed HACCP-based food safety management tools for child nutrition

professionals and serve as a good resource for food establishments that need to develop or enhance their current food safety management systems. The resources include a workshop that provide helpful training and tools that food establishments can refer to as they work to build their food safety management system. The materials can be used as a model to build checklists, activities, standard operating procedures, SOPs, and log templates. The workshop to aid in writing, updating, and revising a HACCP-Based Food Safety Plan is located at https://theicn.org/icn-resources-a-z/writing-a-haacp-based-food-safety-plan-for-schools/. In addition, there are Food Safety SOP Resources that incorporate HACCP-based Standard Operating Procedures located at: https://theicn.org/icn-resources-a-z/food-safety/#66da58d4edcafd35f. This resource may be used as a template to design or evaluate a food establishment's current food safety management systems. The materials serve as a model for example standard operating procedures, logs, templates, and SOP summary tables.

BB. Major Food Allergen Framework

The need for effective management of major food allergens within food establishments is ever-growing. This document provides a voluntary operational framework for food allergy prevention and control for food establishments. This document outlines practices that may assist food establishments in allergen control including topics such as training of food handlers, food handling policies and practices, tools to notify consumers about major food allergens, food allergy reaction and emergency response, and equal consideration for other community food sources.

This document and summary document are available for download at:

http://www.foodprotect.org/media/guide/major-food-allergen-framework.pdf

http://www.foodprotect.org/media/guide/major-food-allergen-framework-summary.pdf

CC: Guidance Document for Safe Use of Reusable Containers, Conference for Food Protection.

This document is designed to guide the safe use of reusable containers for retail food establishment operators intending to use these types of containers and to provide guidance to regulatory authorities evaluating or approving retail refilling operations.

At the 2023 Conference for Food Protection meeting the Safe Use of Reusable Containers committee conveyed the concern that the Food Code did not align with practices in the field as it pertains to refilling reusable containers at retail. The committee agreed the filling of customer-owned containers and third-party supplied reusable containers in retail food establishments was common despite limited allowance in the Food Code. The committee also agreed that local, national, and global legislation and movements to reduce solid waste from disposable food containers would increase reuse requirements and the demand for reusable container options from consumers,

businesses, and environmental groups. In addition, legislative bodies will likely look toward reusable container options for food service packaging to help address issues of waste, human health, and climate change.

This document is accessible for download at:

Guidance Document for the Safe Reuse of Containers | Conference-Developed Guides and Documents | Conference for Food Protection (https://www.foodprotect.org/guides-documents/guidance-document-for-the-safe-reuse-of-containers/)

DD. Guidance Document for Retail Sushi HACCP Standardization

The Guidance for Retail Sushi HACCP Standardization document has been developed as a tool for the purpose of assisting regulatory and industry personnel. In achieving greater uniformity. This document was created to supplement the templates and guidance provided for acidified rice that are part of the Conference for Food Protection Conference-developed Guides and Documents. The goal of this guidance is to help jurisdictions achieve a more standardized review of HACCP Plans.

This document can be accessed at the following web site: http://www.foodprotect.org/media/guide/final-doc-cfp-c3-sushi-rice-standardization-5-2023.pdf.

Amend 4. Supporting Documents to revise Section 4. Food Defense Guidance from Farm to Table with updated content to read as follows:

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all inclusive. It contains links to websites and describes publications from federal agencies (primarily FDA, CDC, and USDA) and industry groups with information of interest for regulators, industry, and consumers. Responsibility for updating the web pages lies with the listed organization and those listed are up to date as of the release of the current Food Code.

U.S. Food and Drug Administration:

The FDA has developed food defense tools, resources, and regulation and guidance documents to help food establishments and food facilities prevent, prepare for, respond to, and recover from acts of intentional adulteration of the food supply.

These resources can be found by visiting Food Defense | FDA (www.fda.gov/food/fooddefense) website or by searching U.S. Food and Drug Administration (fda.gov) on the FDA website includes:

- Guidance for Industry: Food Security Preventive Measures Guidance for Retail Food Stores and Food Service Establishments: This guidance is designed as an aid to operators of retail food stores and food service establishments (for example, bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fundraisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for home-bound persons, mobile food carts, restaurants, and vending machine operators). This guidance identifies the kinds of preventive measures they may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions.
- Food Defense 101 Front-line Employee Training: The web-based course provides front-line employees with simple procedures to protect the food supply against an intentional attack.
- Food Defense Plan Builder: This is a user-friendly tool designed to help owners and operators of a food facility in the development of a food defense plan that is specific to their facility. The plan builder is designed for food manufacturers and processors but can also be used by retail and foodservice operators to develop food defense plans.
- Food Related Emergency Exercise Bundle (FREE-B): Exercise scenarios based on both intentional and unintentional food contamination events. FREE-B assists government regulatory and public health agencies in assessing the readiness of their entity to respond to a food contamination event. The FREE-B is designed to allow for multiple jurisdictions and organizations (medical community, private sector, law enforcement, first responder communities) to 'play' with the host agency, or, quite simply, for an individual agency to test their own plans, protocols, and procedures independently.
- Food Defense Mitigation Strategies Database (FDMSD): Online database designed to help owners and operators of a food facility with identifying mitigation strategies to protect the food against intentional adulteration. The FDMSD includes mitigation strategies for some common points, steps, and procedures that are often found at food facilities.
- "See Something, Say Something" Poster: FDA collaborated with partner agencies in the Food and Agriculture Sector Council to develop a poster for food facilities and food establishments to raise awareness of the indicators of terrorism and terrorism related crime, as well as the importance of reporting suspicious activity to state and local law enforcement.

Other FDA Resources:

- To report an emergency involving food, drugs, medical devices, dietary supplements, or cosmetics, call 1-866-300-4374 or 1-301-796-8240.
- To report a problem with FDA-regulated products by phone: Call 1-888-INFO-FDA (1-888-463-6332) or Consumer Complaint Coordinators | FDA.
- Use the MedWatch Online Voluntary Reporting Form (fda.gov) to report adverse events with human food and medical products.
- Use the Safety Reporting Portal (hhs.gov) online form to report problems with pet food, dietary supplements, and tobacco products. This form also accepts mandatory reports, such as Reportable Food Registry for Industry.

U.S. Department of Agriculture:

USDA Food Safety and Inspection Service (FSIS) promotes food defense by encouraging establishments to voluntarily adopt a functional food defense plan; implement food defense practices (including inside, outside, and personnel security measures); and conduct training and exercises to ensure preparedness. (Note: resources may be found by searching Home | Food Safety and Inspection Service (fsis.usda.gov) for keywords Food Defense, Security, and other similar keywords or visiting Food Defense | Food Safety and Inspection Service (fsis.usda.gov/food-safety/food-defense-and-emergency-response/food-defense)).

<u>Food Defense | Food Safety and Inspection Service</u> (fsis.usda.gov/food-safety/food-defense-and-emergency-response/food-defense): This site discusses a comprehensive approach that addresses food defense.

