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Supplement to the 2009 FDA Food Code

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INTRODUCTION

The Food and Drug Administration (FDA) is pleased to issue this Supplement to the 2009 Food Code (hereafter referred to as Supplement). This Supplement updates the 2009 Food Code to address several recommendations made at the 2010 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 the current science and emerging food safety issues, and imminent health hazards related to food safety.

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 2013. 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 2013. 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, 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 2009 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.

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 2009 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. This entire Supplement to the 2009 Food Code is intended to keep the 2009 Food Code up-to-date. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2009 Food Code effective upon issuance via web posting or hard copy release.

Part 1. Summary of Changes

The amendments to the 2009 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

1. FOODBORNE ILLNESS ESTIMATES, RISK FACTORS, AND INTERVENTIONS

Revised the foodborne illness statistics to state the 2011 CDC estimates of foodborne illness in the United States

Chapter 1 Purpose and Definitions

No Change.

Chapter 2 Management and Personnel

2-102.12

Added new §2-102.12, Certified Food Protection Manager, to require that at least one food establishment employee with management and supervisory responsibility be a Certified Food Protection Manager (CFPM). (CFP Issue 2010-II-021)

2-102.20

Revised the section to redesignate the existing paragraph into ¶(A) and adding a new ¶(B) to specify what constitutes compliance with §2-102.12. (CFP Issue 2010-II-021)

2-103.11

Revised the section to add new ¶(F) to address deliveries to a food establishment during non-operating hours and added new ¶(O) to specify that the development and implementation of all required procedures is to be among the expected duties of the person in charge of a food establishment and revised ¶(M) to require the person in charge to inform employees, in a verifiable manner, of requirements to report information about their health and activities as they relate to diseases transmissible through food and redesignated existing ¶(M) as new ¶(N) ; renumbered ¶¶(F) through (M) as new ¶¶(G) through (N); and updated cross reference in new ¶(L) based on changes made in §3-301.11. (CFP Issues 2010-I-011, 2010-I-022, and 2010-I-024)

Part 2-5

Added new Part 2-5, Responding to Contamination Events and new Subpart, 2-501, Procedures for Responding, and new §2-501.11 Clean-up of Vomiting and Diarrheal Events. (CFP Issue 2010-III-023)

Chapter 3 Food

3-301.11

Added new ¶(D) to specify that the prohibition of bare hand contact with ready-to-eat foods does not apply to the handling of ready-to-eat foods as they are being added as ingredients to a food that is to be cooked in the food establishment to a minimum temperature specified in the Code and redesignated existing ¶(D) as new ¶(E); updated internal cross references in ¶(B) and new subparagraph (E)(7). (CFP Issue 2010-III-013)

3-302.11

Revised to add new subparagraph (A)(3) to allow for storage of packaged meats in a manner that precludes the potential for cross contamination and redesignated existing subparagraphs (A)(3) through (A)(8) to be subparagraphs (A)(4) through (A)(9); changed cross reference in ¶(B) lead-in sentence from subparagraph (A)(4) to subparagraph (A)(5). (CFP Issue 2010-III-20)

3-302.15

Added new ¶(C) to address devices used on-site to generate chemicals for washing raw, whole fruits and vegetables. (CFP Issue 2010-III-005)

3-401.12(C)

Editorial change to revise ¶C to a risk designation of Priority Item "P".

3-401.14(F)(5)

Editorial change to correct the cross reference from ¶3-302.11(D) to ¶3-302.11(A).

3-501.17(A)

Editorial change to add new sentence at the end of ¶(A) that reads: "The day of preparation shall be counted as Day 1. ^{Pf}

3-501.19 (B)

Editorial change to revise paragraph to add the term "without" to the introductory sentence so that it reads: (B) If time without temperature control is used . . ."

3-801.11(D)

Editorial change to update cross reference to ¶3-301.11 (B) and (E).

Chapter 4 Equipment, Utensils, and Linens

4-501.114

Added new ¶(F) as requirements for devices that generate chemical sanitizers on-site and moved the priority designation “p” to immediately follow the requirements in the introductory paragraph; deleted “or” from end of ¶(D) and added “and” at end of ¶(E). (CFP Issues 2010-I-019 and 2010-III-005)

Chapter 5 Water, Plumbing, and Waste

5-203.15(A)

Editorial change to add the correct risk designation as a Priority Item “P”.

Chapter 6 Physical Facilities

No Change.

Chapter 7 Poisonous or Toxic Materials

7-204.11

Revised the section to redesignate the existing paragraph into a new lead-in paragraph with ¶¶(A) and (B); added “chemical sanitizers, including chemical sanitizing solutions generated on site” to new lead in paragraph; and added a new ¶(B) to provide additional sanitizer requirements. (CFP Issue 2010-III-005)

7-204.12

Revised ¶(A) to add that chemicals generated on-site for the washing or peeling of raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315; added risk designation to ¶(B) as a Priority Item, “P”; and changed “food establishment” to “FOOD ESTABLISHMENT” in SMALL CAPS. (CFP Issue 2010-III-005)

7-204.14

Added new subparagraphs (A)(3) and (A)(4) to expand the criteria for use of drying agents to include other regulatory procedures that can be used to determine GRAS status of drying agents; redesignated existing subparagraphs (A)(3), (A)(4), and (A)(5) to become new subparagraphs (A)(5), (A)(6) and (A)(7); removed 21 CFR 181 reference in new subparagraph (A)(5) and inserted new cross reference to Federal Food Drug and Cosmetic Act; updated the cross reference in new subparagraph (A)(6) to include part 174; and updated the internal cross references in ¶(B). (CFP Issue 2010-III-024)

Chapter 8 Compliance and Enforcement

8-405.11(B)

Revised the paragraph to redesignate it into subparagraphs (1) and (2) to maintain consistency with the three tier risk designation ranking system and allow, with Regulatory Authority agreement, up to 72 hours to correct violations of a Priority Item or up to 10 days to correct violations of a Priority Foundation Item or HACCP Plan deviations. (CFP Issue 2010-I-017)

Annex 1 Compliance and Enforcement

No Change.

Annex 2 References

2. Bibliography

Preface

Added new references and redesignated numbering.

2-102.12

Added references for new §2-102.12.

2-201.12

Added new references and redesignated numbering.

2-501.11

Added references for new §2-501.11.

3-301.11

Added new references and redesignated numbering.

3-401.14

Added references for §3-401.14.

4-501.114

Added four new references, 3. through 6. and redesignated numbering.

7-204.11

Added two new references, 2. and 3.

7-204.14

Added five new references, 10. through 14.

Annex 3 Public Health Reasons

2-102.12

Added public health reasons for new §2-102.12 to address the presence of a certified food protection manager. (CFP Issue 2010-II-021)

2-103.11

Revised the public health reasons to address deliveries to a food establishment during non-operating hours and added new language to specify that the development and implementation of all required procedures and informing employees in a verifiable manner of requirements to report information about their health and activities as they relate to diseases transmissible through food, is to be among the expected duties of the person in charge of a food establishment. (CFP Issues 2010-I-011, 2010-I-022 and 2010-I-024)

Part 2-2 Employee Health

Revised Subpart 2-201, question 1, to update the cross reference to ¶3-301.11(E).

2-501.11

Added public health reasons for new §2-501.11 to address clean-up of vomiting and diarrheal events. (CFP Issue 2010-III-023)

3-301.11

Added a new paragraph 6 to explain why the prohibition of bare hand contact with ready-to-eat foods does not apply to the handling of foods as they are being added as ingredients to a food that is to be cooked in the food establishment to a minimum temperature specified in the Code; deleted the last sentence in paragraph 2 of ¶3-301.11(D), and redesignated ¶3-301.11(D) as ¶3-301.11(E).
(CFP Issue 2010-III-013)

3-302.11

Added new paragraphs to explain the requirements for storage of packaged meats in a manner that precludes the potential for cross contamination. (CFP Issue 2010-III-020)

3-302.15

Revised paragraph 1 to add language regarding chemicals for washing fruits and vegetables; revised paragraph 2, last sentence, to remove the incorrect reference to subparagraph 2-301.12 (F); and revised paragraph 4, sentence 4, to add the word “not” to correct the sentence to read as: “Pre-cut or pre-washed produce in open bags should not be washed before use” and included web link to additional guidance on cut tomatoes, dated June 8, 2010.