- Food Defense for In-Commerce Firms: Provides resources and information on food defense for in-commerce firms.
- Food Defense Guidelines for the transportation and Distribution of Meat, Poultry and Processed Egg Products: The FSIS Food Defense Guidelines for the Transportation and Distribution of Meat, Poultry, and Processed Egg Products is designed to assist those handling food products during transportation and storage. These guidelines provide a list of defense measures that can be taken to prevent intentional contamination of meat, poultry, and processed egg products during loading, unloading, transportation, and in-transit storage.

USDA Food and Nutrition Resources (FNS) for Schools:

 A Biosecurity Checklist - School Foodservice Programs | Missouri Department of Elementary and Secondary Education (mo.gov): USDA FNS has prepared a Biosecurity Checklist for School Foodservice Programs for developing a biosecurity management plan. Its purpose is to help protect the health of the children and adults in the school by strengthening the safety of the foodservice operation.

- Emergency_readiness_plan_a_guide_for_the_school_foodservice_operation.pdf (hhs.gov): Emergency Readiness Plan: Forms for the School Foodservice Operation includes several prototype forms to assist foodservice professionals when writing an emergency readiness plan.
- Responding_Food_Recall_FNS_05302014.pdf (azureedge.us): Provides an overview of the recall process for USDA foods with a focus on school meals programs. Particular attention is given to the roles of various entities in communicating information to ensure that recalls are handled in a timely and effective manner.

Other USDA Resources:

USDA Meat & Poultry Hotline: 1-888-MPHotline (1-888-674-6854).

Industry Publications:

A variety of resource are available from industry groups. (Note: these documents may also be found by searching for keywords Food Defense, Security, and other similar keywords):

- National Restaurant Association | National Restaurant Association: provides access to security information and guidelines targeted specifically the restaurant industry.
- FMI | The Food Industry Association: provides access to security information and guidelines targeted specifically to food retailers.
- FMI | Voice of The Food Industry Blog: provides access to information.
- Conference-Developed Guides and Documents | Conference for Food Protection: Provides guidance documents related to retail food safety.

Guidance on Responding to Food Emergencies

- Environmental Health Services Program Home | EHS | CDC: This site provides free tools and guidance, training, and research for environmental health practitioners and programs serving states, tribes, localities, and territories.
- Information on Specific Types of Emergencies| Emergency Preparedness and Response (cdc.gov): Provides resources for preparedness and response to specific types of emergencies.

• Conference for Food Protection: Provides resources, specifically emergency action plan information: Emergency Action Plan for Retail Food Establishments | Conference of Food Protection)

Annex 3 Public Health Reasons/Administrative Guidelines

Amend Public Health Reasons § 1-201.10 to remove the "s" in the title Standards for Accreditation of Food Protection Manager Certification Programs in paragraph 5 under Accredited Program to read as follows:

1-201.10 Statement of Application and Listing of Terms

...NO CHANGE...

Accredited Program.

...NO CHANGE...

Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the *Standard for Accreditation of Food Protection Manager Certification Programs* available from the Conference for Food Protection, 2792 Miramar Lane, Lincoln, CA 95648 and found at http://www.foodprotect.org/

...NO CHANGE...

Amend Public Health Reasons § 1-201.10 to add new public health reason for defined terms "Food Defense" and "Food Safety Management System" after the term "Food establishment and food processing plant" and before the term "In-Shell Product" to read as follows:

1-201.10 Statement of Application and Listing of Terms

...NO CHANGE...

Food Defense.

Food defense was added as a defined term to address the recommendations made by the Conference for Food Protection Food Defense Committee during the 2021-2023 biennium. Adding the definition of food defense broadens the scope of the Food Code and addresses the desires from the retail food stakeholders to protect our food supply.

While intentional adulteration occurs infrequently, its consequences when it does occur, can be impactful on those involved. There have been several intentional adulteration events related to food establishments in the United States. Examples include:

 1984 Intentional adulteration by the Rajneeshee group of 10 salad bars in Oregon

- 2002-2003 Intentional adulteration of meat in grocery stores with nicotine in Michigan
- 2009 Intentional adulteration of salsa with pesticides at a restaurant in Kansas
- 2016 Intentional adulteration of produce at local grocery stores in Michigan
- 2016 Intentional adulteration of food at restaurants in South Lake Tahoe in California

The development and implementation of food defense measures may prevent or minimize acts of intentional adulteration.

Food Safety Management System.

The definition of food safety management system includes tools such as operating procedures, training plans, and monitoring functions and components that are developed and implemented to address the Person in Charge duties under § 2-103.11 that contribute to foodborne illness. Food safety management systems will vary among food establishments because they are based on the specific operations that will be conducted.

Procedures are a set of actions adopted by management for accomplishing a task in a way that minimizes food safety risks. These can be in the form of, but not limited to, instructions/illustrations, recipe cards with process instructions, wall charts, standard operating procedures, wallet cards, employee health policies, etc. so food employees can use them as a reference when performing operational tasks. The goal is to have well-documented systems that include written procedures describing who, what, where, when, and how the activity must be performed.

Training educates employees on food safety tasks/procedures within the food establishment and how to implement them. Information may be presented in various formats such as computer-based training, on-the-job training, instructions/illustrations, recipe cards with instructions, wall charts, wallet cards, live demonstration, or other methods used to familiarize and train the food employees on the procedures used within the food establishment. The goal is to provide and document training for all food safety tasks in a format and frequency adequate to ensure employees have the knowledge to carry out the procedures consistently and effectively.

Monitoring encompasses routine observations and measurements to determine if food safety procedures are being followed. Monitoring systems may include but are not limited to automated systems, digital thermometers, logs, charts, checklists, and other job aids and tools to monitor the critical limits. The monitoring system should also include who, what, where when and how monitoring is to be performed. The goal is to have a well-documented system that can be verified.

Overall, maintaining documentation of activities within a food safety management system is vital to its success.

Amend Public Health Reasons for § 2-102.10 to replace the term "American National Standards Institute (ANSI)" with new name "ANSI National Accreditation Board (ANAB)" and removed the "s" in the word "Standard" in paragraphs 3-4, 6-10 (including footnote) to read as follows:

2-102.20 Food Protection Manager Certification.

Many food protection manager certification programs have shared a desire to have the food manager certificates they issue universally recognized and accepted by others – especially by the increasing number of regulatory authorities that require food manager certification.

Needed has been a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and administration.

After a multi-year effort involving a diversity of stakeholder groups, the Conference for Food Protection (CFP) completed work on its **Standard for Accreditation of Food Protection Manager Certification Programs** found at:

http://www.foodprotect.org/food-protection-manager-certification/. In 2002 the Conference entered into a cooperative agreement with the ANSI National Accreditation Board (ANAB) to provide independent third-party evaluation and accreditation of certification bodies determined to be in conformance with these Conference standards. ANAB published its first listing of accredited certifiers in 2003.

The Acting Commissioner of the Food and Drug Administration, in his address before the 2004 biennial meeting of the Conference for Food Protection, commended this Conference achievement and encouraged universal acceptance based on the ANAB-CFP Accreditation Program.

Distributed at this meeting was the following letter addressed to the Conference Chair and signed by the Director of FDA's Center for Food Safety and Applied Nutrition. The letter puts forth the Agency's basis for its support of universal acceptance of food protection manager certifications.