3-304.14

Revised the section to clarify wiping cloth use limitations, including the acceptable uses of dry, disposable single-use towels. (CFP Issue 2010-I-021)

3-502.12

Amended paragraph 2 to correct units for oxygen transfer rate to and Oxygen Transfer Rate of 10,000 cc/m²/24 hours at 24° C.

4-501.114

Added new paragraphs to address the requirements in new ¶(F) on the efficacy of solutions produced by pesticide generating devices (A device used to generate hard food contact surface sanitizers on-site is considered a pesticide device) and efficacy standards for those solutions and provided information on how to verify that efficacy is met. (CFP Issue 2010-III-005)

7-204.11

Added two new paragraphs following the existing paragraph, to address chemical agents being applied as a sanitizer and OSHA limits for gases dissolved in solutions. (CFP Issue 2010-III-005)

7-204.12, 7-204.13, 7-204.14

Revised for §7-204.12 paragraph 3 to now indicate that chemicals for washing fruits and vegetables can be generated on-site. (CFP Issue 2010-III-005)

Revised for §7-204.14 paragraphs 1-3 to add information about food additives, food contact substances, GRAS and prior sanctioned. (CFP Issue 2010-III-024)

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

Table 2

Editorial change to restructure Table 2 so the header rows for “Naturally Occurring” and “Added Chemicals” match the table content; moved Allergens under “Naturally Occurring”.

Annex 5 Conducting Risk-based Inspections

No Change.

Annex 6 Food Processing Criteria

No Change.

Annex 7 Models Forms, Guides, and Other Aids

Form 1-D, Application for Bare Hand Contact Procedure

Editorial change to update the title of Form 1-D to reference ¶3-301.11(E).

Guide 3-B, Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices

Editorial change to revise Section B, Risk Factors and Interventions, under Control of Hands as a Vehicle of Contamination, Item 7, IN/OUT and Applicable Code Sections, to update the cross reference to ¶3-301.11(E).

Editorial change to revise Section B, Risk Factors and Interventions, under Potentially Hazardous Food (PHF) (Time Temperature Control for Safety Food (TCS Food), Item 16, Applicable Code Sections, to add §3-304.14 to the list of applicable code sections.

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

Preface

Amend Preface Section 1 to revise the foodborne illness statistics to state the 2011 CDC estimates of foodborne illness in the United States to read as follows:

1. FOODBORNE ILLNESS ESTIMATES, RISK FACTORS, AND INTERVENTIONS

Foodborne illness in the United States is a major cause of personal distress, preventable illness and death, and avoidable economic burden. Scallan et al. (2011a,b) estimated that foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the United States each year. The occurrence of approximately 1,000 reported disease outbreaks (local, regional, and national) each year highlights the challenges of preventing these infections.

Most foodborne illnesses occur in persons who are not part of recognized outbreaks. For many victims, foodborne illness results only in discomfort or lost time from the job. For some, especially preschool age children, older adults in health care facilities, and those with impaired immune systems, foodborne illness is more serious and may be life threatening.

Paragraphs 3 – 7 No Change.

Chapter 1

Purpose and Definitions

No Change.

Amend Chapter 2 to add new §2-102.12, Certified Food Protection Manager, to read as follows:

2-102.12 Certified Food Protection Manager

(A) At least one EMPLOYEE that has supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM.

(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 food preparation.

Amend §2-102.20 to separate the provision into two paragraphs by redesignating the existing paragraph as ¶A and adding a new ¶B to read as follows:

2-102.20 Food Protection Manager Certification

2-102.20 Food Protection Manager Certification.

(A) A PERSON IN CHARGE who demonstrates knowledge by being a FOOD protection manager that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs is deemed to comply with ¶2-102.11(B).

(B) A FOOD ESTABLISHMENT that has an EMPLOYEE that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs is deemed to comply with §2-102.12.

Amend §2-103.11 to add new ¶(F), revise existing ¶(M) and redesignate existing ¶(M) as new ¶(N); redesignate by renumbering ¶¶(F) through (M) as new ¶¶(G) through (N); add new ¶(O); and updated cross reference in new ¶(L) based on changes made in §3-301.11 to read as follows:

Duties

2-103.11 Person in Charge.

The PERSON IN CHARGE shall ensure that:

(A) – (E) No Change.

(F) EMPLOYEES are verifying that FOODS delivered to the FOOD ESTABLISHMENT during non-operating hours are from APPROVED sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, UNADULTERATED, and accurately presented;^{Pf}

(G) EMPLOYEES are properly cooking POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD), being particularly careful in cooking those FOODS known to cause Severe foodborne illness and death, such as EGGS and COMMINUTED MEATS, through daily oversight of the EMPLOYEES' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under § 4-203.11 and ¶ 4-502.11(B);^{Pf}

(H) EMPLOYEES are using proper methods to rapidly cool POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS) that are not held hot or are not for consumption within 4 hours, through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures during cooling;^{Pf}

(I) CONSUMERS who order raw; or partially cooked READY-TO-EAT FOODS of animal origin are informed as specified under § 3-603.11 that the FOOD is not cooked sufficiently to ensure its safety;^{Pf}

(J) EMPLOYEES are properly SANITIZING cleaned multiuse EQUIPMENT and UTENSILS before they are reused, through routine monitoring of solution temperature and exposure time for hot water SANITIZING, and chemical concentration, pH, temperature, and exposure time for chemical SANITIZING;^{Pf}

(K) CONSUMERS are notified that clean TABLEWARE is to be used when they return to self-service areas such as salad bars and buffets as specified under § 3-304.16;^{Pf}

(L) Except when APPROVAL is obtained from the REGULATORY AUTHORITY as specified in ¶ 3-301.11(E), EMPLOYEES are preventing cross-contamination of READY-TO-EAT FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT;^{Pf}

(M) EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties;^{Pf}

(N) FOOD EMPLOYEES and CONDITIONAL EMPLOYEES are informed in a verifiable manner of their responsibility to report in accordance with LAW, to the PERSON IN CHARGE, information about their health and activities as they relate to diseases that are transmissible through FOOD, as specified under ¶ 2-201.11(A);^{Pf} and

(O) Written procedures and plans, where specified by this Code and as developed by the FOOD ESTABLISHMENT, are maintained and implemented as required.^{Pf}

Amend Chapter 2 to add new Part 2-5, Responding to Contamination Events and new Subpart, 2-501, Procedures for Responding, and new Section 2-501.11 Clean-up of Vomiting and Diarrheal Events to read as follows:

Chapter 2

Management and Personnel

Parts

- 2-1 SUPERVISION**
- 2-2 EMPLOYEE HEALTH**
- 2-3 PERSONAL CLEANLINESS**
- 2-4 HYGIENIC PRACTICES**
- 2-5 RESPONDING TO CONTAMINATION EVENTS**

2-5 RESPONDING TO CONTAMINATION EVENTS

Subpart

2-501 *Procedures for Responding*

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

A FOOD ESTABLISHMENT shall have procedures for EMPLOYEES to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the FOOD ESTABLISHMENT. The procedures shall address the specific actions EMPLOYEES must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter.^{Pf}

Amend §3-301.11 to revise ¶(B) to add cross reference ¶¶ (D) and (E); add new ¶(D), re-designate existing ¶(D) as new ¶(E); and revise the internal cross reference in new subparagraph (E)(7) to reference subparagraphs (E)(1)-(6) to read as follows:

**Preventing
Contamination
by Employees**

3-301.11 Preventing Contamination from Hands.

(A) No Change.

(B) Except when washing fruits and vegetables as specified under §3-302.15 or as specified in ¶¶ (D) and (E) of this section, FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT.^P

(C) No Change.

(D) Paragraph (B) of this section does not apply to a FOOD EMPLOYEE that contacts exposed, READY-TO-EAT FOOD with bare hands at the time the READY-TO-EAT FOOD is being added as an ingredient to a FOOD that:

(1) contains a raw animal FOOD and is to be cooked in the FOOD ESTABLISHMENT to heat all parts of the FOOD to the minimum temperatures specified in ¶¶3-401.11(A)-(B) or §3-401.12; or

(2) does not contain a raw animal FOOD but is to be cooked in the FOOD ESTABLISHMENT to heat all parts of the FOOD to a temperature of at least 74°C (165°F).

(E) FOOD EMPLOYEES not serving a HIGHLY SUSCEPTIBLE POPULATION may contact exposed, READY-TO-EAT FOOD with their bare hands if:

(1) - (6) No Change.

(7) Documentation that corrective action is taken when Subparagraphs (E)(1) - (6) of this section are not followed.

Amend § 3-302.11 to add new subparagraph (A)(3), re-designate existing subparagraphs (A)(3) through (A)(8) to be subparagraphs (A)(4) through (A)(9) and change cross reference in ¶(B) lead-in sentence from subparagraph (A)(4) to subparagraph (A)(5) to read as follows:

**Preventing Food
and Ingredient
Contamination**

**3-302.11 Packaged and Unpackaged Food - Separation,
Packaging, and Segregation.**

(A) FOOD shall be protected from cross contamination by:
(1) – (2) No Change.

(3) Not storing and displaying COMMINUTED or otherwise non-intact MEATS above whole-muscle intact cuts of MEAT unless they are PACKAGED in a manner that precludes the potential for cross-contamination;

(4) Cleaning EQUIPMENT and UTENSILS as specified under ¶ 4-602.11(A) and SANITIZING as specified under § 4-703.11;

(5) Except as specified under Subparagraph 3-501.15(B)(2) and in ¶ (B) of this section, storing the FOOD in packages, covered containers, or wrappings;

(6) Cleaning HERMETICALLY SEALED CONTAINERS of FOOD of visible soil before opening;

(7) Protecting FOOD containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

(8) Storing damaged, spoiled, or recalled FOOD being held in the FOOD ESTABLISHMENT as specified under § 6-404.11; and

(9) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 from READY-TO-EAT FOOD.

(B) Subparagraph (A)(5) of this section does not apply to:

(1) – (5) No Change.

Amend §3-302.15 to add new ¶(C) to address devices used on-site to generate chemicals for washing raw, whole fruits and vegetables to read as follows:

3-302.15 Washing Fruits and Vegetables.

(A) – (B) No Change.

(C) Devices used for on-site generation of chemicals meeting the requirements specified in 21 CFR 173.315, Chemicals used in the washing or to assist in the peeling of fruits and vegetables, for the washing of raw, whole fruits and vegetables shall be used in accordance with the manufacturer's instructions.^{Pf}

Amend §3-401.12 to change ¶C to a Priority Item "P" to read as follows:

3-401.12 Microwave Cooking.

Raw animal FOODS cooked in a microwave oven shall be:

(A) – (B) No Change.

(C) Heated to a temperature of at least 74°C (165°F) in all parts of the FOOD;^P and

(D) No Change.

Amend subparagraph 3-401.14(F)(5) to correct the cross reference from ¶3-302.11(D) to ¶3-302.11(A) to read as follows:

3-401.14 Non-Continuous Cooking of Raw Animal Foods.

(A) – (F)(4) No Change.

Raw animal FOODS that are cooked using a NON-CONTINUOUS COOKING process shall be:

(F) Prepared and stored according to written procedures that:

(5) Describe how the FOODS, after initial heating but prior to cooking as specified under ¶(D) of this section, are to be separated from READY-TO-EAT FOODS as specified under ¶3-302.11 (A).^{Pf}

Amend §3-501.17 to revise ¶(A) to add new sentence at the end of ¶(A) to read as follows:

**3-501.17 Ready-to-Eat, Potentially Hazardous Food
(Time/Temperature Control for Safety Food),
Date Marking.**

**on-premises
preparation**

- *prepare and hold cold*

(A) Except when PACKAGING FOOD using a REDUCED OXYGEN PACKAGING method as specified under § 3-502.12, and except as specified in ¶¶ (D) and (E) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) prepared and held in a FOOD ESTABLISHMENT for more than 24 hours shall be clearly marked to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded when held at a temperature of 5°C (41°F) or less for a maximum of 7 days. The day of preparation shall be counted as Day 1. ^{Pf}

Amend §3-501.19 to revise ¶(B) to add the term “without” to the introductory sentence so that it reads as follows:

3-501.19 Time as a Public Health Control.

(A) No Change.

***Time –
maximum up to
4 hours***

(B) If time without temperature control is used as the public health control up to a maximum of 4 hours:

(1) – (5) No Change.

(C) – (D) No Change.

Amend ¶3-801.11 to revise ¶(D) to update the cross reference in ¶(D) to ¶3-301.11(B) and (E) to read as follows:

**Additional
Safeguards**

3-801.11 Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) – (C) No Change.

(D) FOOD EMPLOYEES may not contact READY-TO-EAT FOOD as specified under ¶¶ 3-301.11(B) and (E).^P

(E) – (F) No Change.

Amend § 4-501.114 to move the Priority Item risk designation “P” to immediately follow the requirements in the introductory paragraph; to delete “or” from end of ¶(D) and add “and” at end of ¶(E); add new ¶(F) to read as follows:

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶4-703.11(C) shall meet the criteria specified under §7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions,^P and shall be used as follows:

(A) – (C) No Change.

(D) If another solution of a chemical specified under ¶¶ (A) - (C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITIZATION and the use of the solution shall be APPROVED;^P

(E) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions;^P and

(F) If a chemical SANITIZER is generated by a device located on-site at the FOOD ESTABLISHMENT it shall be used as specified in ¶¶(A) - (D) of this section and shall be produced by a device that:

(1) Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),^P

(2) Complies with 40 CFR 152.500 Requirement for

Devices and 40 CFR 156.10 Labeling Requirements,^P

(3) Displays the EPA device manufacturing facility registration number on the device,^{Pf} and

(4) Is operated and maintained in accordance with manufacturer's instructions^{Pf}.

**Chapter
5**

Water, Plumbing, and Waste

Amend §5-203.15 to revise ¶(A) to add the correct risk designation as a Priority Item "P" to read as follows:

5-203.15 Backflow Prevention Device, Carbonator.

(A) If not provided with an air gap as specified under §5-202.13, a dual check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 25.4 mm (100 mesh to 1 inch) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.^P

(B) No Change.

**Chapter
6**

Physical Facilities

No Change.

Amend §7-204.11 to redesignate the provision into a new lead-in paragraph with ¶¶(A) and (B); add “chemical sanitizers, including chemical sanitizing solutions generated on site” to new lead in paragraph; and add a new ¶(B) to read as follows:

Chemicals**7-204.11 Sanitizers, Criteria.**

Chemical SANITIZERS, including chemical sanitizing solutions generated on-site, and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall:

(A) Meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)^P, or

(B) Meet the requirements as specified in 40 CFR 180.2020 Pesticide Chemicals Not Requiring a Tolerance or Exemption from Tolerance-Non-food determinations.^P

Amend §7-204.12 to revise ¶(A) to add that chemicals generated on-site for the washing or peeling of raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315; add risk designation to ¶(B) as a Priority Item, “P”; and change “food establishment” to “FOOD ESTABLISHMENT” in SMALL CAPS to read as follows:

7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.