"The 2004 biennial meeting of the **Conference for Food Protection** is a fitting occasion for FDA's Center for Food Safety and Applied Nutrition to commend the Conference for its significant achievements in support of State and local food safety programs.

The FDA in a Memorandum of Understanding recognizes the Conference for Food Protection as a voluntary national organization qualified to develop standards to promote food protection. Conference recommendations contribute to improvements in the model FDA Food Code and help jurisdictions justify, adopt and implement its provisions.

Conference mechanisms involving active participation by representatives

of diverse stakeholder groups produce consensus standards of the highest quality. An excellent example is the Conference's *Standard for Accreditation of Food Protection Manager Certification Programs*, and its announcement of the new on-line listing of accredited certifiers of industry food protection managers. Many years in their development, these Conference standards identify the essential components necessary for a credible certification program. Components cover a wide range of requirements such as detailed criteria for exam development and administration, and responsibilities of the certification organization to candidates and the public.

FDA applauds the Conference for this significant achievement and encourages agencies at all levels of government to accept certificates issued by listed certifiers as meeting their jurisdictions' food safety knowledge and certification requirements. The ANSI National Accreditation Board (ANAB) has independently evaluated these certification programs under an agreement with the Conference for Food Protection. Governments and industry widely recognize and respect ANSI as an accrediting organization. ANAB has found certifiers it lists as accredited (http://www.ansi.org/) under "conformity assessment" — "personnel certification accreditation" to conform to the Conference's **Standard for Accreditation of Food Protection Manager Certification Programs.***

The Food Code states the person in charge of a food establishment is accountable for developing, carrying out, and enforcing procedures aimed at preventing food-borne illness. Section 2-102.11 states that one means by which a person in charge may demonstrate required knowledge of food safety is through certification as a food protection manager by passing an examination that is part of an accredited program.**

FDA encourages food regulatory authorities and others evaluating credentials for food protection managers to recognize the Conference for Food Protection/ANAB means of accrediting certification programs. This procedure provides a means for universal acceptance of individuals who successfully demonstrate knowledge of food safety. The procedure provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria. In addition, universal acceptance eliminates the inconvenience and unnecessary expense of repeating training and testing when managers work across jurisdictional boundaries.

FDA, along with State, local, tribal, and other Federal agencies and the food industry, share the responsibility for ensuring that our food supply is safe. It is anticipated that this new Conference for Food Protection/ANAB program will lead to enhanced consumer protection, improve the overall level of food safety, and be an important component of a seamless national food safety system.

Footnote:

*The ANAB-CFP Accreditation Program list of accredited organizations utilizing the Conference for Food Protection (CFP) Standards may be viewed on-line by going to: https://www.ansica.org/wwwversion2/outside/ALLdirectoryListing.asp?menuID=8&prgID=8&status=4

Amend Public Health Reasons § 2-103.11 to add a new paragraph 1 and make existing paragraph 1 into new paragraph 2; and add new paragraph 13 to read as follows:

2-103.11 Person in Charge.

A primary responsibility of the person in charge is to ensure compliance with Code requirements. During an inspection, 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 Person in Charge. This is accomplished by having discussions with the PIC and verified through observation that the systems or controls are being implemented. This concept is commonly referred to as Active Managerial Control.

Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

...NO CHANGE...

Paragraph (R) "EMPLOYEES are aware of food defense, such as signs of intentional acts of adulteration as it relates to their assigned duties..." allows for flexibility in the operation to develop and implement operational-specific awareness programs for food employees to make sure they are aware of food defense and the role the employee plays in protecting our food supply from intentional adulteration. Food establishments may consider reviewing topics such as, but not limited to:

- Understanding what food defense is and the difference between food safety and food defense;
- Recognizing the importance of the role of the employee and how it can play into food defense measures;
- Implementation of food defense measures;

^{**} Accredited program does not refer to training functions or educational programs.

- Identifying signs of potential suspicious activities or threats; and
- Actions employees should take if a suspicious activity or threat is identified within the food establishment.

Amend Annex 3 Public Health Reasons § 2-201.13 to add a new header titled: "Culture-Independent Diagnostic Tests (CIDT) for Medical Clearance" after paragraph 3; add new paragraphs 4 and 5 after existing paragraph 3; add a new header titled: "Reinstatement of Asymptomatic Food Employees" above newly designated paragraph 6 (previous paragraph 4) to read as follows:

2-201.13 Removal of Exclusions and Restrictions.¹

Food employees diagnosed with Norovirus, hepatitis A virus, *Shigella* spp., *E. coli* O157:H7 or other STEC, nontyphoidal *Salmonella* and symptomatic with diarrhea, vomiting, or jaundice, are excluded under subparagraph 2-201.12 (A)(2) or 2-201.12(B)(2). However, these symptomatic, diagnosed food employees differ from symptomatic, undiagnosed food employees in the requirements that must be met before returning to work in a full capacity after symptoms resolve.

The person in charge may allow undiagnosed food employees who are initially symptomatic and whose symptoms have resolved to return to work in a full capacity 24 hours after symptoms resolve.

However, diagnosis with a listed pathogen invokes additional requirements before the person in charge may allow diagnosed food employees to return to work in full capacity.

Culture-Independent Diagnostic Tests (CIDT) For Medical Clearance

Detection of Shiga-toxin producing *Escherichia coli*, Shiga-toxin producing species, and nontyphoidal *Salmonella* Stool culture tests have largely been replaced by culture-independent diagnostic tests (CIDT) (tests that determine microbial presence without growing the bacterium in the laboratory). These tests have a higher degree of specificity than culture-based testing and are generally much faster than culture-based tests, and are more likely to have false positive test results than false-negative results, since they capture all microbes, including non-viable microbes. The use of these tests is less likely to allow infected asymptomatic employees back to work while still shedding pathogenic microbes, and allow another more widely accessible, faster test option for all.

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¹In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

The allowance of these tests as an option for medical clearance does not replace stool culture tests, but instead provides other options for the employee that provide the same degree of public health protection from infected employees.

Reinstatement of Asymptomatic Food Employees

Asymptomatic food employees diagnosed with Norovirus, *Shigella* spp., *E. coli* O157:H7 or other STEC may not return to work in a full capacity for at least 24 hours after symptoms resolve. The person in charge shall only allow these food employees to work on a restricted basis 24 hours after symptoms resolve and they shall only allow this if not in a food establishment that serves a highly susceptible population. These restricted food employees remain restricted until they are medically cleared or otherwise meet the criteria for removal from restriction as specified under subparagraphs 2-201.13(D) (1)-(2); 2-201.13(E)(1)-(2); or 2-201.13(F)(1)-(2).

...NO CHANGE...

Amend Public Health Reasons § 2-301.12 Cleaning Procedure, to add new paragraphs 3, 5, 8, 9; revised old paragraph 3 to be new paragraph 4; revised old paragraph 5 to be new paragraph 6; paragraph 7 remained the same; revised old paragraph 8 to be new paragraph 10 to read as follows:

2-301.12 Cleaning Procedure.

Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to RTE food as well as other pathogens that can be transmitted from environmental sources. Many employees fail to wash their hands as often as necessary and even those who do may use flawed techniques.

In the case of a food worker with one hand or a hand-like prosthesis, the Equal Employment Opportunity Commission has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable the food worker with one hand to adequately generate the necessary friction to achieve the intent of this requirement.