(A) Chemicals, including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables.^P

(B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a FOOD ESTABLISHMENT shall meet the requirements specified in 21 CFR 173.368 Ozone.^P

Amend §7-204.14 to add new subparagraphs (A)(3) and (A)(4); redesignate existing subparagraphs (A)(3), (A)(4), and (A)(5) to become new subparagraphs (A)(5), (A)(6), and (A)(7); remove 21 CFR 181 reference in new subparagraph (A)(5) and insert new cross reference to Federal Food Drug and Cosmetic Act; update the cross reference in new subparagraph (A)(6) to include part 174; and update the internal cross references in ¶(B) to read as follows:

7-204.14 Drying Agents, Criteria.

Drying agents used in conjunction with SANITIZATION shall:

(A) Contain only components that are listed as one of the following:

(1) Generally recognized as safe for use in FOOD as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe,^P

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe,^P

(3) Generally recognized as safe for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to FOOD as described in 21 CFR 170.30 Eligibility for classification as generally recognized as safe (GRAS),^P

(4) Subject of an effective Food Contact Notification as described in the Federal Food Drug and Cosmetic Act (FFDCA) Section 409(h),^P

(5) APPROVED for use as a drying agent under a prior sanction as described in the Federal Food Drug and Cosmetic Act (FFDCA) § 201(s)(4);^P

(6) Specifically regulated as an indirect FOOD ADDITIVE for use as a drying agent as specified in 21 CFR Parts 174-178,^P or

(7) APPROVED for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles;^P and

(B) When SANITIZATION is with chemicals, the approval required under Subparagraph (A)(5) or (A)(7) of this section or the regulation as an indirect FOOD ADDITIVE required under Subparagraph (A)(6) of this section, shall be specifically for use with chemical SANITIZING solutions. ^P

**Chapter
8**

Compliance and Enforcement

Amend §8-405.11 to revise ¶(B) to redesignate the paragraph into subparagraphs (1) and (2) to read as follows:

**Violation of
Priority Item or
Priority
Foundation Item**

8-405.11 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall at the time of inspection correct a violation of a PRIORITY ITEM or PRIORITY FOUNDATION ITEM of this Code and implement corrective actions for a HACCP PLAN provision that is not in compliance with its CRITICAL LIMIT. ^{Pf}

(B) Considering the nature of the potential HAZARD involved and the complexity of the corrective action needed, the REGULATORY AUTHORITY may agree to or specify a longer time frame, not to exceed:

(1) 72 hours after the inspection, for the PERMIT HOLDER to correct violations of a PRIORITY ITEM; or

(2) 10 calendar days after the inspection, for the PERMIT HOLDER to correct violations of a PRIORITY FOUNDATION ITEM or HACCP PLAN deviations.

**Annex
1**

Compliance and Enforcement

No Change.

2. BIBLIOGRAPHY

Preface

Amend References for the Preface to add new references and redesignate numbering to read as follows:

1. No Change.

2. Center for Disease Control and Prevention (CDC), 2011. Vital Signs: Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food --- Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996—2010. *Morb. Mortal. Wkly. Rep.* 60:1-7.
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Chapter 1 Purpose and Definitions

No Change in Annex 2, References, for Chapter 1.

Chapter 2 Management and Personnel

2-102.12 Certified Food Protection Manager.

Amend References to add new §2-102.12, Certified Food Protection Manager, to add references to read as follows:

1. Hedberg, C.W., S.J. Smith, E. Kirkland, V. Radke, T.F. Jones, C.A. Selman and the EHS-Net Working Group. 2006. Systematic Environmental Evaluations to Identify Food Safety Differences between Outbreak and Nonoutbreak Restaurants. *J. Food Protect.* 69(11): 2697-2702.
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2-201.12 Exclusions and Restrictions.

Amend References for §2-201.12 to add a new reference and redesignate numbering to read as follows:

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

Amend References to add new §2-501.11, Clean-up of Vomiting and Diarrheal Events, to add references to read as follows:

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3-301.11 Preventing Contamination from Hands.

Amend References for §3-301.11 to add new references and redesignate numbering to read as follows:

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3-401.14 Non-Continuous Cooking of Raw Animal Foods.

Amend References for §3-401.14 to add references to read as follows:

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2. Code of Federal Regulations, Title 9, § 318.23 Heat-processing and stabilization requirements for uncured meat patties found at http://edocket.access.gpo.gov/cfr_2011/janqtr/pdf/9cfr318.23.pdf
3. Code of Federal Regulations, Title 9, § 381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips found at http://edocket.access.gpo.gov/cfr_2011/janqtr/pdf/9cfr381.150.pdf

Chapter 4 Equipment, Utensils, and Linens

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness

Amend references for §4-501.114 to add four new references 3. through 6. and redesignate numbering to read as follows:

1. and 2. **No Change.**
3. Code of Federal Regulations, Title 40 Part 152.500 Pesticide registration and classification procedures, Requirements for devices found at http://edocket.access.gpo.gov/cfr_2009/julqtr/pdf/40cfr152.500.pdf
4. Code of Federal Regulations, Title 40 Part 156.10 Labeling requirements for pesticides and devices found at http://edocket.access.gpo.gov/cfr_2009/julqtr/pdf/40cfr156.10.pdf
5. EPA's Good Laboratory Practices Standards (GLPS) found at <http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html>

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7. Miller, M.P., Principal Investigator, 1984. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.

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9. National Sanitation Foundation, Ann Arbor, MI. November, 1990. Report on the Bacterial Effectiveness of a Chlorine Sanitizing Solution at Contact Times of Less than Ten Seconds. Purchase Order #FDA 665531-00-90-RB

Chapter 5 Water, Plumbing, and Waste

No Change in Annex 2, References, for Chapter 5.

Chapter 6 Physical Facilities

No Change in Annex 2, References, for Chapter 6.

Chapter 7 Poisonous or Toxic Materials

7-204.11 Sanitizers, Criteria

Amend References for §7-204.11 to add two new references 2. and 3. to read as follows:

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions) found at:
http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/40cfr180.940.pdf

2. Code of Federal Regulations, Title 40 Part 180.2020 Pesticide Chemicals Not Requiring a Tolerance or an Exemption From Tolerance-Non-Food determinations found at: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/40cfr180.2020.pdf

3. Code of Federal Regulations, Title 29 Part 1910.1000 Occupational Safety and Health Standards found at:
http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/29cfr1910.1000.pdf

7-204.14 Drying Agents, Criteria.

Amend References for §7-204.14 to add five new references, 10. through 14. to read as follows:

1. Code of Federal Regulations, Title 21, Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe.
2. Code of Federal Regulations, Title 21, Parts 175, Indirect Food Additives: Adhesives and Components of Coatings.
3. Code of Federal Regulations, Title 21, Parts 178, Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers.
4. Code of Federal Regulations, Title 21, Parts 176, Indirect Food Additives: Paper and Paperboard Components.
5. Code of Federal Regulations, Title 21, Parts 177, Indirect Food Additives: Polymers.
6. Code of Federal Regulations, Title 21, Part 186, Indirect Food Substances Affirmed as Generally Recognized as Safe.
7. Code of Federal Regulations, Title 21, Part 181, Prior-Sanctioned Food Ingredients.
8. Code of Federal Regulations, Title 21, Part 182, Substances Generally Recognized as Safe.
9. Code of Federal Regulations, Title 21, Part 170.39, Threshold of regulation for substances used in food-contact articles.
10. Code of Federal Regulations, Title 21, Part 170.30, Eligibility for classification as generally recognized as safe (GRAS)
11. Code of Federal Regulations, Title 21, Part 174, Indirect Food Additives: General.