Hand Contamination:

Food contaminated by the hands of food employees is a major source of foodborne illness outbreaks traced to retail food establishments. Hand contamination in the food service industry can result from a variety of activities, such as exposure to raw animal products, raw produce products with soil contamination, organic refuse, and bodily fluid residue (e.g., human saliva, mucus, sweat, vomitus, or feces) from other food employees or consumers. The types of activities conducted by food service employees may also lead to increased levels of fatty and proteinaceous material contamination of their hands. This fatty and proteinaceous material and all other types of hand contamination may or may not be visible on the hands.

The greatest concentration of microbes exists around and under the fingernails of the hands. The area under the fingernails, known as the "subungal space", has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to decontaminate. There are two different types of microbes on the hands, transient and resident microbes. A moderate number of these organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin, and they are not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential contamination of food and food-contact surfaces, but in some cases when food employees are exposed to foodborne pathogenic microbes on a long-term basis, these pathogens have been found also as residents on food employee hands^{1,2}.

Handwashing:

Soap, friction, and running water effectively remove proteinaceous and fatty material contamination from hands and reduce pathogens of concern. Soap has a surfactant effect in removing grease, soil, and debris from the hands. Most of the soil contamination on food employee hands is insoluble or oil soluble, rather than water soluble soil. Soap is necessary to remove this insoluble soil from the hands, through what is known as "emulsification" of this oily film. Transient microorganisms are part of this insoluble soil on the hands and are removed through this emulsification process. The emulsification, or mechanical "scrubbing" of the hands has been reported to play a greater role in removing transient pathogens from the hands, than the actual "bactericidal" action of any soap³. The temperature of the water used in handwashing is an important variable in the solubility or emulsification of the soil since the solubility of most types of soil increases as the temperature is increased. Generally, solubility increases with warmer water temperatures, however, skin damage can occur with repeated handwashing using high water temperatures.

All aspects of proper handwashing are important in reducing microbial transients on the hands. However, friction and water have been found to play the most important role. This is why the amount of time spent scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

The amount of soap required is equivalent to the amount necessary to emulsify the soil or oil and organic contaminants on the hands. When an antimicrobial soap is used, at least 3-5 ml is recommended for best results⁴. Research has shown a minimum 10-15 second scrub is necessary to remove transient pathogens from the hands and when an antimicrobial soap is used, a minimum of 15 seconds is required⁴.

Every stage in handwashing has an additive effect in transient microbial reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When done properly, each stage of handwashing further decreases the

transient microbial load on the hands. It is equally important to avoid recontaminating hands by avoiding direct hand contact with heavily contaminated environmental sources, such as manually operated handwashing sink faucets, paper towel dispensers, and rest room door handles after the handwashing procedure. This can be accomplished by obtaining a paper towel from its dispenser before the handwashing procedure, then, after handwashing, using the paper towel to operate the hand sink faucet handles and restroom door handles.

Poorly maintained bulk soap dispensers have also been identified as a potential source of food employee hand contamination^{5,6,8}. Practices such as "topping off" a bulk soap dispenser, or refilling a used bulk soap dispenser, or even diluting a used soap dispenser without prior dismantling, cleaning and sanitization of the dispenser before refilling, are likely to become the source of biofilm formation within the dispenser and result in contaminated soap. This microbial contamination in bulk soap dispensers has been traced to contaminated hands after handwashing with the contaminated soap⁶.

Unless the bulk soap dispenser and the pump with within the dispenser can be completely dismantled, cleaned, and sanitized between refills, the soap dispenser should be discarded and replaced with a new dispenser and/or soap pump, to ensure the prevention of biofilm formation and soap free of contamination. Also soap in a bulk soap dispenser that has been diluted with water more than soap manufacturer recommended levels, will not adequately emulsify organic and fatty proteinaceous contamination of the hands, and is also more likely to be highly contaminated. Diluting soap containers with water beyond manufacturers recommendations or refilling bulk soap dispensers without dismantling, cleaning, and sanitizing prior to refilling should be considered a violation of providing adequate soap for handwashing in a food establishment.

Handwashing done properly can result in a 2-3 log reduction in transient bacteria and a 2-log reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens, (i.e., > 10⁴ microbes, as found on hands contaminated with bodily wastes and infected bodily fluids) handwashing may be ineffective in completely decontaminating the hands. Therefore, a further intervention such as a barrier between hands and ready-to-eat food is necessary.

Footnote References:

- 1. Kerr, K.G., Birkenhead, D., Seale, K., Major, J., and Hawkey, P.M., 1993. Prevalence of *Listeria* spp. on the hands of food workers. J.F.P., 56(6): 525-527.
- 2. Seligmann,R., and S. Rosenbluth. 1975. Comparison of bacterial flora on hands of personnel engaged in non-food and in food industries: a study of transient and resident bacteria. J. Milk Food Technol. 38: 673-677.
- 3. Lane, C.G., and Blank, I.H., 1942. Cutaneous Detergents. J.A.M.A. 118 (10): 804-816.
- 4. Larson, E.L., 1995. APIC Guideline for handwashing and hand antisepsis in health care settings, AJIC, 23(4): 251-269.

- 5. Schaffner, D.W., Jensen, D., Gerba, C.P., Shumaker, D., and Arbogast, J.W., 2018. Influence of soap characteristics and food service facility type on the degree of bacterial contamination of open, refillable bulk soaps. J.F.P. 81 (2): 218-225.
- 6, Zapka, C.A., Campbell, E.J., Maxwell, S.L., Gerba, C.P., Dolan, M.J., Arbogast, J.W., and Macinga, D.R., 2011. Bacterial hand contamination and transfer after use of contaminated bulk-soap-refillable dispensers. App. Env. Microbiol., May, 2898-2904. Doi:10.1128/AEM.02632-10.
- 7. Lorenz, L.A., B.D. Ramsey, D.M. Goeres, M.W. Fields, C.A. Zapka, and D.R. Macinga. 2012. Evaluation and remediation of bulk Soap dispensers for biofilm. Biofouling. 28: 99-109.

Amend Public Health Reasons § 2-301.16 to revise paragraphs 2 and 3 to read as follows:

2-301.16 Hand Antiseptics

...NO CHANGE...

The term "sanitizer" is typically used to describe control of bacterial contamination of inert objects or articles, or equipment and utensils, and other cleaned food-contact surfaces. The Food Code definition of "sanitizer" (a form of the defined term "sanitization") requires a minimum microbial reduction of 5 logs, which is equal to a 99.999% reduction. The FDA bases the 5-log reduction on the AOAC International's "Official Methods of Analysis 2003," which requires a minimum 5-log reduction in microorganisms to achieve "sanitization."

Reducing microorganisms from human skin is a totally different process than sanitizing surfaces and sterilization of human skin is nearly impossible to achieve without damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms on hands than the 5-log reduction required for "sanitization." Therefore, the effect achieved from using antimicrobial hand agents (often called "hand sanitizers") is not consistent with the definition of "sanitization" in the Food Code.

...NO CHANGE...

Amend Public Health Reasons § 2-501.11 to revise paragraphs 6 and 9 to read as follows:

2-501.11 Clean-up of Vomiting and Diarrheal Events.

...No Change...

Effective clean-up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a detailed cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact and nonfood-contact surfaces may not be effective against some viruses such as norovirus. It is therefore important that food establishments have

procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that include the use of EPA-registered disinfectants against norovirus.

Consumers are at risk of contracting Norovirus illness from direct exposure to vomitus or from exposure to airborne Norovirus from vomitus. Additionally, exposed food employees are also at risk of contracting Norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers.

The Food Code specifies that the Person in Charge is to exclude or restrict a food employee who exhibits, or reports a symptom, or who reports a diagnosed illness or a history of exposure to Norovirus. A clean-up and response plan is intended to address situations where a food employee or other individual becomes physically ill in areas where food may be prepared, stored or served. Once such an episode has occurred, timely effective clean-up is imperative. Key to achieving an appropriate, timely response by food employees is the availability and access to a written plan upon which to refer to for reference.

When developing a written plan that addresses the need for the cleaning and disinfection of a vomitus and/or diarrheal contamination event, a food establishment should consider:

- The conditions under which the plan will be implemented;
- The availability of effective disinfectants, such as EPA registered disinfection products sufficient to inactivate norovirus, personal protective equipment, and other cleaning and disinfecting tools (such as mops, buckets, etc.,)intended for response and their proper use;
- The circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;
- Notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;
- The procedures for minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service, and storage;
- The segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers, and others in the facility to the discharges or to surfaces or food that may have become contaminated;
- The procedures for containment and removal of any discharges, including airborne particulates;
- The procedure for cleaning and disinfecting of any surfaces that may have become contaminated;
- The procedures for the evaluation and disposal of any food that may have been exposed to discharges;
- Procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter; and

• The procedures for minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in §2-201.12 of the Food Code.

...NO CHANGE...

Amend Annex 3 Public Health Reasons for § 3-201.11 under the section Labeling for Whole-muscle, Intact Beef Steaks to delete the word "not" between "have" and "undergone" in sentence 3 to read as follows:

3-201.11 Compliance with Food Law.

...NO CHANGE...

Labeling for Whole-muscle, Intact Beef Steaks

In the past, some steaks were labeled "intact" in order for a food establishment operator to determine a steak is a whole muscle, intact cut of beef that could therefore be undercooked and served without a consumer advisory. Processors could accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products. However, such intact labeling in practice was very rare. Rather, FSIS regulations and policies identify steaks that are non-intact (i.e., steaks that have undergone mechanical tenderization including injection, vacuum tumbling with solutions, reconstruction, cubing, or pounding). Therefore, Section 3-201.11 has been revised to better reflect that a food establishment operator should obtain steaks that are either not labeled as non-intact (e.g., mechanically tenderized, blade tenderized, needle tenderized, contains X% added solutions, or formed) or do not appear non-intact due to cubing or pounding. FDA has also developed an intact steak decision-tree to help food establishment operators determine whether a steak is intact or non-intact and can be found at the following link: www.fda.gov/media/163808/download

Amend Public Health Reasons § 3-301.11 to add new paragraphs 3, 4 and 5 to follow existing paragraph 2 to read as follows:

3-301.11 Preventing Contamination from Hands.

...NO CHANGE...

3-301.11(E) Prior Approval for Food Employees to Touch Ready-to-Eat Food with Bare Hands

...NO CHANGE...

In the rare situations when a barrier between the hands and ready-to-eat food will not be feasible, it is vital to add additional measures to the handwashing procedure as outlined in ¶3-301.11(E) as an additional layer of protection to prevent the spread of

pathogenic microbes from the hands to ready-to-eat food items. In addition to other required control measures, food employees must utilize at least two of the five listed additional control measures, including: 1. Double handwashing; 2. Nail brush use; 3. Hand antiseptic after handwashing as specified under §2-301.16; 4. Incentive programs such as paid sick leave that assist or encourage food employees not to work when ill; or 5. Other control measures approved by the regulatory authority.

Using a second handwash, or "double handwashing" can result in decreasing the level of contamination on the hands beyond what could be achieved from a single handwash procedure. Using a second handwash procedure can reduce microbial contamination on the hands by an additional half-log to 1 log from that achieved with a single handwash procedure. Double handwashing, as listed in ¶3-301.11(E)(6)(a), means handwashing 2 times (subsequentially) and at the same location immediately before handling RTE food with bare hands. This is in addition to other required handwashing events for food employees, such as after using the restroom. The double handwash technique involves washing and drying the hands at the handwashing sink as described in §2-301.12, and immediately repeating the handwash procedure (including rinsing, applying a hand cleanser, scrubbing, rinsing, and drying the hands with an approved hand drying device) at the same handwashing sink.

Fingernail brushes, if used properly, have been found to be effective tools in decontaminating the area under fingernails on the hand. Proper use of single-use, disposable fingernail brushes, or designated individual fingernail brushes for each employee, during the handwashing procedure can achieve up to a 5-log reduction in microorganisms on the hands. If fingernail brushes are used, they must be for individual use only, and not shared by other employees. Fingernail brushes cannot be shared by employees because they may become the source of spreading microbial pathogens from one employee to the next employee without a means to disinfect the used brush between employees.

...NO CHANGE...

Amend Public Health Reasons § 3-304.17 to add new paragraphs 1-3 and 5-6; revise old paragraph 1 to be new paragraphs 4 and 5 and revise old paragraph 2 to be new paragraphs 7 and 8 to read as follows:

3-304.17 Refilling Returnables

The CFP convened the 2020 Biennial Meeting and three issues related to refillable containers submitted to CFP Council I were transferred to Council III at the 2021 meeting. Issue 2020 I-024 Creation of a Committee to Address Reusable Scenarios in Food Retail was combined with Issue 2020 I-022, Amend Food Code to Harmonize the Definition of Reusable Container and Issue 2020 I-023, Amend Food Code to Address New Reusable Scenarios in Food Retail. Council III voted, and subsequently approved, to create the Safe Use of Reusable Containers Committee.

At the 2023 Conference for Food Protection meeting the committee conveyed the

concern that the Food Code did not align with practices in the field as it pertains to refilling reusable containers at retail. The committee agreed the filling of customerowned containers and third-party supplied reusable containers in retail food establishments was common despite limited allowance in the Food Code. The committee also agreed that local, national, and global legislation and movements to reduce solid waste from disposable food containers would increase reuse requirements and the demand for reusable container options from consumers, businesses, and environmental groups. In addition, legislative bodies will likely look toward reusable container options for food service packaging to help address issues of waste, human health, and climate change.

With this feedback, FDA agreed to amend §3-304.17 Refilling Returnables to provide guidance on the minimum standards that must be met to protect food safety when refillable containers are used and allow wider and more standardized use of reusable containers.

Food establishments may allow the use of reusable containers for refilling, such as consumer owned containers, third-party provided containers, or an in-house program for return and exchange for cleaned and sanitized containers. Containers pose a risk of cross-contamination and must be cleaned, sanitized, inspected, and care must be given to prevent contamination of the premises. If not handled correctly, pathogens or chemicals may be transferred to food by consumers or employees directly, or indirectly.