12. Federal Food Drug and Cosmetic Act, Section, 409 (h),
<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/FDCActChapterIVFood/ucm107843.htm>

13. Federal Food Drug and Cosmetic Act, Section 201(s)(4)
<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/FDCActChapterslandIIShortTitleandDefinitions/ucm086297.htm>

14. Food Contact Notification, Ingredients and Packaging,
<http://www.fda.gov/Food/FoodIngredientsPackaging/default.htm>

**Annex
3**

***Public Health Reasons/
Administrative Guidelines***

Chapter 1 Purpose and Definitions

No Change in Annex 3, Public Health Reasons, for Chapter 1.

Chapter 2 Management and Personnel

2-102.12 Certified Food Protection Manager.

Amend Public Health Reasons to add new §2-102.12 to read as follows:

2-102.12 Certified Food Protection Manager

The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks and other economic, staffing, cultural and behavioral challenges make it imperative that food protection managers know and control the risk factors that impact the safety of the food they sell or serve. Food protection managers have an important role in formulating policies, verifying food employees carry out these policies, and communicating with these same employees to give information about recommended practices to reduce the risk of foodborne illness. A Centers for Disease Control and Prevention Environmental Health Specialist-Network (EHS-Net) study suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak for an establishment and was a distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had not.

FDA's Retail Food Risk Factor Studies suggest that the presence of a certified manager has a positive correlation with more effective control of certain risk factors, such as poor personal hygiene, in different facility types.

There are a number of state and local agencies that currently mandate food protection manager certification. It is appropriate for State and local agencies, by way of codes and ordinances or by policy to establish criteria for what types of permitted establishments could be exempt from the mandatory manager certification requirement and for determining the conditions under which the minimum number of certified food protection managers must be some number greater than one.

Factors to consider when establishing such criteria include:

- the size and scope of the operation;
- the hours of operation;
- the types of foods sold or served;
- the extent to which food is prepared on site;
- the number of staff,
- type of population served, e.g. highly susceptible or not; and
- the number of meals served.

Duties 2-103.11 Person in Charge.

Amend Public Health Reasons for §2-103.11 to insert new paragraphs 3 and 4 to follow existing paragraph 2; redesignate existing paragraphs 3 and 4 to become new paragraphs 5 and 6; add three paragraphs to the end of the section to read as follows:

A primary responsibility of the person in charge is to ensure compliance with Code requirements. 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.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

When food and other purchased goods are delivered and placed into designated locations within the food establishment during non-operating hours, the Person in Charge must make sure food employees inspect such product and verify that it is from the appropriate supplier, is in the desired condition, and was delivered to a proper storage location. Distributors deliver and place food and other goods in refrigeration units, freezers, and dry storage areas for confirmation of receipt and inspection by employees immediately upon arrival to the food establishment. Distributors contracted by the food establishment are often given a key to allow access into the establishment outside of normal working hours. Upon delivery, all food must be appropriately stored in a safe and secure manner within the food establishment. For example, potentially hazardous foods (time/temperature control for safety foods) must be stored within refrigeration units and held at temperatures of 41°F or below. Likewise, if the food product is frozen, it must be placed into the freezer.

To minimize the potential for access to the food establishment and the food by an unauthorized person, precautions should be applied overall to the food establishment

and especially when access to the facility is made under key access deliveries. Additional information on food defense can be viewed at: <http://www.fda.gov/Food/FoodDefense/default.htm>

Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans. Restaurant and retail food service managers need to be aware of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; to know the eight major food allergens; to understand food allergen ingredient identities and labeling; and to avoid cross-contact during food preparation and service. The 2008 Conference of Food Protection (CFP) passed Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of the Person in Charge. Accordingly, the Person in Charge's Duties under paragraph (M) were amended to assure the food safety training of employees includes food allergy awareness in order for them to safely perform duties related to food allergies.

Paragraph (M) "EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties" allows industry to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

Paragraph (N) emphasizes the important role the Person in Charge (PIC) has in making sure employees properly report certain information about their health status as it relates to diseases that are transmitted by food. In an effort to reinforce dialogue between food employees and the PIC, there must be a way to verify that food employees and conditional employees are informed of their responsibility to report such information. Examples of ways to verify that employees have been appropriately informed include:

- The ability to provide documentation that all food employees and conditional employees are informed of their responsibility to report to management, such as completion of Form 1-B, "Conditional Employees or Food Employees Reporting Agreement" in Annex 7 or other similar state or local forms containing the same information;
- Presenting evidence such as curriculum and attendance rosters documenting that each employee has completed a training program which includes all the information required for reporting in Form 1-B;
- Implementation of an employee health policy that includes a system of employee notification using a combination of training, signs, pocket cards or other means to convey all the required information (Refer to Annex 3, 2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201, for further guidance);
- Other methods that satisfactorily demonstrate that all food employees and conditional employees are informed of their responsibility to report to the PIC

information about their health and activities as it relates to diseases that are transmissible through food, as specified under ¶2-201.11 (A)

In various places throughout the Code, it is specified that either written operating procedures or operational plans be developed. The link between management responsibility for developing and implementing the procedures or plans is now established as a new duty for the Person in Charge (PIC). This new provision does not establish new requirements in the development of plans or procedures; rather it emphasizes the importance of the role the PIC plays in ensuring active managerial control of the food establishment with the development and implementation of plans and/or procedures as specified in this Code. Examples of Code provisions that call for the development of plans or procedures can be found in: §2-501.11, ¶¶3-301.11(D) and 3-401.14 (F), §§ 3-501.19, and 5-205.14. Ultimately, responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems. There are many tools that industry can use to develop an effective system to achieve active managerial control of foodborne illness risk factors. An important tool in controlling risk factors inherent in a food establishment is the development and implementation of written procedures or plans.

(Also refer to Annex 4 – Management of Food Safety Practices (1) (D) for further information):

2-2 Employee Health

Amend Public Health Reasons for Part 2-2 Employee Health, Subpart 2-201, question 1, to update the cross reference to ¶3-301.11(E) to read as follows:

Overall goals No Change.

2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201

The information provided in Subpart 2-201 is designed to assist food establishment managers and regulatory officials in removing infected food employees when they are at greatest risk of transmitting foodborne pathogens to food. Practical applications of the information in Subpart 2-201 by a food establishment manager may involve using Subpart 2-201 as a basis for obtaining information on the health status of food employees and can also be used as a basis in developing and implementing an effective Employee Health Policy. Regulatory officials can benefit by using the information provided below as a basis for determining compliance with Subpart 2-201 during a facility food safety inspection.

The development and effective implementation of an employee health policy based on the provisions in Subpart 2-201 may help to prevent foodborne illness associated with

contamination of food by ill or infected food employees. The person in charge and food employees should be familiar with and able to provide the following information through direct dialogue or other means when interviewed by facility managers or regulatory officials. Compliance must be based, however, on first hand observations or information and cannot be based solely on responses from the person in charge to questions regarding hypothetical situations or knowledge of the Food Code. Also, when designing and implementing an employee health policy, the following information should be considered and addressed:

1. Does the establishment have an Employee Health Policy? If so, are the food employees aware of the employee health policy, and is it available in written format and readily available for food employees? (Note: A written Employee Health Policy is not a Food Code requirement unless the facility is operating under a pre-approved alternative procedure specified under ¶3-301.11(E)).
2. Does the establishment require conditional employees and food employees to report certain illnesses, conditions, symptoms, and exposures?
3. Are the reporting requirements explained to all employees?
4. What are the reporting requirements for conditional employees, food employees, and the food establishment manager?
5. Are conditional employees asked if they are experiencing certain symptoms or illnesses upon offer of employment? If so, which symptoms or illnesses?
6. If a food employee reports a diagnosis with one of the 5 listed pathogens in the Food Code, what questions are asked of the food employee? (The first question every food manager should ask a food employee who reports diagnosis with a listed pathogen is if the employee is currently having any symptoms.)
7. Who does the establishment notify when a food employee reports a diagnosis with one of the listed pathogens?
8. What gastrointestinal symptoms would require exclusion of a food employee from the food establishment?
9. What history of exposure is a conditional employee or food employee required to report?
10. If a food employee reports a gastrointestinal symptom, what criteria are used to allow the employee to return to work?

2-201.11 No Change.

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

Amend Public Health Reasons to add new §2-501.11 to read as follows:

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

When an employee, customer, or other individual vomits or has a diarrheal event in a food establishment, there is a real potential for the spread of harmful pathogens in the establishment. Putting the proper response into action in a timely manner can help

reduce the likelihood that food may become contaminated and that others may become ill as a result of the accident.

According to the CDC, Norovirus is the leading cause of foodborne disease outbreaks in the United States. More specifically, Noroviruses are the most common cause of sporadic cases and outbreaks of acute gastroenteritis. Norovirus is the most common cause of gastroenteritis in people of all ages and it is responsible for greater than 50% of all foodborne gastroenteritis outbreaks. CDC estimates that 21 million cases of acute gastroenteritis are due to Norovirus infection.

Noroviruses can be highly contagious, and it is thought that an inoculum of as few as 10-18 viral particles may be sufficient to infect an individual. Transmission occurs via foodborne and person-to-person routes, airborne inhalation of vomitus droplets, and also through contact with contaminated environmental surfaces. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed.

In addition, the potential transmission level of Norovirus shed in the feces at levels up to 1 trillion viral particles per gram of feces and one projectile vomiting incident can contaminate the environment with 300,000 viral particles. One study found that employees who reported having cleaned up vomitus were more likely to contract illness than those who did not.

Norovirus causes acute onset of vomiting (often explosive) and diarrhea (also often explosive) which can contaminate surfaces and become airborne increasing the chances of additional infections. A recent study has also shown that the bathroom environment was identified as a major reservoir of human Norovirus, even in the absence of an ill individual on site. Studies have shown that Norovirus can survive on fomite surfaces for up to at least 5 days at room temperature and that routine cleaning, without a disinfectant specifically to address Norovirus, may be ineffective in eliminating its presence on fomite surfaces and can even serve as a means of spreading the virus to other fomites.

Effective clean up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact surfaces and disinfecting countertops and floors, such as certain quaternary ammonium compounds, may not be effective against Norovirus. It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration.

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.

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

- the procedures for containment and removal of any discharges, including airborne particulates;
- the procedure for cleaning, sanitizing, and, as necessary, the disinfection 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;
- the availability of effective disinfectants, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and their proper use;
- procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter;
- 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 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;
- minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in §2-201.12 of the Food Code;
- minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and
- the conditions under which the plan will be implemented.

When a food employee has been diagnosed, has recent history or exposure to, or is the suspect source of a confirmed disease outbreak of Norovirus, it must be reported to the person in charge per the FDA Food Code in subparagraphs 2-201.11 (A)(2)(a), 2-201.11(A)(4)(a), 2-201.11(A)(5)(a), and ¶2-201.11(B). If a food employee has been diagnosed with Norovirus it must also be reported to the regulatory authority. Refer to public health reasons for §2-201.11 Responsibility of the Person in Charge, Food

Employees, and Conditional Employees for more information about appropriate employee health policies.

Chapter 3 Food

Preventing Contamination by Employees

3-301.11

Preventing Contamination from Hands.

Amend Public Health Reasons for §3-301.11 to add new paragraph 6 between existing paragraphs 5 and 6; redesignate existing paragraph 6 as paragraph 7; delete the last sentence in paragraph 2 of ¶3-301.11(D), and redesignate ¶3-301.11(D) as ¶3-301.11(E) to read as follows:

Paragraphs 1 – 5

No Change.

If a ready-to-eat food is being added as an ingredient to a food item that is subsequently subjected to a pathogen kill step (such as adding cheese or other ready-to-eat toppings to a pizza dough or adding vegetables to a raw meat dish before cooking) then strict prohibition of bare hand contact is not necessary. Cooking foods to the temperatures required in the Food Code will reduce the likelihood of survival of pathogens that might be transferred from an employee's hands to the surface of the ready-to-eat foods. The exception specifically targets bare hand contact with ready-to-eat food at the time it is added as an ingredient to food that will be cooked in the food establishment to the minimum temperatures specified in the Food Code. The exception does not apply when adding ready-to-eat foods as ingredients to foods that will only be lightly heated, melted, or browned rather than cooked to the minimum temperatures specified in this section. Nor does this exception apply when adding ready-to-eat foods as ingredients to foods that are intended for preparation by the consumer offsite. When proper heat treatment is used in combination with the exclusion/restriction of ill food workers and proper handwashing, the proper heat treatment provides an additional means of interrupting disease transmission.

Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.14.

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

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause.¹ Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are

¹Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks – United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewish, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used.

Because highly susceptible populations include persons who are immunocompromised, the very young and the elderly, establishments serving these populations may not use alternatives to the no bare hand contact with ready-to-eat food requirement.

Acceptability of an alternative procedure to no bare hand contact requires prior approval from the regulatory authority based on the food establishment having a written employee health policy that details how the establishment complies with management of ill employees as specified under sections 2-201.11 - .13 and management of handwashing practices as specified under Part 2-3 of the Code. The approval should also be based on evidence provided through written procedures and documentation that at least all of the following are addressed:

(A) **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in section 2-301.14, including after using the toilet and between tasks that may recontaminate the hands.

(B) **Hygienic Practices** as specified in Part 2-4.

(C) **Employee Health** regarding:

(1) **Reporting of diseases and medical conditions**, and

(2) **Exclusions and restrictions**, i.e., that food employees and conditional employees report their health status as specified in section 2-201.11; ill food employees are restricted or excluded as specified in section 2-201.12; and the exclusions and restrictions are removed as specified in section 2-201.13;

(D) How the alternative practices and procedures will control the hazard through an active managerial control program. Such a program includes monitoring and verifying the institution of the provisions described in paragraphs A-C above and satisfies the following:

(1) The public health hazard associated with bare hand contact specific to the food establishment operation is identified and understood. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

(2) The ready-to-eat foods that will be contacted with bare hands are identified and both procedures and practices are in place so that food employees wash their hands before returning to their work station and cross-contamination from touching raw and ready-to-eat food is precluded.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

(3) Institution of an effective training program for food employees that emphasizes not working when ill with any of the gastrointestinal symptoms listed in the Code, and explains good hygienic practices, proper handwashing procedures, and safe food preparation procedures. This should include a documented training plan that specifies how management responsibility for training has been designated, training program content, and the frequency of administration including periodic refresher sessions.

(E) The alternative procedure should clearly describe monitoring, documentation, and verification actions to ensure that the practices and procedures are followed. Corrective actions need to be predetermined for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

(F) Documentation of the practices, procedures, and corrective actions related to an alternative to no bare hand contact with ready-to-eat food must be maintained and readily available at the food establishment at all times for use by the person in charge and for review by the regulatory authority.

**Preventing
Food and
Ingredient
Contamination**

**3-302.11 Packaged and Unpackaged Food – Protection
Separation, Packaging, and Segregation.**

***Amend Public Health Reasons for §3-302.11 to add new paragraphs explaining
the requirements for storage of meats to read as follows:***

It is important to separate foods in a ready-to-eat form from raw animal foods during storage, preparation, holding and display to prevent them from becoming contaminated by pathogens that may be present in or on the raw animal foods. An exception is permitting the storage and display of frozen, commercially packaged raw animal food adjacent to or above frozen, commercially packaged ready-to-eat food. The freezer equipment should be designed and maintained to keep foods in the frozen state. Corrective action should be taken if the storage or display unit loses power or otherwise fails. Raw or ready-to-eat foods or commercially processed bulk-pack food that is packaged on-site presents a greater risk of cross-contamination. Additional product handling, drippage during the freezing process, partial thawing or incomplete seals on the package increase the risk of cross-contamination from these products packaged in-house.