The existing provisions in the Food Code, specifically the cleaning and sanitization provisions in Parts 4-6 and 4-7, if carried out properly, are sufficient to ensure that the container is safe to refill or reuse if performed in conjunction with a visual inspection by a food employee to verify that the container still meets the intent of the provisions in Parts 4-1 and 4-2.

As amended, §3-304.17 requires the minimum standards that the container be appropriate for reuse, via cross-reference to Parts 4-1 and 4-2, cleaned and sanitized via cross-reference to Parts 4-6 and 4-7, and visually inspected by a food employee. Reusing single-service and single-use articles is prohibited by the Food Code.

Paragraphs (A) and (B) of §3-304.17 are written with flexibility in mind as three common sources of reusable containers exist: consumer-owned, facility owned, and third-party owned. If a facility chooses to refill a container, they may ask for necessary information on materials, condition, and cleaning and sanitizing methods used to meet the intent of these paragraphs. This can be done in conjunction with the required visual inspection by a food employee. These requirements can also be written into a contract or certificate of analysis (COA) if a third-party is utilized. Depending on the information gathered by the employee or listed in the contract or COA, the container may be deemed ready for use, rejected for use, or needing additional cleaning and sanitizing. This method ensures a risk-assessment is made and appropriate actions are taken to ensure the container meets minimum standards

and poses little risk for cross-contamination before refilling.

Additionally, equipment must be designed to prevent the contamination of the premises when refilling. This could be done through equipment design, the use of utensils, secondary containers, or other effective means as outlined in ¶3-304.17(B).

Amend Public Health Reasons § 3-502.12 to revise paragraph 1 to read as follows:

3-305.11 Food Storage.

3-305.12 Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Leaks and drips of condensate from pipes, tubes, and hoses, and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

Refer also to the public health reasons for § 2-501.11.

Amend Public Health Reasons §3-502.11 to add new paragraph 8 to read as follows:

3-502.11 Variance Requirement.

...NO CHANGE...

Section 3-502.11 describes specialized processes in which a variance must be obtained from the regulatory authority before preparing the food product in such a manner. Specialized processes such as smoking, using food additives or components such as vinegar, or curing food are examples of food preservation techniques used to prevent spoilage in food. There may be other technologies that are emerging as alternatives for extension of product shelf life and reduction of pathogenic organisms and may require prior approval through a variance. Traditionally, the most popular preservation techniques used for the reduction of microbial contamination of food have been the manipulation of the water activity and/or pH, heat treatment, the addition of chemical preservatives, and the control of storage temperature of foods. Whether the specialized processing methods in §3-502.11 are referred to as food preservation or not, an establishment is required to provide scientific evidence or analysis that shows the rationale for how the potential public health hazards will be addressed and how food safety would not be compromised along with the actual variance request. Refer to Annex 6: Food Processing Criteria for more detailed information on food preservation techniques such as smoking and curing.

Amend Annex 3 Public Health Reasons § 4-302.14 to revise the section title to add the term "Disinfecting" and revise the paragraph to include language regarding

disinfectants and testing devices to read as follows:

4-302.14 Sanitizing and Disinfecting Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing and disinfecting solutions are required for 2 reasons:

- 1. The use of chemical sanitizers or disinfectants require minimum concentrations of the sanitizer or disinfectant during the sanitization or disinfectant step to ensure sanitization or disinfection.
- 2. Too much sanitizer or disinfectant in the final step could be toxic.

Amend Annex 3 Public Health Reasons § 4-501.116 to revise the section tag line (title) to include the term "Disinfectant" and to update language to include the term disinfectant throughout the paragraph to read as follows:

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer or Disinfectant Concentration.

The effectiveness of chemical sanitizers and disinfectants are determined primarily by the concentration and pH of the sanitizer or disinfectant solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer or disinfectant solution.

Amend Annex 3 Public Health Reasons § 4-601.11 to revise the term nonfood contact to nonfood-contact to make it grammatically consistent throughout the Food Code to read as follows:

4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood-contact surfaces so that pathogenic microorganisms will not be allowed to accumulate, and insects and rodents will not be attracted.

Amend Annex 3 Public Health Reasons §4-602.13 to revise the term nonfood contact to nonfood-contact to make it grammatically consistent throughout the Food Code to read as follows:

4-602.13 Nonfood-Contact Surfaces.

The presence of food debris or dirt on nonfood-contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

Add Annex 3 Public Health Reasons § 4-1001.11 to address disinfection to read as follows:

Objective

4-1001.11 Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.

Food establishments must be able to control microorganisms that pose a risk to employees and patrons to protect public health within their establishment. Since sanitizers only reduce, as opposed to eliminate, the number of microorganisms on a surface and do not control all types of microorganisms, i.e., bacteria, fungi, viruses, and spores, a disinfectant with an appropriate EPA-registered efficacy claim may be required.

Several examples of situations when a higher level of antimicrobial efficacy may be warranted are listed below:

- Clean-up of bodily fluid spills
- Microorganism of concern is not listed on the product label, (i.e., viruses, biofilm, fungus)
- A higher level of antimicrobial efficacy is warranted
- When required by a regulatory authority

Add Annex 3 Public Health Reasons § 4-1002.11 to address disinfection to read as follows:

Frequency

4-1002.11 Disinfectant Use

Frequency of disinfection varies depending on circumstances at the time of disinfection. During outbreaks surfaces should be disinfected at the frequency recommended by public health officials or other regulatory authorities. Surfaces should also be disinfected immediately after a bodily fluid event.

Add Annex 3 Public Health Reasons § 4-1003.11 to address disinfection to read as follows:

Methods

4-1003.11 Chemical.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Amend Annex 3 Public Health Reasons § 6-202.15 to revise paragraph 2 to read as follows:

6-202.15 Outer Openings, Protected.

...NO CHANGE...

In the National Fire Protection Association's NFPA 101, Life Safety Code, 2024 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

...NO CHANGE...

Amend Annex 3 Public Health Reasons § 7-102.11 to include the term disinfectants after the term sanitizers in sentence 1 to read as follows:

7-102.11 Common Name.

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners, sanitizers, and disinfectants in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Amend Annex 3 Public Health Reasons §§ 8-201.12 and 8-203.10 to add new header and revise paragraphs 2-4 to read as follows:

Construction inspection and approval

- 8-201.12 Contents of the Plans and Specifications.
- 8-201.15 When a Food Safety Management System is Required.
- 8-203.10 Preoperational Inspections.

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this FDA/CFP Food Establishment Plan Review Guide – 2000 has been used in the FDA State Training Team Plan Review courses. It can be accessed through

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatory AssistanceandTrainingResources/ucm101639.htm.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique

opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Food Safety Management Systems (FSMSs) are a part of that foundation and, ideally, are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about FSMSs and their scope.

FSMSs play an important role in controlling hazards in retail food establishments by incorporating a specific set of actions (e.g. procedures, training and monitoring) to help achieve active managerial control of foodborne illness risk factors. The Conference for Food Protection requested that FSMSs as defined be incorporated into the Food Code. FDA Retail Food Risk Factor Study results found that food establishments with well-developed and documented systems (i.e., a FSMS that is complete, consistent, and primarily written) had the greatest impact on compliance and maintaining the FSMS documentation was vital to its success. To further support this conclusion, the study results revealed that FSMSs were the strongest predictor of data items being out-of-compliance in both fast food and full-service restaurants and those with well-developed FSMSs had significantly fewer food safety behaviors/practices out-of-compliance than those with less developed FSMSs.