With regard to the storage of different types of raw animal foods as specified under subparagraph 3-302.11(A)(2), it is the intent of this Code to require separation based on anticipated microbial load and raw animal food type (species). Separating different types of raw animal foods from one another during storage, preparation, holding and display will prevent cross-contamination from one to the other. The required separation is based on a succession of cooking temperatures as specified under § 3-401.11 which are based on thermal destruction data and anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are required to be cooked to an internal temperature of 145°F for 15 seconds, shall be stored above or away from raw poultry, which is required to be cooked to an internal temperature of 165°F for 15 seconds due to its considerably higher anticipated microbial load. In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution.

Storing or displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat can also present a cross-contamination hazard unless they are packaged and displayed in a manner that creates a barrier to prevent leakage of contents from one package to the other. Cooking recommendations assume that lower levels of contamination will be present in whole muscle products than in non-intact meats. If the whole muscle product is subject to cross-contamination, the

recommended cooking temperature may not be sufficient to ensure the safety of the product.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

3-302.15

Washing Fruits and Vegetables.

Amend Public Health Reasons for §3-302.15 to revise paragraphs 1, 2, and 4; in paragraph 1, add language regarding chemicals for washing fruits and vegetables; in paragraph 2, last sentence, remove the incorrect reference to ¶2-301.12 (F); in paragraph 4, sentence 4, add the word “not”; add new web link to the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010, to read as follows:

Pathogenic microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the majority of organisms and/or chemicals present; however, more recent studies have demonstrated washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells to survive under adverse environmental conditions and also reduces the ability to remove pathogens by washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed under running, potable water or with chemicals as specified in Section 7-204.12, or both, before eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still important to remove soil and debris first.

Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that soaking or submerging produce during cleaning be avoided. It is important to follow practices that minimize pathogens in the water or on the surface of produce. It is important that proper handwashing procedures are followed, in accordance with Section 2-301.12 Cleaning Procedure, before and after handling fresh produce.

Paragraph 3 No Change.

Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the package label, and can be used as ready-to-eat without further washing. The label should also state if further washing is recommended or necessary. Precut or prewashed produce in open bags should not be washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are considered potentially hazardous food (PHF) requiring time/temperature control for safety (TCS) and should be refrigerated at 41°F or lower to prevent any pathogens that may be present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm>, the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010 available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ucm215053.htm> and the FDA Program Information Manual, Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments dated July 7, 2010 available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ucm218750.htm>

Paragraphs 5 – 7 No Change.

3-304.14 Wiping Cloths, Use Limitation.

Amend Public Health Reasons for §3-304.14 to add a new paragraph 2, replace the words “at all times” to “between uses” in paragraph 1 and add a new paragraph 3 to clarify the acceptable uses of dry, disposable, single-use towels to read as follows:

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution of adequate concentration between uses. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

Wiping down a surface with a reusable wet cloth that has been properly stored in a sanitizer solution is an acceptable practice for wiping up certain types of food spills and wiping down equipment surfaces. However, this practice does not constitute cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code.

The same is true of the practice of wiping down a surface using dry disposable towels and a spray bottle containing pre-mixed sanitizing solution. This practice is not prohibited, however it alone does not constitute proper cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code.

Further, for the purpose of wiping up food spills from surfaces in situations where full cleaning and sanitizing is not required (such as when a soft drink overflows onto the side of a cup or onto a countertop) the use of dry cloths and disposable towels is also acceptable as long as the cloth or towel is used for no other purpose. Again, this does not constitute a proper cleaning and sanitizing procedure for a food contact surface, when such is called for in 4-6 and 4-7 of the Food Code.

In order to effectively clean and sanitize food contact surfaces, where and when required to satisfy the requirements in Parts 4-6 and 4-7 of the Food Code, the surface must be first cleaned properly to remove organic material. In most cases this requires use of detergents or other cleaners such as described in Section 4-603.14 of the Food Code. After the surface is clean to sight and touch, a sanitizing solution of adequate temperature with the correct chemical concentration should then be applied to the surface. The sanitizing solution must stay on the surface for a specific contact time as specified in this Code and in accordance with the manufacturer's EPA-registered label, as applicable.

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

Amend Public Health Reasons for §3-502.12 in paragraph 2, to correct the units for oxygen transfer rate to read as follows:

This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging materials that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cc/m²/24 hours at 24° C. A reduced oxygen atmosphere will result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.

Chapter 4 Equipment, Utensils, and Linens

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

Amend Public Health Reasons for §4-501.114 to add nine new paragraphs following the existing paragraph 7 to read as follows:

Paragraphs 1 – 7 No Change.

A variety of hard food contact surface sanitizers such as sodium hypochlorite or hypochlorous acid, can be generated on-site by technologies known as electrolyzed water, electro chemically activated water, and electro activated water in pesticide generating devices. Paragraph 4-501.114(F) addresses the efficacy and use of these on-site generated solutions and Section 4-703.11 requires that the conditions of use yields sanitization as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

Because EPA does not require registration of solutions generated and used on-site, the user of the equipment should look to the device manufacturer for data to validate the efficacy of the solution produced by the device as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site in the food establishment.

Any data used to validate efficacy of on-site generated sanitizer solutions should include validation testing that includes all factors that could impact the efficacy of the sanitizer solution, including water hardness, pH, temperature, and a time element because efficacy can reduce with time. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices. See the EPA web site at <http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html>. According to the web site, "EPA's Good Laboratory Practice Standards (GLPS) compliance monitoring program ensures the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under FIFRA section 5 of the Toxic Substances Control Act (TSCA), and pursuant to testing consent agreements and test rules issued under section 4 of TSCA."

Verifying the adequacy of chlorine-based solutions can be accomplished on an on-going basis by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using acceptable test methods and equipment.

The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment consistently generates a solution on-site at the necessary concentration to achieve sanitization.

Devices can be used for years to produce chemicals intended for the washing of fruits and vegetables, (e.g., hypochlorous acid, ozone, and chlorine dioxide). Other devices that are capable of producing hard food contact surface cleaning and sanitizing solutions on-site (e.g., chlorine, hypochlorous acid that are generated by processes known as electrolyzed water, electro chemically activated water, and electro activated water).

A device used to generate hard food contact surface sanitizers on-site is considered a pesticide device. The Environmental Protection Agency (EPA) defines a device in 40 CFR 152.500, Requirements for devices, as “(a) A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.”

The EPA does not require the registration of pesticide devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as well as 40 CFR 152.500 Requirements for Devices and 156.10 Labeling Requirements. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this regulation include, but are not limited to:

- The name, brand, or trademark under which the product is sold
- An ingredient statement
- Statements concerning effectiveness of the product
- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

Maintaining and cleaning devices used for the on-site generation of sanitizing solutions in accordance with manufacturer's specifications will help to ensure that they continue to generate the sanitizer chemicals in the form and concentration for which their efficacy was assessed.

Chapter 5 Water, Plumbing, and Waste

No Change in Annex 3, Public Health Reasons, for Chapter 5.

Chapter 6 Physical Facilities

No Change in Annex 3, Public Health Reasons, for Chapter 6.

Chapter 7 Poisonous or Toxic Materials

Chemicals 7-204.11 Sanitizers, Criteria.

Amend Public Health Reasons for §7-204.11 to add two new paragraphs following the existing paragraph, to address chemical agents being applied as a sanitizer and OSHA limits for gases dissolved in solutions to read as follows:

See explanation in §4-501.114.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940, Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food contact sanitizing solutions) or 40 CFR 180.2020, Non-food determinations. Because there is no EPA registration of solutions generated and used on-site, the user of the equipment should look to the equipment manufacturer for data to validate the efficacy of the solution that is generated by the device as well as the conditions for use of the solution.