Food safety management systems should be developed or in the process of being developed by the time of the preoperational inspection and put into effect when the food operation begins. Within 4 years of the regulatory authority's adoption of this Code, § 8-201.15 requires food safety management systems to be developed and maintained, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures, training plans, and monitoring records should include definitive practices and expectations that ensure compliance with the requirements of this Code as specified in § 2-103.11.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with paragraph 2-103.11(O) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

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

Amended Section 2. Reduced Oxygen Packaging, Part (B)(1) Definitions to read as follows:

2. Reduced Oxygen Packaging

(A) Introduction

...NO CHANGE...

(B) Definitions

The term ROP can be used to describe any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include packaging options such as:

(1) *Cook-chill* packaging, in which cooked food is hot filled into impermeable packaging (such as bag or film on trays) that are then sealed or crimped closed. The packaged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

...NO CHANGE...

Amended Annex 6 Food Processing Criteria to add new Section 4 Acidification (Sushi Rice) to read as follows:

Annex 6 Food Processing Criteria

- 1. Introduction
- 2. Reduced Oxygen Packaging
- 3. Smoking and Curing
- 4. Acidification (Sushi Rice)

...NO CHANGE...

4. Acidification (Sushi Rice)

Rice and potatoes have a history of association with foodborne illness caused by *Bacillus cereus*, therefore products containing rice, or potatoes should be evaluated for time/temperature control requirements. Rice is often used as a basis for sushi, which can include a combination of sushi rice, cooked and uncooked seafood, vegetables, and seaweed in various shapes and sizes.

Cooked rice is a Time/temperature control for safety food (TCS) with known hazards associated with it. For a TCS product to be stored without temperature control, there

must be processes in place to assure that the rapid and progressive growth or toxin production of infectious or toxigenic microorganisms cannot occur. This is commonly done by modifying the pH of the cooked rice to a pH of <4.2 or below. Proper acidification and distribution of acid is essential to prevent bacterial growth, especially *Bacillus cereus*.

Acidification of TCS foods with the intent of making them non-TCS is considered a special process in the Food Code. In the case of sushi rice, this process takes a TCS food (cooked rice) and adds acid (typically vinegar) to drop the pH and allow the cooked rice to be held without time or temperature controls. This acid addition needs to adjust the equilibrium pH to less than 4.2 to control the identified hazards. Addition of vinegar for flavor only, when pH is not monitored, is not considered a special process and rice must be temperature controlled just like any other TCS food. It is also important to remember once the acidified rice is combined with other sushi ingredients the final product would be considered TCS again requiring time and temperature control.

Retail food establishments that wish to handle food outside the Food Code parameters can do so by use of a Variance and HACCP Plan. HACCP plans specify the process and how food safety hazards will be controlled. §8-103.11 Documentation of Proposed Variance and Justification outlines criteria for obtaining a regulatory variance, and §8-201.14 Contents of a HACCP Plan identifies required elements needed in a HACCP plan. The variance issued by the regulatory authority allows the food establishment to implement the HACCP plan which controls food safety hazards in an alternate manner. Refer to §8-103.10 Modifications and Waivers for additional information about variances.

Most HACCP Plans for sushi rice have a critical limit of 4.2 pH or less. A critical limit is a prescribed parameter (e.g. minimum and/or maximum value) that must be met to ensure that food safety hazards are controlled at each critical control point (CCP). A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Each control measure at a CCP has one or more associated critical limits. Critical limits may be based upon factors like temperature, time, moisture level, water activity or pH. They must be scientifically based and measurable.

When establishing a critical limit using pH, a food establishment can refer to the interaction tables in $\S1-210.10$ under the definition for Time/Temperature Control for Safety Food. The tables show whether a food can support microbial growth based on the interaction between pH and A_w .

The critical limit for acidification of cooked rice is a pH of 4.2 or less. This assumes that the cooking process destroys all the vegetative pathogens, and the only concern is either recontamination or spores that survive the cooking process, which can germinate and produce toxin. *Clostridium botulinum* is not generally the concern with rice because it requires an anaerobic environment. *Salmonella* and *Staphylococcus aureus* could be contaminants in rice but are typically destroyed with normal cooking processes. *Bacillus cereus* is of concern. Several sources of information show the lower growth

limit for *Bacillus cereus* at pH 4.6 – 5.0 but the National Advisory Committee On Microbiological Criteria For Foods (NACMCF)

(https://www.fsis.usda.gov/sites/default/files/media_file/documents/JFP-Parameters-Determining-Inoculted-Pack-Challenge-Study-2009.pdf) uses the more conservative growth limit at pH of 4.3.

In addition, even though the rice is acidified, the pH of the cooked rice has little impact on acidifying raw fish or fillings for the sushi roll so these sushi rolls will still require refrigeration if they contain other fillings that are considered TCS.

The Conference for Food Protection Single Hazard Special Processes HACCP Committee created a guidance document and standardized template for preparing sushi rice. It is currently available on the CFP website at: http://www.foodprotect.org/guides-documents/single-hazard-special-process-haccp-template-guidance-document-and-sample-templates/ along with the Guidance Document for Retail Sushi HACCP Standardization: https://www.foodprotect.org/guides-documents/guidance-document-for-retail-sushi-haccp-standardization/.

Reference:

Center for Agriculture and Food Security and Preparedness. nd. Cultural Food Safety App Smartphone and Tablet Application | The Center for Agriculture and Food Security and Preparedness

Annex 7 Model Forms, Guides, and Other Aids

Amend Form 3-A Food Establishment Inspection Report Item #16 to add in the term "disinfectant" to read as follows:

FORM 3-A

Food Establishment Inspection Report Pageof												
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License/Permit # Permit Holder					Purpose of Inspection				Est. Type		Risk Category	
			FOODBO	 DRNE ILLNESS RISK FACTOR	RS AND	P	UBLIC HEA	TH INTERVE	NTIONS			
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Person in Charge (Signature)						Date	
Inspector (Signature)						Date	

CPF00-12-03 PG2 A-2

APPENDIX A

Food Establishment Inspection Report Page of						
As Governed by State Code Section XXX.XXX						
Do Good County	License/Permit #		Date			
12344 Any Street, Our Town, State, 11111						
Establishment Address	City/State	Zip Code	Telephone			
OBSER	RVATIONS AND CORRECTIVE ACT	IONS				
Item Violations cited in this report must b	e corrected within the time frames below or as	stated in Section 8-405.	11 of the Food Code.			
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3						
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CPF00-12-03 PG3 A-3

Amend Guide 3B, Section C, Supervision, Item #1, to add new paragraphs for inclusion in B(3) and under applicable code sections §2-102.11 and §2-103.11 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 <u>IN</u> compliance if the PIC meets at least <u>one</u> of the options. The three options for demonstration of knowledge allowed by the Food Code are:
 - 1. Certification by an ACCREDITED PROGRAM as specified in 2-102-20.
 - 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) and (18). 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

of the operation and extent of the food operation.