Some sanitizers produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. Occupational Safety and Health Administration (OSHA) limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000, Air contaminants. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility.

- 7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.**
- 7-204.13 Boiler Water Additives, Criteria.**
- 7-204.14 Drying Agents, Criteria.**

Amend Public Health Reasons for §7-204.12 to revise paragraph 3 to now indicate that chemicals for washing fruits and vegetables can be generated on-site and for §7-204.14 to revise paragraphs 1 through 3 to add information about food additives, food contact substances, GRAS and prior sanctioned to read as follows:

If the chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are approved food additives or food-contact substances, generally recognized as safe, prior sanctioned or exempted by the threshold of regulation process can be used. Information regarding food contact substances notification may be found on the FDA website under the Food Topic in Ingredients and Packaging section at <http://www.fda.gov/Food/FoodIngredientsPackaging/default.htm>.

Chemicals that are not generally recognized as safe, or not authorized by FDA for these uses may be submitted for review by filing a Food Additive Petition, a Food Contact Notification (FCN), or a request for exemption under the Threshold of Regulation. Wash chemicals, boiler water additives, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR. If the chemicals are hard food-contact sanitizers, or washes for raw agricultural commodities (RACs) that are used on a farm or in a packing house, then this is under the jurisdiction of the EPA.

21 CFR Section 173.315 specifically identifies chemicals that may be used in washing fruits and vegetables, regardless of whether the chemicals are commercially produced or generated on site. Sodium hypochlorite is listed in 21 CFR 173.315 for use in washing fruits and vegetables at levels not exceeding the minimum amount required to accomplish the intended technical effect. FDA has no objection to the use of calcium hypochlorite in the place of sodium hypochlorite under 21 CFR 173.315.

Boiler water additives that may be safely used in the preparation of steam that may contact food, and their condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

Annex

4

Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors

Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Amend Table 2 to restructure the table so the header rows for “Naturally Occurring” and “Added Chemicals” match the table content; moved Allergens under “Naturally Occurring”.

Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures		
Chemical Hazards	Associated Foods	Control measures
Naturally Occurring:		
Scombrototoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies bonito, mackerel; Also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature abused prior to arrival in facility.
Ciguatoxin	Reef fin fish from extreme SE US, Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, and snappers	Ensure fin fish have not been caught: <ul style="list-style-type: none"> • Purchase fish from approved sources. • Fish should not be harvested from an area that is subject to an adverse advisory.
Tetrodotoxin	Puffer fish (Fugu; Blowfish)	Do not consume these fish.
Mycotoxins Aflatoxin	Corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination.	Check condition at receiving; do not use moldy or decomposed food.
Patulin	Apple juice products	Buyer Specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing.
Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved source.
Shellfish toxins Paralytic shellfish poisoning (PSP)	Molluscan shellfish from NE and NW coastal regions; mackerel, viscera of lobsters and Dungeness, tanner, and red rock crabs	Ensure molluscan shellfish are: <ul style="list-style-type: none"> • from an approved source; and • properly tagged and labeled.
Diarrhetic shellfish poisoning (DSP)	Molluscan shellfish in Japan, western Europe, Chile, NZ, eastern Canada	
Neurotoxin shellfish poisoning (NSP)	Molluscan shellfish from Gulf of Mexico	
Amnesic shellfish poisoning (ASP)	Molluscan shellfish from NE and NW coasts of NA; viscera of Dungeness, tanner, red rock crabs and anchovies.	

Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures		
Chemical Hazards	Associated Foods	Control measures
Naturally Occurring:		
Pyrrolizidine alkaloids	Plants food containing these alkaloids. Most commonly found in members of the Boraginaceae, Compositae, and Leguminosae families.	Do not consume of food or medicinals contaminated with these alkaloids.
Phytohaemagglutinin	Raw red kidney beans (Undercooked beans may be more toxic than raw beans)	Soak in water for at least 5 hours. Pour away the water. Boil briskly in fresh water, with occasional stirring, for at least 10 minutes.
Allergens	Foods containing or contacted by: Milk Egg Fish Crustacean shellfish Tree nuts Wheat Peanuts Soybeans	Use a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients.
Added Chemicals:		
Environmental contaminants: Pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
PCBs	Fish	Comply with fish advisories.
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.
Toxic elements/compounds Mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel and swordfish. Grains treated with mercury based fungicides	Pregnant women/women of childbearing age/nursing mothers, and young children should not eat shark, swordfish, king mackerel or tilefish because they contain high levels of mercury. Do not use mercury containing fungicides on grains or animals.
Copper	High acid foods and beverages	Do not store high acid foods in copper utensils; use backflow prevention device on beverage vending machines.

Annex 4, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures		
Chemical Hazards	Associated Foods	Control measures
Lead	High acid food and beverages	Do not use vessels containing lead.
Added Chemicals:		
Preservatives and Food Additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Fresh fruits and Vegetables Shrimp Lobster Wine	Sulfiting agents added to a product in a processing plant must be declared on labeling. Do not use on raw produce in food establishments.
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach Meat and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrites.
Flavor enhancers Monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints)	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.

**Annex
5**

Conducting Risk-based Inspections

No Change in Annex 5.

**Annex
6**

Food Processing Criteria

No Change in Annex 6.

**Annex
7**

Model Forms, Guides, and Other Aids

FORM 1-D Application for Bare Hand Contact Procedure

Amend Form 1-D in the title to change reference to ¶3-301.11(E) to read as follows:

**FORM
1-D**

**Application for Bare Hand Contact Procedure
(As specified in Food Code ¶3-301.11(E))**

Guide

3-B **Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices**

Amend Section B, Risk Factors and Interventions, under Control of Hands as a Vehicle of Contamination, Item 7, IN/OUT and Applicable Code Sections, to update cross reference to ¶3-301.11(E) to read as follows:

B. RISK FACTORS AND INTERVENTIONS***Control of Hands as a Vehicle of Contamination*****7. No bare hand contact with RTE foods or a pre-approved alternate properly followed**

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance only when employees are observed using suitable utensils or gloves to prevent bare hand (or arm) contact with ready-to-eat foods or are observed properly following a pre-approved alternative procedure to no bare hand contact. This item should be marked OUT of compliance if one person is observed touching ready-to-eat food with their bare hands in the absence of a prior approval and written procedures for bare hand contact. Refer to subparagraph 3-301.11(E)(1)-(7) for a listing of conditions that must be met in order to receive prior approval by the Regulatory Authority. Bare hand contact by food employees serving a Highly Susceptible Population is prohibited and no alternative to bare hand contact is allowed.

N.A. This item may be marked N.A. for establishments that provide only packaged, or bulk food items that are not ready-to-eat.

N.O. This item may be marked N.O. for establishments that prepare ready-to-eat foods only, but no food preparation is performed at the time of inspection.

Applicable Code Sections:

3-301.11 Preventing Contamination from Hands

3-801.11(E) Pasteurized Foods, Prohibited Re-Service, and Prohibited Foods

Amend Section B, Risk Factors and Interventions, under Potentially Hazardous Food (PHF) (Time Temperature Control for Safety Food (TCS Food), Item 16, Applicable Code Sections to add §3-401.14 to the list of applicable code sections to read as follows:

Potentially Hazardous Food (PHF) (Time Temperature Control for Safety Food (TCS Food)

16. Proper cooking time and temperatures

***NOTE* through Cooking Chart – No Change.**

Applicable Code Sections:

- 3-401.11 Raw Animal Foods-Cooking
- 3-401.12 Microwave Cooking
- 3-401.14 Non-Continuous Cooking of Raw Animal Foods

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

No new terms added.