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

Applicable Code Section:

2-101.11 Assignment ^(Pf)
2-102.11(A), B) and (C)(1), (4)-(16) (18) Demonstration ^{(Pf), (C)}
2-103.11 (A)-(O) and (Q-R) Person-In-Charge-Duties ^(Pf)

Amend Guide 3B, Section C, Proper eating, tasting, drinking, or tobacco products use, Item #6, to revise the term nonfood contact to nonfood-contact to read as follows:

Good Hygienic Practices

6. Proper eating, tasting, drinking, or tobacco products use

This item should be marked IN or OUT of compliance based on direct observations or discussions of the appropriate hygienic practices of food employees. This item should be marked IN compliance when a food employee is observed drinking from a closed beverage container subsequently stored on a nonfood-contact surface and separate from exposed food, clean equipment, and unwrapped single- service and single-use articles. This item should be marked OUT of compliance when food employees are observed improperly tasting food, eating, drinking, or using tobacco products, or there is supporting evidence of these activities taking place in non-designated areas of the establishment. An open container of liquid in the kitchen preparation area does not necessarily constitute marking this item OUT. Further discussion with a food employee or the PIC may be needed to determine if the liquid, if labeled, is used as an ingredient in food, or may be an employee beverage that is consumed in another designated area. If the liquid is an open beverage that is consumed in a designated area, it must still be stored in a manner to prevent the contamination of food, equipment, utensils, linens and single-service/single-use articles.

...NO CHANGE...

IN/OUT

Amend Guide 3B, Section C, Supervision, Item #16, to revise the title of the section, update the marking instructions and include new applicable Code sections to read as follows:

16. Food-contact and nonfood-contact surfaces: cleaned, sanitized and disinfected

IN/OUT This item must be marked IN or OUT of compliance based on direct observations of foodcontact surfaces and non food-contact surfaces (when required) of equipment and utensils; actual measurements/readings of chemical sanitizer concentration, hot water sanitizing temperature, pH, hardness, water pressure, etc. using test strips, heat-sensitive tapes, and equipment gauges; observations of disinfecting when required and cleaning and sanitizing procedures; and discussion of disinfecting, cleaning and sanitizing procedures and frequency with the PIC or other food employees. This item must be marked IN compliance when manual and/or mechanical methods of disinfecting, cleaning and sanitizing are effective and performed at the prescribed frequency. There should be an overall assessment of the foodcontact surfaces of equipment and utensils in clean storage and in use to determine compliance. For example, this item is not marked OUT of compliance based on one visibly soiled utensil, such as a plate or knife. This item must be marked OUT of compliance when manual and/or mechanical methods of cleaning, sanitizing and disinfecting (when required) of food-contact surfaces of equipment and utensils are ineffective, or if one multiuse piece of equipment such as a slicer or can opener is visibly soiled and being used at the time of the inspection. This item is also marked OUT if it is observed that equipment or utensils that have

come into contact with a major food allergen such as fish was not cleaned and sanitized prior to use for other types of raw animal foods or food-contact and non-food contact equipment come in contact with a bodily fluid.

- **N.A.** This item may be marked N.A. only when there is no requirement to clean equipment and utensils such as when only prepackaged foods are sold.
- **N.O. Do Not Mark** this item N.O.

Applicable Code Sections:

...NO CHANGE...

4-1001.11 Food-Contact, nonFood-Contact Surfaces and Utensils (P)

4-1002.11 Disinfectant Use (P)

4-1003.11 Chemical (P)

Amend Guide 3B, Section C, Food/Color Additives and Toxic Substances, Item #28, to include disinfection to read as follows:

28. Toxic substances properly identified, stored, and used; held for retail sale, properly stored

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food labeling, storage, reconstitution, and application of bulk and working containers of cleaning agents, sanitizers, and disinfectants, personal care items, first aid supplies, medicines, pesticides, and potential toxic and poisonous substances. This item should be marked IN compliance when bulk and working containers of cleaning agents, sanitizers and disinfectants are labeled; sanitizing and disinfecting solutions are not exceeding the maximum concentrations; personal care items, first aid supplies, medicines, and chemicals are stored separate from and not above food, equipment, utensils, linens, and single-service and single-use articles; and restricted use pesticides are applied only by or under the supervision of a certified applicator. This item should be marked OUT of compliance if a cleaning agent, sanitizer or disinfectant is not properly identified and stored; if a sanitizing or disinfecting solution has a higher concentration than prescribed and medicines and first aid kits are improperly labeled and stored. Violations of solutions exceeding the recommended concentration in chemical washes for fruits and vegetables (§7-204.12) would be marked under Item #42.

Amend Guide 3B, Section D, Approved Thawing Methods Used, Item #35, to add new risk designation to 3-305.13 in the applicable code section to read as follows:

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 (A), (B), (C), and (E) Thawing (Pf)

Amend Guide 3B, Section D, Food and nonfood-contact surfaces cleanable, properly designed, constructed and used, Item #47, to remove hyphen between the terms non-food; to add new marking instructions; and to add new risk designation to 3-304.17 in the applicable code section to read as follows:

Utensils, Equipment and Vending

47. Food and nonfood-contact surfaces cleanable, properly designed, constructed and used Equipment and utensils must be properly designed and constructed, and in good repair. Refillable containers must be cleaned, sanitized, and inspected prior to filling, and must not contaminate the premises. Proper installation and location of equipment in the food establishment are important factors to consider for ease of cleaning in preventing accumulation of debris and attractants for insects and rodents. The components in a vending machine must be properly designed to facilitate cleaning and protect food products (e.g., equipped with automatic shutoff, etc.) from potential contamination. Equipment must be properly used and in proper adjustment, such as calibrated food thermometers.

Applicable Code Sections:

3-304.16 Using Clean Tableware for Second Portions and Refills (C) 3-304.17 Refilling Returnables (Pf)(C)

...NO CHANGE...

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

48. Warewashing facilities, installed, maintained, used, test kit or other device

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 the 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 or when the concentration of the sanitizing or disinfecting solution is not accurately determined by using a test kit or other device in accordance with the manufacturer's label instructions.

Applicable Code Sections:

NO CHANGE
4-302.14 Sanitizing and Disinfecting Solutions, Testing Devices (Pf)
NO CHANGE
4-501.116 (A-B) Warewashing Equipment, Determining Chemical Sanitizer or Disinfectant Concentration $^{(Pf)(C)}$
NO CHANGE

Amend Guide 3B, Section D, Non-food-contact surfaces clean, Item #49, to remove hyphen between the terms non-food in the Item number title and in the applicable code section title to read as follows:

49. Nonfood-contact surfaces clean

Observations should be made to determine if the frequency of cleaning is adequate to prevent soil accumulations on non-food-contact surfaces.

Applicable Code Sections:

4-601.11(B) and (C) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils (C) 4-602.13 Nonfood-Contact Surfaces (C)

Part 3. New Terms Added to the Index to the Food Code

Active Managerial Control

Disinfection

Food Defense

Food Safety Management System

Medical Clearance

Laboratory tests for reinstatement after exclusion with STEC, *Shigella* or *Non-Typhoidal Salmonella*

Water-based Fire Protection System